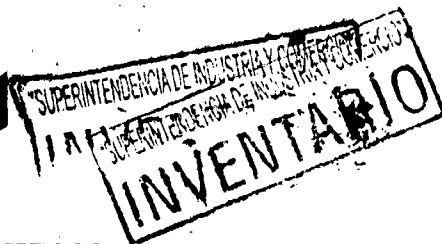




Organizacion y
Digitalizacion CSA Ltda

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DELEGATURA PROPIEDAD INDUSTRIAL

División de Nuevas Creaciones

PCT

SOLICITUD

PATENTE DE INVENCION

ENTRADA EN FASE NACIONAL

09-11070

21. EXPEDIENTE No.

54. TITULO CATÉTER PERMANENTE CON CARACTERÍSTICAS ANTI-COAGULANTES

CLASIFICACION INTERNACIONAL

71. SOLICITANTE ASH ACCESS TECHNOLOGY, INC.

DOMICILIO LAFAYETTE, IN, ESTADOS UNIDOS DE AMÉRICA

74. APODERADO JUAN PABLO CADENA SARMIENTO

22. SANTAFE DE BOGOTA, D.C.

PETITORIO

AS: 109.409



SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Tra. 11 PATENTEIYII Eve: 379 FASENACIONALI
Act. 411 PRESENTACION Folios: 148

FORMULARIO ÚNICO DE SOLICITUD DE PATENTE PCT ENTRADA EN FASE NACIONAL

1

SOLICITUD DE:

☒ Patente de Invención.

☐ Patente de Modelo de Utilidad.

☐ Capítulo I.

☒ Capítulo II.

2

SOLICITANTE

Nombre: **ASH ACCESS TECHNOLOGY, INC.**

Dirección: 3601 Sagamore Parkway North, Suite B,
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Nacionalidad o Domicilio: Estados Unidos de América

Lugar de Constitución: Estados Unidos de América

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E-mail

IDENTIFICACIÓN

C.C. ☐ NIT ☐

C.E. ☐ Otro ☐

Cual _____

Número _____

3

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C.E. ☐ Otro ☐

Cual _____

Número 80.410.337 TP 57492

4

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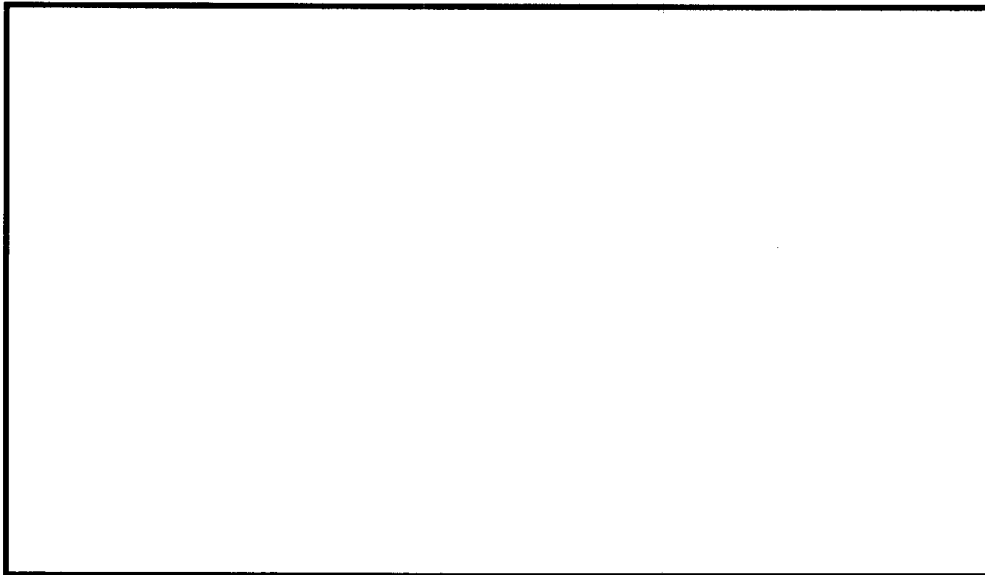
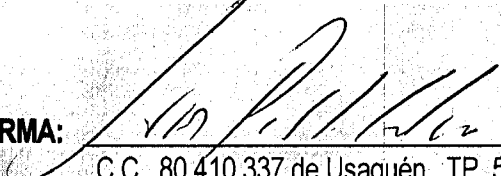
09- 955; 08-98,244; 09-4,842

Fecha

05-02-2009

Instrucciones para el diligenciamiento del presente formulario, ver reverso de esta página.

- ☒ Comprobante de pago de la tasa de presentación de la solicitud. \$ 540.000
- ☒ Documento que acredita la existencia y representación legal cuando el solicitante sea persona jurídica.
- ☒ Poderes, si fuere el caso. **Fotocopia autenticada**
- ☐ Documento de cesión del inventor al solicitante o a su causante.
- ☒ Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos)
- ☐ Copia del examen preliminar internacional efectuado por la Autoridad Internacional de Examen preliminar (IPEA)
- ☐ Traducción de examen preliminar internacional efectuado por la IPEA.
- ☐ De ser el caso, copia del contrato de acceso.
- ☐ De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas.
- ☐ De ser el caso, certificado de depósito del material biológico.
- ☐ Arte final 12x12.
- ☐ De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud.
- ☐ De ser el caso, modificaciones efectuadas a la solicitud internacional.
- ☒ Otros: Tarjeta de Propietarios
Documentos PCT
Comprobante(s) de pago de la tasa por concepto de Reivindicaciones adicionales. \$100.000
(4*\$25.000)

11 FIGURA CARACTERÍSTICA:**12** Solicito la concesión de la patente,**NOMBRE:** JUAN PABLO CADENA SARMIENTO**FIRMA:**
C.C. 80.410.337 de Usaquén TP 57492 del C.S.J.

109 409³

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 09 - 955
FECHA : ENERO 6 DE 2009

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
SARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	92973716	06/01/2009	5,012,000.00
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	92973720	06/01/2009	69,123,040.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	1 TRAMITES DE SOL. DE PATENTE DE IN	540,000.00
		TOTAL :	\$ 540,000.00

SDN: QUINIENTOS CUARENTA MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

109 409 4

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

CERTIFICACION DE EXCEDENTE : 08 - 98,244
FECHA : DICIEMBRE 17 DE 2008

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 09-011070- -00000-0000

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Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
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***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	80854012	17/12/2008	30,330,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09	OTROS SERVICIOS DE PROPIEDAD I	
		99 OTROS SERVICIOS ADMINISTRATIVOS	50,000.00
		TOTAL :	\$ 50,000.00

SON: CINCUENTA MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

ESTA CERTIFICACION DE EXCEDENTE DE PAGO SOLO PODRA SER UTILIZADA
COMO PARTE DE LA CANCELACION DE UNA TARIFA VIGENTE Y NO PODRA SER
SUSTITUIDA POR NINGUN RECIBO.

109 409

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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FECHA : ENERO 21 DE 2009

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	105762016	20/01/2009	37,982,200.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-09	OTROS SERVICIOS DE PROPIEDAD I	998 VALOR COMPLEMENTO TARIFA A#0 ANTR
		TOTAL :	\$ 50,000.00

SON: CINCUENTA MIL PESOS

RESPONSABLE : _____

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

PATENTE

☒

PCT/US2007/015283

MODELO DE UTILIDAD

DISEÑO INDUSTRIAL

SOLICITANTE/S. RAZON SOCIAL O APELLIDOS Y NOMBRES ASH ACCESS TECHNOLOGY, INC.

DOMICILIO LAFAYETTE, IN. ESTADOS UNIDOS DE AMERICA

APODERADO JUAN PABLO CADENA SARMIENTO

TITULO CATETER PERMANENTE CON CARACTERISTICAS ANTI-COAGULANTES

CLASIFICACION

EXPEDIENTE No.

FECHA DE SOLICITUD

ROLLO MICROFILM

CERTIFICADO No.

FECHA DE CONCESION

VIGENCIA DESDE

HASTA

PRORROGA

CAMBIO DE NOMBRE

TRASPASO A

INVENTOR (ES) STEPHEN R. ASH, KENNETH E. BROWN.

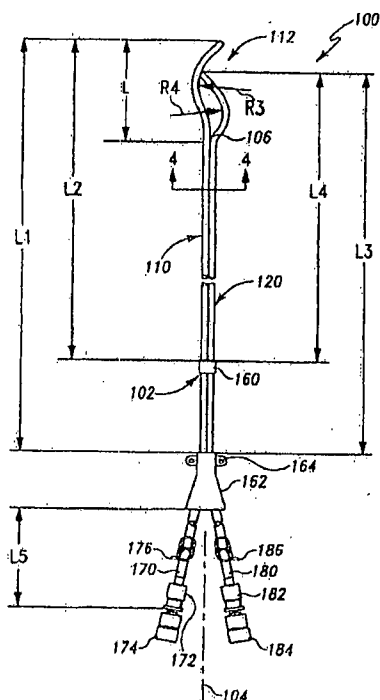
OTROS

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(10) International Publication Number
WO 2008/008221 A3

[Continued on next page]

(57) **Abstract:** A catheter (100, 200, 300, 400) for providing blood flow includes first and second lumen parts (110, 120, 210, 220, 310, 320, 410, 420) having a distal portion (112, 212, 312, 404) with at least one port for delivering and receiving flow from a patient and a non-linear profile along the distal portion.



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International application No.

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A. CLASSIFICATION OF SUBJECT MATTER IPC: A61M 5/00(2006.01),25/00(2006.01),31/00(2006.01) USPC: 604/93.01,264,284,523,524,525,526 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/93.01,264,284,523,524,525,526 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,916,313 B2 (CUNNINGHAM) 12 July 2005 (12.07.2005), Figures 1-2, column 5, lines 22-39, column 8, lines 1-5, column 6, lines 5-19, column 7, lines 58-60.	1,2,6-11,13,17-19
Y	US 5,374,245 (MAHURKAR) 20 December 1994 (20.12.1994), Figures 13, 14, 16, column 6, lines 32-42, column 5, lines 31-33.	3,12
Y	US 5,827,305 (GORDON) 27 October 1998 (27.10.1998), Figures 1-3, Figures 8-10, column 8, lines 30-31.	14-17
A	US 5,533,980 (SWEENEY et al) 9 July 1996 (09.07.1996).	14-16
A	US 2005/0277862 A1 (ANAND) 15 December 2005 (15.12.2005).	1
A	US 5,542,937 (CHEE et al) 6 August 1996 (06.08.1996).	3
☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
Special categories of cited documents:		
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date, of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 28 May 2008 (28.05.2008)		Date of mailing of the international search report 11 JUL 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Kevin C Simons <i>Kevin C Simons</i> Telephone No. (571) 272-3700 <i>JS</i>

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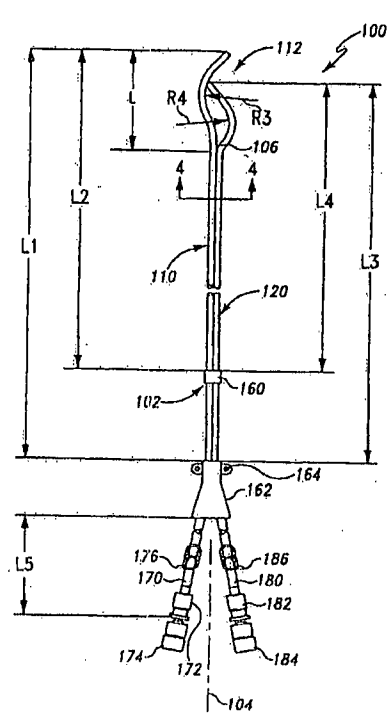
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11/528,733 27 September 2006 (27.09.2006) US
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- (72) Inventors; and
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BROWN, Kenneth, E. [US/US]; 3641 Chesterfield Way, West Lafayette, IN 47906 (US).
- (74) Agents: COLLIER, Douglas, A. et al.; Krieg Devault LLP, One Indiana Square, Suite 2800, Indianapolis, IN 46204-2079 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
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[Continued on next page]

(54) Title: INDWELLING CATHETER WITH ANTI-CLOTTING FEATURES



(57) Abstract: A catheter (100, 200, 300, 400) for providing blood flow includes first and second lumen parts (110, 120, 210, 220, 310, 320, 410, 420) having a distal portion (112, 212, 312, 404) with at least one port for delivering and receiving flow from a patient and a non-linear profile along the distal portion.

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11

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PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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INDWELLING CATHETER WITH ANTI-CLOTTING FEATURES

CROSS-REFERENCE TO RELATED APPLICATIONS

5 The present application claims the benefit of U.S. Provisional Patent Application No. 60/819,927 filed on 11 July 2006, and Utility Application No. 11/528,733 filed on 27 September 2006 which are hereby incorporated by reference in their entirety.

BACKGROUND

10 Patients with end stage renal disease (ESRD) must routinely receive dialysis treatments in order to live. Indwelling catheters are a useful dialysis access method for hemodialysis because they reduce the number of vein penetrations needed for repeated dialysis. Chronic central venous catheters for dialysis (CVCD) are the major long-term dialysis access for over 25% of ESRD patients or hemodialysis.

15 In a standard flow-through dialysis system, the CVCD must provide a first route for removal of blood and a second route for return of blood at a rate of at least 300 ml/min. A CVCD for a standard flow-through dialysis system can be formed by inserting two separate catheters into the jugular vein in a manner that forms a tunnel over the clavicle. In this arrangement, the catheter tips rest near the junction of the superior vena cava with the right atrium. The tip of the blood removal catheter, or
20 arterial catheter, is placed 3-4 cm above the tip of the downstream blood return catheter, or venous catheter, in order to prevent mixture of cleansed blood with blood entering the arterial catheter.

25 As an alternative to the separate catheter for the standard flow-through dialysis system, a single-bodied catheter with two separate lumens can be used for dialysis access. In this arrangement, the tip of the arterial lumen is placed 3-4 cm above the tip of the venous lumen. Like the standard flow-through arrangement, this arrangement also prevents mixture of cleansed blood with blood entering the arterial lumen. As yet another alternative, dialysis can also be performed by using a single catheter with a single lumen. In this case, the dialysis machine delivers a quantity of untreated blood and then
30 returns treated blood in alternating cycles.

Blood enters and exits the catheter lumen through ports or holes in the catheter. The design of these ports is highly variable, and similar concepts are employed in both single and dual lumen catheters. A first example is a catheter lumen having a single port at the tip for entrance or exit of blood. A second example is a catheter lumen having a
35 blood exchange port located on the side of the lumen body toward its distal tip. Another

example is a catheter lumen having multiple blood exchange ports axially placed around the side of the lumen body toward its distal tip. While all of the above CVCD designs work, there is room for improvement in the field, and there are problems with all current port designs for dialysis catheters.

5 Arterial catheter lumens that contain only one blood exchange port, no matter its location, run the risk of obstruction of the port by neighboring vein walls, by blood clotting in the exchange port, and by growth of a fibrin sheath around the distal end of the lumen and exchange port. Venous catheter lumens that contain only one blood
10 the exchange port and by growth of a fibrin sheath around the distal end of the lumen and the exchange port. Obstruction of the blood exchange port prevents the desired blood exchange rate of at least 300 ml/min from occurring. The degree of obstruction may render the indwelling catheter(s) ineffective for dialysis access. Therefore, when this level of obstruction occurs, the indwelling catheter(s) must be replaced.

15 Arterial catheter lumens containing multiple blood exchange ports around the distal end of the catheter reduce the occurrence of vein obstruction. However, the presence of multiple ports increases the risk of obstruction by blood clots because the multiple ports allow blood to flow into the lumen when idle, which can wash out the anticoagulant solution. The diminished presence of anticoagulant solution at the distal
20 end of the catheter increases the amount of blood clotting in the ports and lumen. Obstruction of the blood exchange ports prevents the desired blood exchange rate of at least 300 ml/min from occurring. The degree of obstruction may render the indwelling catheter(s) ineffective for dialysis access. Therefore, when this level of obstruction occurs, the indwelling catheter(s) must be replaced.

25 Thus, there is a general need in the industry to provide methods and devices for the prevention of obstructions in the blood exchange ports of catheters and around the distal end of catheters. It is desired that these methods and devices prevent obstructions of the lumen due to clotting and fibrous sheath encasement of the tip of the catheter, as well as maintain the catheter anti-coagulant lock solution inside the lumen during idle periods
30 between dialysis.

SUMMARY

The present invention is directed to an indwelling catheter. More particularly, but not exclusively, one aspect relates to an indwelling catheter adapted to prevent clotting and sheathing of the catheter's distal end. One application of the catheter includes non-exclusive use as a catheter for dialysis (CVCD). Other applications are also contemplated.

In one aspect, a catheter includes an elongate body that includes a pair of lumen parts each having a lumen or passage for fluid flow therethrough. Each of the lumen parts extends between a distal and a proximal end and includes a port at or adjacent the distal end thereof in communication with the lumen.

In a further aspect, along the distal portion of the lumen parts, the lumen parts separate from one another. At least one of the lumen parts extends transversely to the longitudinal axis in a non-linear configuration. In another embodiment, each of the lumen parts extends transversely to and forms a non-linear profile relative to the longitudinal axis.

In one embodiment, the catheter also includes a pair of end caps and distally opening distal ports at the distal ends of respective ones of the lumen parts and an actuating mechanism at the proximal end of the catheter. Each of the end caps are coupled to the actuating mechanism with at least one actuating member extending in a wall along the respective lumen. The actuating mechanism is operable to independently and remotely move each of the end caps with the respective actuating member toward and away from the port of the respective lumen part between closed and open positions to permit fluid flow through the respective port.

In another embodiment, the lumen parts each includes a distally opening distal end port in the distal end thereof, and no end caps or valve structure is provided to close the distal end ports.

These and other aspects are further discussed below.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a plan view of one embodiment catheter.

Fig. 2 is a plan view of a distal portion of the catheter of Fig. 1 enlarged relative
5 to Fig. 1.

Fig. 3 is a plan view of a distal portion of another embodiment catheter.

Fig. 4 is a cross-section along line 4-4 of Fig. 1.

Fig. 5 is a plan view of another embodiment catheter.

Fig. 6 is a side elevation view of a distal tip of the catheter of Fig. 1.

10 Fig. 7 is a top plan view of the tip of Fig. 6.

Fig. 8 is a bottom plan view of the tip of Fig. 6.

Fig. 9 is a plan view of a distal portion of another embodiment catheter.

Fig. 10 is a plan view of another embodiment catheter.

15 Fig. 11 is a perspective view of a portion of the catheter of Fig. 10 with its port in an open condition.

Fig. 12 is a longitudinal section view of the catheter portion in Fig. 11.

Fig. 13 is a plan view of a distal portion of another embodiment catheter and a guidewire.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the inventions, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the inventions is thereby intended. Any alterations and further modifications of the principles of the inventions as illustrated or described herein are contemplated as would normally occur to one skilled in the art to which the inventions relate.

The present invention provides a catheter with a non-linear configuration at least along a distal portion thereof that is implanted in a vascular structure of the patient. Applications of the catheter include those requiring long-term vascular access procedures, including hemodialysis and apheresis. Applications in short-term procedures are also contemplated. The catheters are inserted percutaneously into the vascular system. The first and second lumen parts can provide flow out of and into the body. As used herein, flow into the body is also referred to as "venous" flow, and flow out of the body is called "arterial" flow.

The non-linear distal portion includes first and second lumen parts that each includes at least one port to permit fluid flow therethrough. The non-linear configuration improves delivery and return of the fluid from the vascular structure and assists to prevent the formation of a fibrous sheath that could impede catheter performance around the distal catheter portion and the at least one port.

In one embodiment, the at least one port can be provided with a mechanism that allows opening and closing thereof. The at least one port will be in the closed position between dialysis procedures to prevent blood from flowing through the port and to prevent clotting within the tip of the catheter. With the at least one port closed, anticoagulant solution injected in the lumen parts is retained within the catheter lumens.

The catheter can be made from any suitable bio-compatible material, including silicone, polyurethane, polyurethane-polycarbonate copolymer, or any other plastic or polymer material. The catheter can also include an antibacterial coating. The catheter can also be treated with an anti-infection agent, such as methylene blue, for example. The catheter can be of any suitable size for placement in a vessel structure,

including sizes ranging from 8 to 15 French. Other sizes are also contemplated. The outer wall surface of the catheter or of the lumen parts forming the catheter can be cylindrical, D-shaped, double D-shaped, or split, for example. The lumen parts can also include a single lumen or multiple lumens extending within the wall of the lumen part. Multiple lumen parts can be fixed to one another along the length of the catheter. In one embodiment, lumen parts are fixed along a substantial portion of the length to a bifurcation in the lumen parts that is fixed in location between a proximal and distal portion of the catheter. In another embodiment, the lumen parts are splittable to vary the location of the bifurcation along the length of the catheter.

Referring to Fig. 1, there is shown a catheter 100 having an elongated body that includes lumen parts 110, 120 that can be coupled together or positioned alongside one another along a proximal portion 102. Proximal portion 102 can extend distally and proximally along a longitudinal axis 104. As also shown in Fig. 2, at a distal end of catheter 100 lumen parts 110, 120 form a bifurcation 106 that forms a general Y-shape that separates the two lumen parts 110, 120. The separated lumen parts 110, 120 extend for a length L along longitudinal axis 104 for placement in a vascular structure of the patient. In one embodiment, one of the lumen parts 110, 120 can be designated to provide fluid flow to the body of the patient and the other lumen part 110, 120 can be designated to receive fluid flow from the body of the patient. For example, lumen part 110 can provide venous flow and lumen part 120 can provide arterial flow.

Catheter 100 includes a distal end portion 112 extending distally from bifurcation 106 along axial length L. Length L can be about 6 centimeters, or other suitable length. Distal end portion 112 has a non-linear profile along longitudinal axis 104. In the illustrated embodiment, distal portion 112 forms a double bend configuration to make it less likely that the distal end portion 112 can be encased in a fibrous sheath formed by the patient's body. For example, lumen part 110 forms a first portion 116 that extends from bifurcation 106 along a bend defined by a radius R1. Lumen part 120 forms a first portion 126 that extends from bifurcation 106 along a bend that is defined by radius R2. Radius R1 and radius R2 are located on the side of the respective lumen part 110, 120 away from longitudinal axis 104 so that the lumen parts 110, 120 separate and diverge

distally away from longitudinal axis 104 and form a convex relationship toward longitudinal axis 104. Radius R1 and radius R2 can be the same, or can differ from one another.

Lumen part 110 also includes a second portion 118 forming a reverse compound curve-like shape with first portion 116. Second portion 118 extends along a bend defined by a radius R3 to a distal tip 114. Lumen part 120 also includes a second portion 128 that forms a reverse compound curve-like shape with first portion 126. Second portion 128 extends along a bend defined by a radius R4 to a distal tip 124. Radius R3 and radius R4 are located toward longitudinal axis 104 so that the second portions 118, 128 are curved away from longitudinal axis 104 and form a concave relationship oriented toward longitudinal axis 104.

The length of portion 128 along axis 104 is less than the length of portion 118 along axis 104 so that the distal tip 124 is spaced proximally of the distal tip 114. The length of second portion 118 and radius R3 is sized so that second portion 118 crosses longitudinal axis 104 from the first side to the second side of longitudinal axis 104 in a transverse relationship to longitudinal axis 104, and distal tip is located at least partially on the second side of longitudinal axis 104. The length of second portion 128 and radius R4 is sized so that second portion 128 crosses longitudinal axis 104 from the second side to the first side of axis 104 in a transverse relationship to longitudinal axis 104, and distal tip 124 is located at least partially on the first side of longitudinal axis 104. The radii R1, R2, R3, and R4 are provided as examples of the curvature of the bends of the lumen parts 110, 120. Each portion of the lumen parts 110, 120 can extend along bends formed by multiple radii and that are regular or irregular in form. In another form, the bends include one or more linear or angular segments.

The double bend configuration of distal portion 112 provides a non-linear profile that assists in preventing the formation of a fibrous sheath encasing distal portion 112 when positioned in the patient's body. The diverging and converging relationship between lumen parts 110, 112 provides a non-linear profile for the lumen parts 110, 120 along distal portion 112.

Fig. 3 shows another embodiment for a distal portion of a catheter 200 that is similar to catheter 100 discussed above, except lumen part 220 of catheter 200 includes a

distal portion with a non-linear profile that includes a single bend. Catheter 200 includes lumen parts 210, 220 extending along longitudinal axis 204. Distal portion 212 extends distally from a bifurcation 206 along a length L, and is implantable in a vascular structure. Length L can be about 6 centimeters, or other suitable length. Lumen parts 5 210, 220 separate from one another, and lumen part 210 diverges distally from longitudinal axis 204 at bifurcation 206. The portions of lumen parts 210, 220 extending proximally from bifurcation 206 can be coupled together or positioned alongside one another along a proximal portion 202 of catheter 200 in a manner like that discussed for catheter 100. In one embodiment, one of the lumen parts 210, 220 can be designated to 10 provide fluid flow to the body of the patient and the other lumen part 210, 220 can be designated to receive fluid flow from the body of the patient. For example, lumen part 210 can provide venous flow and lumen part 220 can provide arterial flow.

Distal end portion 212 forms a double bend along lumen part 210 and a single bend along lumen part 220 to make it less likely that the distal end portion 212 can be 15 encased in a fibrous sheath formed by the patient's body. For example, lumen part 210 forms a first portion 216 that extends from bifurcation 206 along a bend defined by a radius R5. Lumen part 220 forms a first portion 226 that extends linearly along and generally parallels longitudinal axis 204. Radius R5 is located on the side of lumen part 210 away from longitudinal axis 204 so that the lumen parts 210, 220 separate and lumen 20 part 210 diverges distally away from longitudinal axis 204 and lumen part 210 forms a convex relationship toward longitudinal axis 204.

Lumen part 210 also includes a second portion 218 forming a reverse compound curve-like form with first portion 216 that extends along a bend defined by a radius R6 to a distal tip 214. Lumen part 220 also includes a second portion 228 that forms a bend 25 from the linear portion 226 that extends along a bend defined by a radius R7 to a distal tip 224. Radius R6 and radius R7 are located toward longitudinal axis 204 so that the portions 218, 228 are curved away from axis 204 and form a concave relationship oriented toward longitudinal axis 204.

The length of second portion 228 along axis 204 is less than the length of second 30 portion 218 along axis 204 so that the distal tip 224 is spaced proximally of the distal tip 214. The length of second portion 218 and radius R6 is sized so that second portion 218

crosses longitudinal axis 204 from a first side to a second side of longitudinal axis 204 in a transverse relationship, and distal tip 214 is located at least partially on the second side of longitudinal axis 204. The length of second portion 228 and radius R7 is sized so that second portion 228 crosses longitudinal axis 204 from the second side to the first side of longitudinal axis 204 in a transverse relationship, and distal tip 224 is located at least partially on the first side. The radii R5, R6, and R7 are provided as examples of the curvature of the bends of distal portion 212 of the lumen parts 210, 220. The bends of each of the lumen parts 210, 220 can extend along curves formed by multiple radii and that are regular or irregular in form. In another form, the curves include one or more linear or angular segments.

The double bend configuration of distal portion 212 provides a non-linear profile that assists in preventing the formation of a fibrous sheath encasing distal portion 212 when positioned in the patient's body. The diverging and converging relationship between lumen parts 210, 212 provides a non-linear profile for the lumen parts 210, 220 along distal portion 212.

Catheters 100, 200 are provided with the respective distal portions 112, 212 preformed to provide the non-linear profile configurations discussed above. It is further contemplated that one or more wires or other stiffening members can be provided in the wall of the lumen parts 110, 120 or lumen parts 210, 220 to assist in maintaining the preformed non-linear profile configuration prior to implantation and after implantation.

Fig. 4 is a cross-section through catheter 100 along line 4-4. Lumen part 110 includes a D-shaped wall 130 that defines a central lumen or flow passage 132 extending therethrough. Wall 130 includes an arcuate portion 134, and a linear portion 136 extending between opposite sides of the arcuate portion 134. Similarly, lumen part 120 includes a D-shaped wall 140 that defines a central lumen or flow passage 142 extending therethrough. Wall 140 includes an arcuate portion 144, and a linear portion 146 extending between opposite sides of the arcuate portion 144. Lumen parts 110, 120 are positioned with linear portions 136, 146 in side-by-side relation along longitudinal axis 104, at least proximally of bifurcation 106. Lumen parts 110 can be secured to one another with an adhesive, extrusion technique, fusion, or mechanical fasteners.

Walls 130, 140 also each define a pair of smaller lumens at or adjacent the junction of the respective linear portion 136, 146 with the arcuate portion 134, 144. Wall 130 includes first and second stiffening elements 150a, 150b in these smaller lumens, and wall 140 includes third and fourth stiffening elements 152a, 152b in these smaller lumens. The stiffening elements extend along the length L of at least distal portion 112, and maintain distal portion in its non-linear configuration discussed above. The stiffening elements 150a, 150b and stiffening elements 152a, 152b are elastic so that when the curved configuration along distal portion 112 is straightened as a result of insertion forces or other forces when implanted, the distal portion 112 is biased to return toward the non-linear profile discussed above when the forces are released. In one embodiment, stiffening elements 150a, 150b and stiffening elements 152a, 152b are elongate wires made from shape memory material such as titanium-nickel alloy or spring steel. The stiffening elements can extend along the entire length of the respective lumen part 110, 120, or can extend along only a portion of the length of the respective lumen part 110, 120. In another embodiment, one or both of the lumen parts are provided with a single stiffening element. In yet another embodiment, more than two stiffening elements are provided in the wall of one or both of the lumen parts.

In another embodiment shown in Fig. 5, a catheter 300 is provided that includes a proximal portion 302 and a distal portion 312. Distal portion 312 is illustrated like that of distal portion 112 of catheter 100, it being understood that other distal portion arrangements could also be provided. Proximal portion 302 includes first and second lumen parts 310, 320 that are configured like lumen parts 110, 120 of catheter 100. However, proximal portion 302 includes an intermediate bend 360 that re-orient a distal segment 362 of proximal portion 302 relative to a proximal segment 364 of proximal portion 302.

Proximal segment 364 extends along longitudinal axis 304, and distal segment 362 extends along longitudinal axis 306. Intermediate bend 360 includes a U-shape so that axes 304, 306 define an angle A therebetween. Lumen parts 310, 320 can be pre-formed to include bend 360. Stiffening elements like stiffening elements 150a, 150b and stiffening elements 152a, 152b maintain catheter 300 with bend 360 during packaging and shipment, during the implantation procedure, and after implantation. Bend 360 is

curved along a radius to provide a smooth transition between the distal and proximal segments 362, 364 to eliminate or prevent the formation of sharp bends or kinking in the lumen parts 310, 320 that could restrict or prevent flow through the passages thereof.

In one embodiment, angle A is about 30 degrees. Other embodiments
5 contemplate an angle A ranging from 5 degrees to 180 degrees. In yet another embodiment discussed below, bend 360 extends 180 degrees so that the axis 306 of distal segment 362 is parallel to the axis 304 of proximal segment 364.

Referring back to Fig. 1, further details associated with proximal portion 102 of catheter 100 will be discussed, it being understood that the proximal portions of the other
10 catheter embodiments could be arranged similarly to or differently than proximal portion 102. Proximal portion 102 includes a cuff 160 extending around lumen parts 110, 120. Cuff 160 provides a scaffold for tissue ingrowth at the location where catheter 100 enters the skin of the patient. Cuff 160 is polyester felt in one embodiment. Other embodiments contemplate any other suitable structure or material for cuff 160. In other
15 embodiments, cuff 160 is omitted.

Proximal portion 102 of catheter 100 also includes a hub 162 that connects to the proximal ends of the respective lumen parts 110, 120. Hub 162 includes a wing 164 that defines holes for receiving sutures to allow securement of catheter 100 to the patient after
20 implantation. Hub 162 also maintains the separation of passages 132, 142 of lumen parts 110, 120. Passages 132, 142 are in fluid communication with respective ones of the first and second leads 170, 180 extending proximally from hub 162. Leads 170, 180 are also made from flexible tubing, and include female fittings 172, 182, respectively, at their proximal ends. Male fittings 174, 184 are removable engageable to the respectively
25 female fittings 172, 182 to provide a cap to maintain the integrity and sterility of the female fittings 172, 182. Leads 170, 180 also include clamps 176, 186, respectively, that releasably clamp the respective lead 170, 180 to restrict or permit fluid flow through the passages 132, 142 of lumen parts 110, 120.

Various lengths for the catheter 100 are contemplated, it being understood that the other catheter embodiments could also be arranged with the same or with different
30 lengths. Catheter 100 includes a dimension L1 from the distal end of hub 162 to the distal end of lumen part 110. Cuff 160 is spaced a dimension L2 from the distal end of

lumen part 110. In one embodiment, dimension L1 ranges from 24 centimeters to 32 centimeters, and dimension L2 ranges from 19 centimeters to 27 centimeters. Catheter 100 includes a dimension L3 from the distal end of hub 162 to the distal end of lumen part 120. Cuff 160 is spaced a dimension L4 from the distal end of lumen part 120. In one embodiment, dimension L3 ranges from 21 centimeters to 29 centimeters, and dimension L4 ranges from 16 centimeters to 24 centimeters. Leads 170, 180 extend proximally from hub 162 along a dimension L5. In one embodiment, dimension L5 is about 3.25 inches. Other embodiments contemplate other dimensions for L1, L2, L3, L4 and L5.

Various arrangements for the distal tips are contemplated. In one embodiment, the configurations of the respective lumen parts 110, 120 shown in Fig. 4 are carried through the distal tips to provide a distally opening port. In another embodiment, shown in Figs. 6-8, distal tips 114, 124 include a distally tapered configuration. In Figs. 6-8, distal tip 114 will be described, it being understood that distal tip 124 could be similarly arranged. Specifically, wall 130 includes a first thickness along a proximal part 190 of tip 114. Stiffening elements 150a, 150b extend in the thickness of wall 130 to a distal end location spaced proximally of distal end 192 of tip 114. The thickness of wall 130 tapers along a distal part 194 of distal tip 114 from the distal end location of stiffening elements 150a, 150b toward distal end 192, where passage 132 opens distally. The cross-section of passage 132 remains constant through distal tip 114 to maximize the area available for flow. The reduced wall thickness along distal part 194 of distal tip 114 increases the flexibility of the distal tip and provides further protection to the vascular structure from trauma should distal tip 114 contact the vessel wall or other anatomic structure.

Distal tip 114 further includes a side port 196 extending along linear wall 136 in the proximal-distal direction. Side port 196 forms an elongated slit that is normally closed, but opens upon application of sufficient fluid pressure to allow at least some fluid flow therethrough. In another embodiment, side port 196 is omitted from distal tip 114. In yet another embodiment, multiple side ports are provided in the distal tip 114.

In yet another embodiment shown in Fig. 9, a catheter 100' is similar to catheter 100 except for the distal tip of the arterial lumen part 120'. Distal tip 124' is arranged so

that the distal opening is oriented in the direction of flow in the vascular structure. Accordingly the distal tip 124' includes a distal end wall 125' that is obliquely oriented to the wall 140 of lumen part 120'. The acutely angled side 127' of distal end wall 125' is positioned toward lumen part 110, and is attached to lumen part 110 to maintain the distal opening oriented in the direction of the fluid flow and away from the vessel wall. The attachment arrangement also prevents the distal opening of distal tip 124' from being obstructed by the wall 130 of lumen part 110 in the vascular structure.

Figs. 10-12 shows another embodiment catheter 400 that is similar to catheter 100, except catheter 400 includes opening and closing mechanisms that are operable with an actuator to selectively open and close the distal ports of the lumen parts. Specifically, catheter 400 includes a first lumen part 410 and a second lumen part 420, and lumen parts 410, 420 form a proximal portion 402 of catheter 400 and a distal portion 404. Lumen parts 410, 420 are substantially identical to lumen parts 110, 120 discussed above, except the stiffening elements are also movable actuating members 450 (Figs. 11-12) provided in the walls of the lumen parts 410, 420 that are longitudinally movable with actuator 460. Actuator 460 is mounted on a proximal hub 470 that receives the lumen parts 410, 420 and maintains the separate flow paths thereof to leads 472, 474, respectively. Actuating members 450 are coupled to respective ones of the end caps 430, 440 at the distal end of the respective lumen parts 410, 420 and are movable longitudinally to open and close the distal port with the respective end cap 430, 440. Actuating members 450 also provide a stiffening element like the stiffening elements 150a, 150b, 152a, 152b discussed above to maintain the shape of the lumen parts 410, 420 and the non-linear profile along distal portion 404.

Proximal portion 402 includes a distal segment 406 extending along longitudinal axis 411 and proximal segment 408 extending along longitudinal axis 401. Proximal segment 408 is connected with distal segment 406 with a 180 degree bend 414 so that longitudinal axes 401, 411 are parallel to one another. Other embodiments contemplate other angular arrangements between axes 401, 411 as discussed above with respect to catheters 100 and 300.

In Figs. 11-12 there is shown one lumen part 410, 420 at distal portion 404 of catheter 400, it being understood that the lumen parts 410, 420 are identical to lumen

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parts 110, 120 discussed above except as otherwise discussed herein. Lumen parts 410, 420 each include a body formed by a wall 418 extending about a lumen or passage 421 that provides for fluid flow through the lumen part. Lumen 421 opens at a distal end 422 of lumen parts 410, 420 to form a distally opening port 416 for ingress and/or egress of fluid flow.

In addition, catheter 400 includes end caps 430, 440 associated with each respective lumen part 410, 420. End caps 430, 440 are movable relative to the distal end of lumen part 410, 420 from an open position, as shown in Fig. 11, to a closed position by manipulating the actuating members 450. The port 416 can be opened by deforming catheter 400 from its closed position by displacing end cap 430, 440 distally from its closed position to the open position. In the open position, cap 430, 440 is spaced from distal end 422, resulting in a change of length of catheter 400, so that port 416 is open to permit fluid passage from or into lumen 421. End caps 430, 440 are coupled to lumen parts 410, 420 with one or more actuating members 450 that extend between lumen parts 410, 420 and end caps 430, 440. Actuating members 450 are in the form of an actuating wire in wall 418 at or adjacent the junction of the linear portion 419 and the rounded, convex portion 423. Each actuating member 450 is positioned in a lumen 451 formed in wall 418 along the length of the respective lumen part 410, 420. Such a lumen 451 for receiving the respective actuating member 450 could be formed by a flat wire coil of stainless steel or shape memory material. Actuating members 450 can also be made from stainless steel, shape memory material, or any suitable material. Actuating members 450 and one or more other actuating members or non-movable stiffening elements can be located at other locations about wall 418.

End caps 430, 440 can be moved to the closed position from the open position by axially and proximally displacing end caps 430, 440 toward port 416 along longitudinal axis 411 and into sealing engagement with the respective lumen part 410, 420. Actuating members 450 are coupled to an actuating mechanism to allow displacement of the actuating members 450, and thus the end caps 430, 440 coupled thereto, proximally along axis 411 to the closed position, as indicated in dashed lines in Fig. 12. To open port 416, actuating members 450 are displaced distally with the actuator mechanism to displace cap 430, 440 distally along axis 411 and relative to port 416 of the respective lumen part 410,

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420. End caps 430, 440 include a tapered proximal portion 432 that can facilitate receipt through port 416 into lumen 421. The tapered portion 432 can also allow end caps 430, 440 to self-center relative to port 416 and provide sealing engagement with wall 418 of the respective lumen part 410, 420. In another embodiment, end caps 430, 440 are configured with a receptacle that receives the end of the respective lumen part therein in the closed position.

Referring back to Fig. 10, when end cap 440 of lumen part 420 is opened, it contacts lumen part 410 at distal portion 404 and displaces it away from longitudinal axis 411, as shown in dashed lines. This in turn can free up or loosen any fibrous sheath formed along the lumen parts 410, 420. Furthermore, opening and closing of the caps 430, 440 frees or loosens any fibrous sheath formed on the distal portions of the lumen parts 410, 420. Furthermore, the non-linear orientation of lumen parts 410, 420 and the movable port structures provided thereon can run along lumen part 410 during opening and closing of the port, displacing and mitigating any build-up of a fibrous sheath. The transverse orientation of the distal tips of lumen parts 410, 420 to longitudinal axis 411 orients the ports in a transverse relationship to the vasculature structure while the end caps 430, 440 displace the ports from the vasculature structures if in contact therewith and prevents or mitigates blockage of flow from the ports by the vascular structure in which the distal tips are positioned.

Fig. 10 further shows lumen parts 410, 420 coupled together at proximal hub 470. Proximal hub 470 includes a configuration that separates the two lumen parts 410, 420 for connection with leads 472, 474, which can be configured like leads 170, 180 discussed above for catheter 100. In one embodiment, one of the lumen parts 410, 420 can be designated to provide fluid flow to the body of the patient and the other lumen part 410, 420 can be designated to receive fluid flow from the body of the patient, as indicated by arrows 412, 413.

Actuator 460 includes first and second slide buttons 462, 464 associated with respective ones of the first and second lumen parts 410, 420 that are mounted or coupled to hub 470. Slide buttons 462, 464 are longitudinally moveable to move one or more actuating members 450 engaged therewith to open and close a respective one of the end caps 430, 440. Slide buttons 462, 464 allow for remote manipulation of the movement of

the actuating members 450 and the associate end cap 430, 440 of the respective lumen part 410, 420 along the wall of the lumen part. The separated slide buttons 462, 464 can be moved axially in either the proximal or distal directions, as desired, to effect corresponding independent and remotely activated movement of the end caps 430, 440, depending on the lumen part 410, 420 manipulated with actuator 460. Such movement allows selective opening and closing of the one or more ports to allow fluid flow therethrough.

In Fig. 13 there is shown another embodiment of distal portion 404 of catheter 400, designated as catheter 400'. Catheter 400' includes lumen parts 410, 420 but another embodiment end cap 430', 440' associated with the respective lumen parts 410, 420. End caps 430', 440' are coupled to the lumen parts with actuating members 450, but include passages 431, 441, respectively, to receive a guidewire 500 to facilitate percutaneous placement of the catheter 400 into the patient.

In use, guide wire 500 is positioned to the catheter implantation location in the patient. Caps 430', 440' are moved to the closed position, and the proximal end of guidewire 500 is threaded through longitudinal passage 431 of end cap 430'. End cap 440' is then opened and the proximal end of guidewire 500 is positioned through passage 421 through the proximal end of lumen part 420. Alternatively, guidewire 500 is positioned through a passage 441 extending longitudinally through end cap 440'. Catheter 400' is then guided along the guidewire 500 to locate the distal ends of lumen parts 410, 420 at the implantation location.

In one procedure employing the catheters discussed herein, the distal end of the longer or venous lumen part is positioned in the right atrium of the heart, and the distal end of the shorter or arterial lumen part is positioned at the junction of the superior vena cava and the right atrium. Other procedures contemplate other implantation locations and techniques. For example, catheter 100 can be positioned to the implantation location by positioning the guidewire through the passage of one of the lumen parts 110, 120 and guiding the catheter 100 along the guidewire to the implantation location. The distal portion of the catheter at the bifurcation can be held together with a releasable band or suture to facilitate insertion. In another procedure, the distal ends of any of the catheter embodiments are positioned in a tunneling device to maintain the non-linear distal

portion in a more linear configuration. The catheter is inserted into the patient in the more linear configuration, and released from the tunneling device after implantation to return toward the non-line profile along the distal portion. In any procedure, the positioning and placement of the catheters can be monitored with ultrasound and

5 fluoroscopy.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. For example, for any embodiment catheter actuating mechanisms are contemplated that include micro-motors or other automatic or mechanical systems for

10 opening and closing the fluid flow ports. All changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A catheter, comprising:

a first lumen part and a second lumen part extending along a longitudinal axis in side-by-side relation, said first and second lumen parts forming a proximal portion and a distal portion of the catheter, wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts separate from one another at a bifurcation between said distal and proximal portions, wherein said first lumen part extends distally from said bifurcation and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis.

2. The catheter of claim 1, wherein said first lumen part and said second lumen part each include a D-shaped wall along said proximal and distal portions, each of said D-shaped walls defining a central passage extending along said respective lumen part.

3. The catheter of claim 2, wherein said first and second lumen parts each include a pair of elongated stiffening elements in said wall, said elongated stiffening elements extending along said proximal and distal portions of the catheter.

4. The catheter of claim 3, wherein said first and second lumen parts each define a distally opening port in a distal end thereof, and further comprising a cap at said distal end of each of said first and second lumen parts, wherein said stiffening elements are coupled to a respective one of said caps and are movable in said wall of said respective lumen part to move said respective cap from an open position spaced from said distal end of said respective lumen part to a closed position engaged to said distal end of said respective lumen part to close said passage thereof.

5. The catheter of claim 4, wherein said stiffening elements of each of said first and second lumen parts are coupled with an actuator adjacent a proximal end of said first and

second lumen parts, said actuator being operable to selectively move each of said caps between said open and closed positions.

6. The catheter of claim 1, wherein said first lumen part is curved so that a distal end thereof is located on said second side of said longitudinal axis.

7. The catheter of claim 6, wherein said second lumen part is curved so that a distal end thereof located on said first side of said longitudinal axis.

8. The catheter of claim 1, wherein said first lumen part has a length along said longitudinal axis that is greater than a length of said second lumen part along said longitudinal axis so that a distal end of said first lumen part is spaced distally of a distal end of said second lumen part along said longitudinal axis.

9. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes form an angle of about 30 degrees.

10. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes are parallel to one another.

11. The catheter of claim 1, wherein:
said first lumen part forms a third bend at said bifurcation and said first bend is distal of said third bend, said first and third bends forming a reverse compound curve along said first lumen part; and
said second lumen part forms a fourth bend at said bifurcation and said second bend is distal of said fourth bend, said second and fourth bends forming a reverse compound curve along said second lumen part.

second lumen parts, said actuator being operable to selectively move each of said caps between said open and closed positions.

5 6. The catheter of claim 1, wherein said first lumen part is curved so that a distal end thereof is located on said second side of said longitudinal axis.

7. The catheter of claim 6, wherein said second lumen part is curved so that a distal end thereof is located on said first side of said longitudinal axis.

10 8. The catheter of claim 1, wherein said first lumen part has a length along said longitudinal axis that is greater than a length of said second lumen part along said longitudinal axis so that a distal end of said first lumen part is spaced distally of a distal end of said second lumen part along said longitudinal axis.

15 9. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes form an angle of about 30 degrees.

20 10. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes are parallel to one another.

25 11. The catheter of claim 1, wherein:
said first lumen part forms a third bend at said bifurcation and said first bend is distal of said third bend, said first and third bends forming a reverse compound curve along said first lumen part; and
said second lumen part forms a fourth bend at said bifurcation and said second
30 bend is distal of said second bend, said second and fourth bends forming a reverse compound curve along said second lumen part.

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12. The catheter of claim 1, wherein at least one of said first and second lumen parts includes a distal tip and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element extending in said first wall thickness, said at least one stiffening element terminating in said proximal part and said distal tip including a distal part and said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip.

13. The catheter of claim 1, wherein said first lumen part extends distally beyond a distal tip of said second lumen part, and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part at said distal end wall.

14. A catheter, comprising:

an elongate body extending between a distal end and a proximal end, said body including a wall defining at least one lumen for fluid flow therethrough, wherein said body includes at least one port at said distal end of said elongate body in communication with said at least one lumen, and further comprising an end cap at said distal end and an actuating mechanism at said proximal end, said end cap being coupled to said actuating mechanism which is operable to remotely move said end cap away from said port to an open position and permit fluid flow through said port and to remotely move said end cap toward said distal end to a closed position to prevent fluid flow through said port, wherein said end cap includes a passage extending therethrough and further comprising a guidewire positionable through said passage and along said elongate body outside said lumen.

15. The catheter of claim 14, further comprising a second elongate body extending between a distal end and a proximal end, said second body including a second wall defining at least one lumen for fluid flow therethrough and at least one second port at said distal end of said second body in communication with said at least one lumen thereof, and

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12. The catheter of claim 1, wherein at least one of said first and second lumen parts includes a distal tip and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element extending in said first wall thickness, said at least one
5 stiffening element terminating in said proximal part and said distal tip including a distal part and said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip.

13. The catheter of claim 1, wherein said first lumen part extends distally beyond a
10 distal tip of said second lumen part, and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part.

14. A catheter, comprising:

15 an elongate body extending between a distal end and a proximal end, said body including a wall defining at least one lumen for fluid flow therethrough, wherein said body includes at least one port at said distal end of said elongate body in communication with said at least one lumen, and further comprising an end cap at said distal end and an
20 actuating mechanism at said proximal end, said end cap being coupled to said actuating mechanism which is operable to remotely move said end cap away from said port to an open position and permit fluid flow through said port and to remotely move said end cap toward said distal end to a closed position to prevent fluid flow through said port, wherein said end cap includes a passage extending therethrough and further comprising a
25 guidewire positionable through said passage and along said elongate body outside said lumen.

15. The catheter of claim 14, further comprising a second elongate body extending between a distal end and a proximal end, said second body including a second wall
30 defining at least one lumen for fluid flow therethrough and at least one second port at said distal end of said second body in communication with said at least one lumen thereof, and

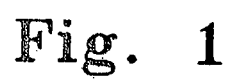
further comprising a second end cap at said distal end, said second end cap being coupled to said actuating mechanism which is operable to remotely move said second end cap away from said second port to an open position and permit fluid flow through said second port and to remotely move said second end cap toward said distal end to a closed position to prevent fluid flow through said second port, wherein with said second end cap in said open position said guidewire is positionable through said at least one lumen of said second elongate body through said proximal end of said second elongate body.

16. The catheter of claim 15, wherein said second end cap includes a passage extending therethrough and said guidewire is positionable through said passage of said second end cap into said at least one lumen of said second elongate body.

17. The catheter of claim 15, wherein said walls of said first and second elongate bodies are secured to one another along a proximal portion of the catheter and said first and second elongate bodies separate from one another at a bifurcation to form a distal portion of the catheter extending distally from the bifurcation, wherein the distal portion includes a non-linear profile along the longitudinal axis.

18. A catheter, comprising:
a first lumen part and a second lumen part extending along a longitudinal axis in side-by-side relation, said first and second lumen parts forming a proximal portion and a distal portion of the catheter, wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts separate from one another at a bifurcation between said distal and proximal portions, wherein said first lumen part extends distally from said bifurcation along a first bend so that said first lumen part is concavely curved relative to said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends linearly and distally from said bifurcation along a second side of said longitudinal axis to a second bend that is curved to locate a distal tip of said second lumen part on said first side of said longitudinal axis.

19. The catheter of claim 18, wherein said first bend of said first lumen part is curved to locate a distal end of said first lumen part on said second side of said longitudinal axis.



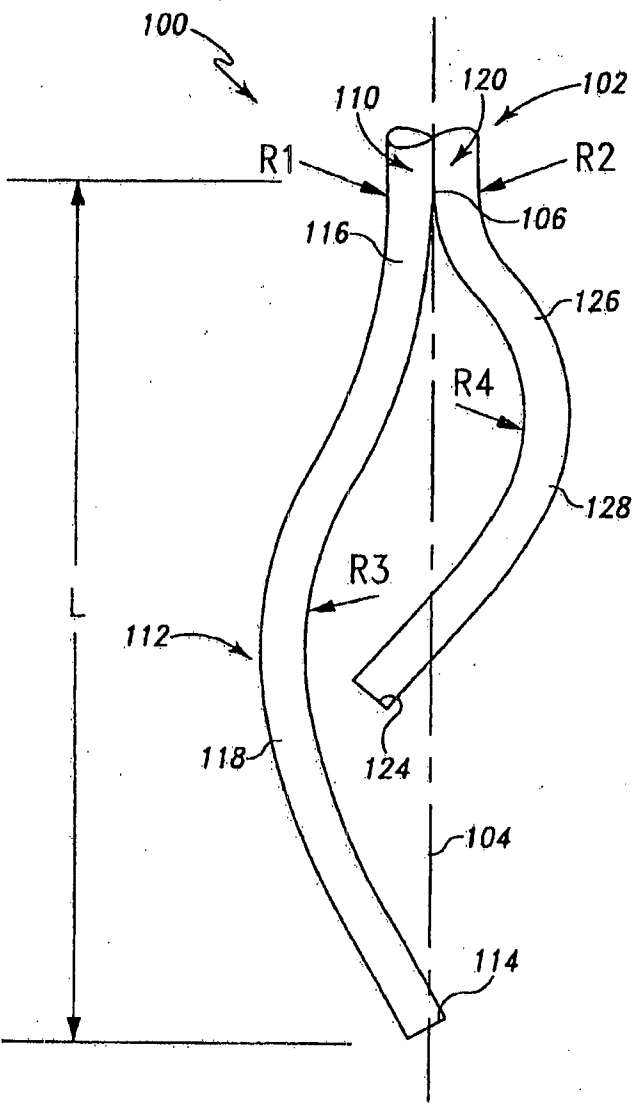


Fig. 2

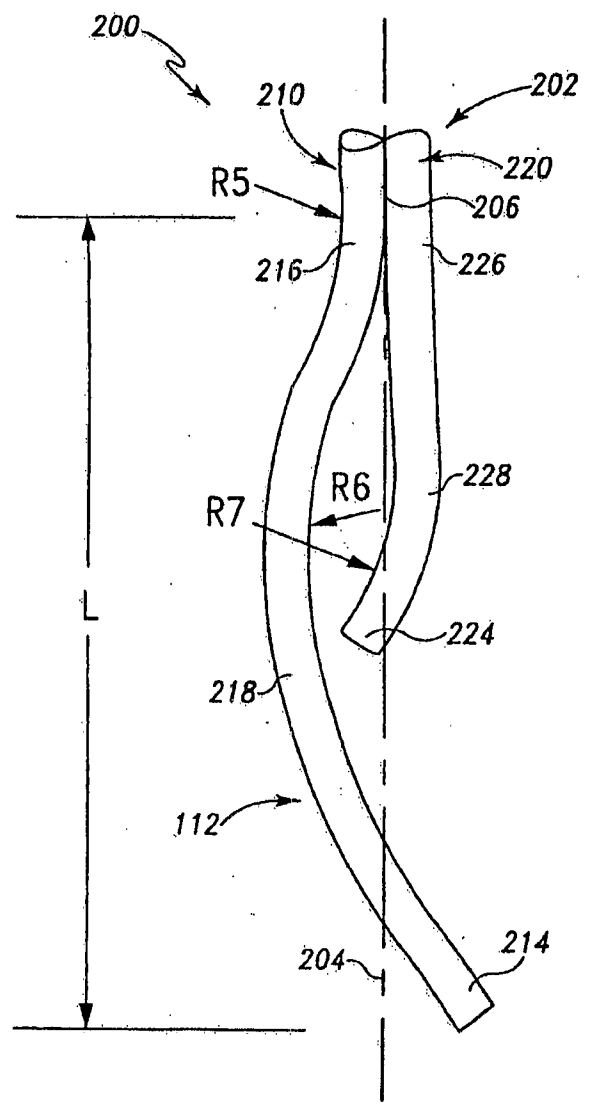


Fig. 3

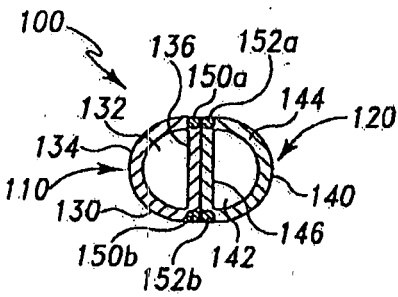


Fig. 4

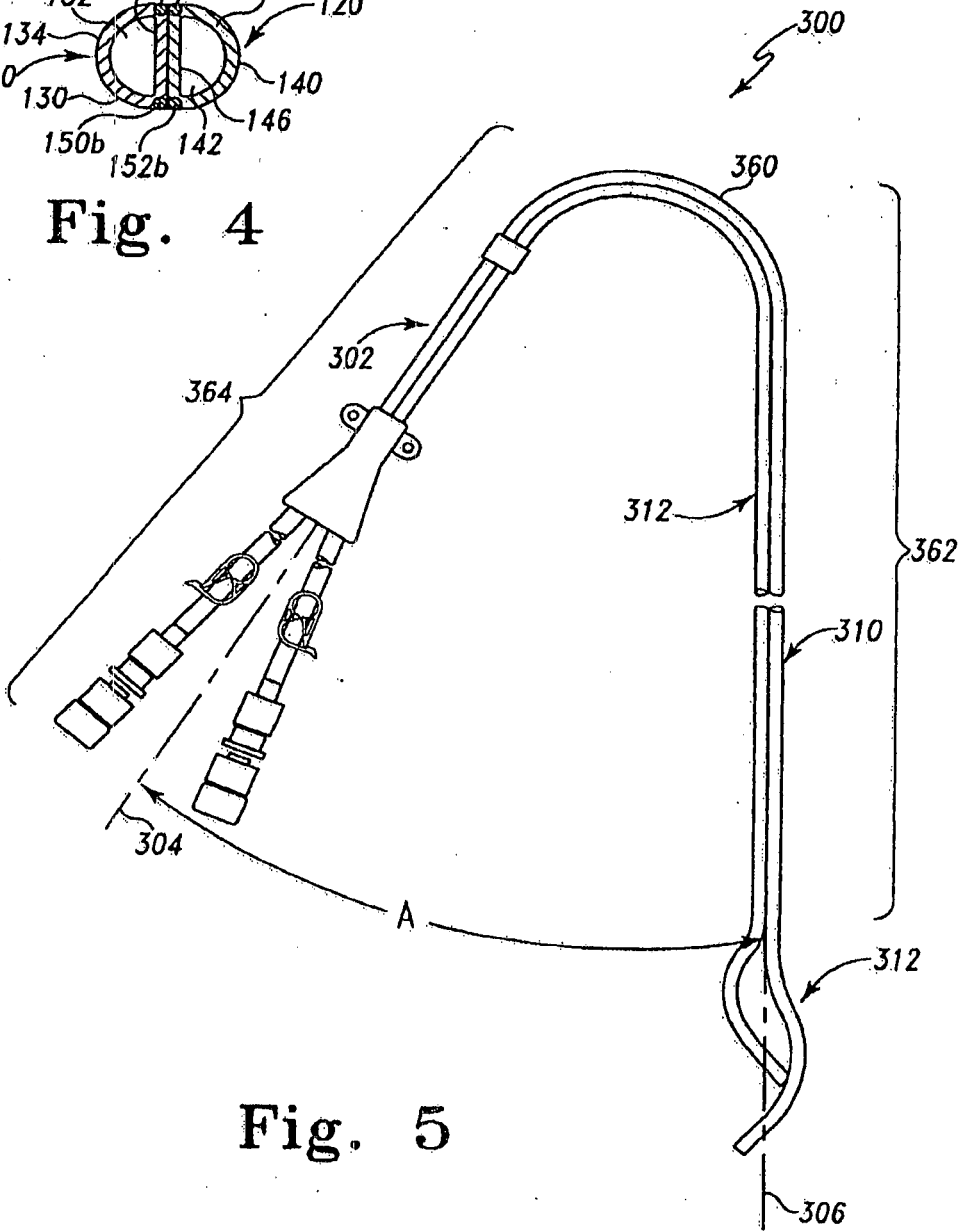


Fig. 5

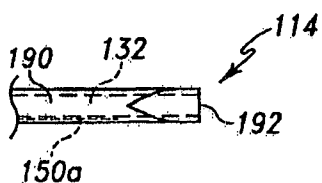


Fig. 6

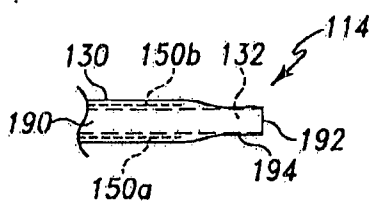


Fig. 7

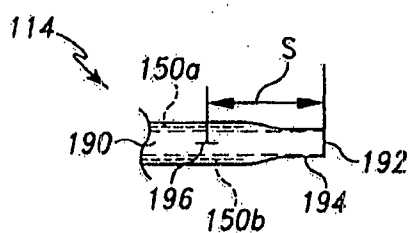


Fig. 8

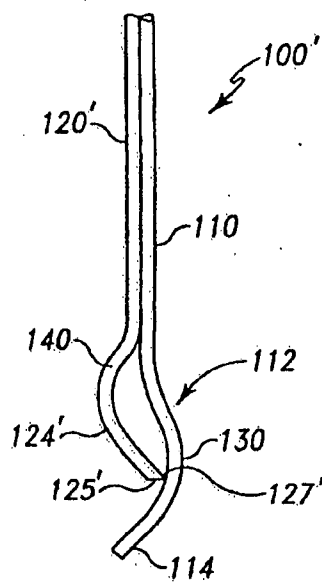


Fig. 9

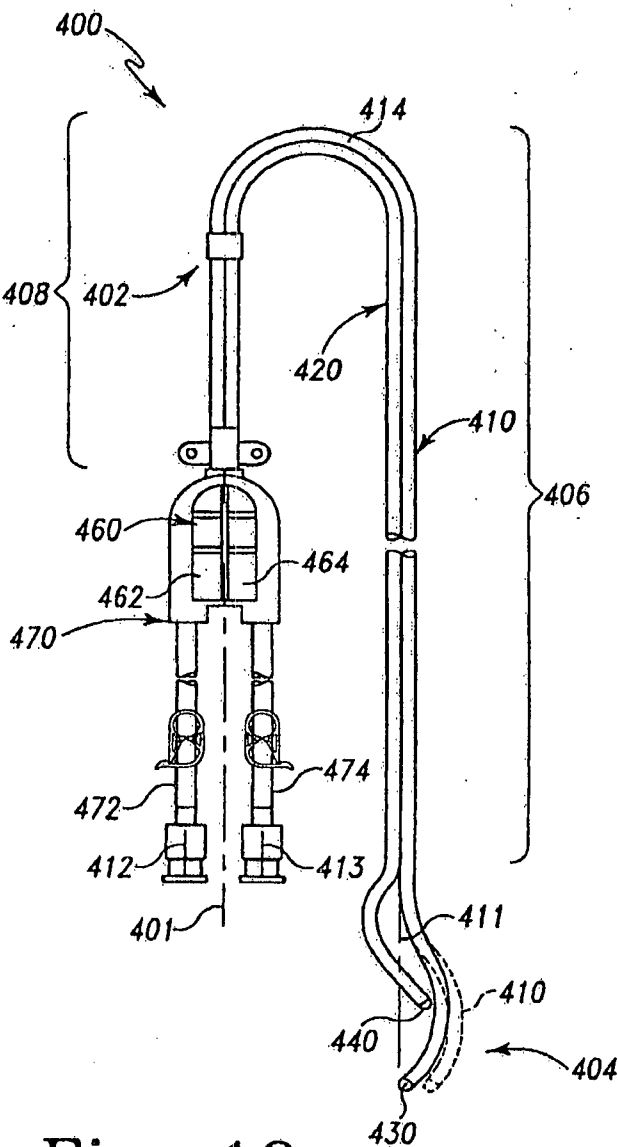


Fig. 10

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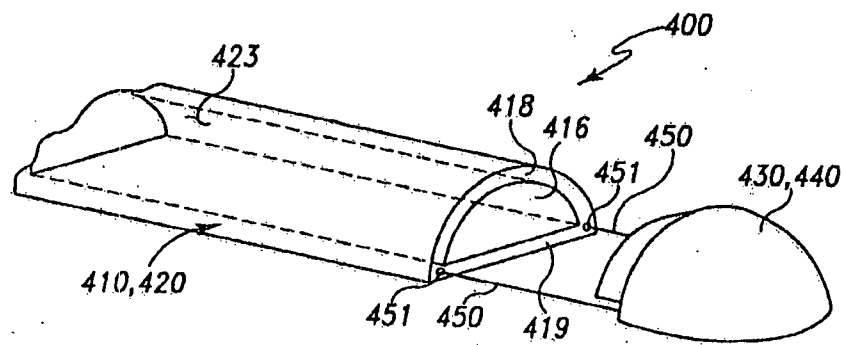


Fig. 11

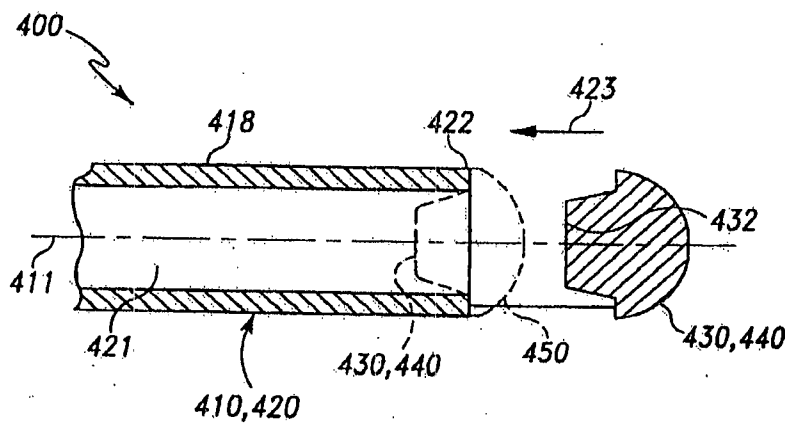


Fig. 12

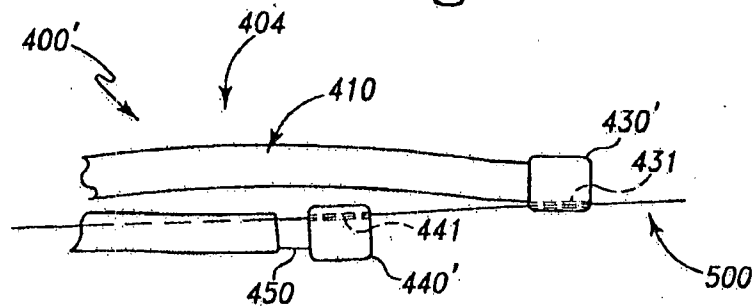


Fig. 13

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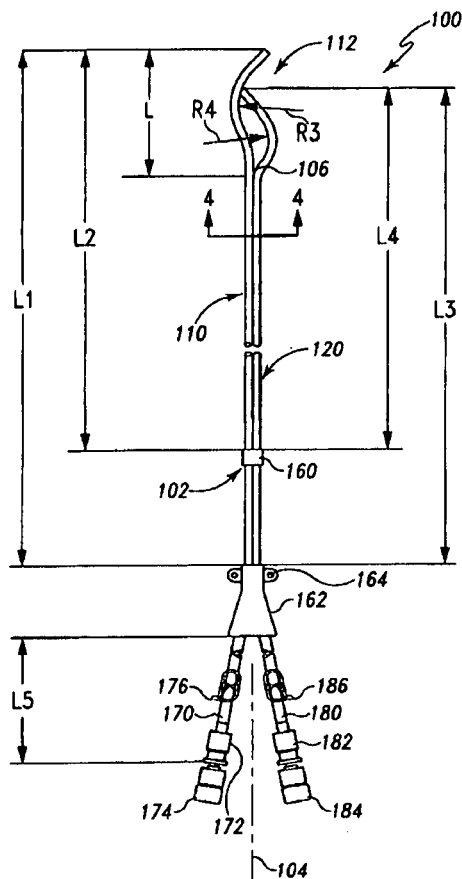
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[Continúa en la página siguiente]

54) Título: CATÉTER PERMANENTE CON CARACTERÍSTICAS ANTI-COAGULANTES



(57) Extracto: Un catéter (100, 200, 300, 400) para suministrar flujo sanguíneo incluye partes de la luz primera y segunda (110, 120, 210, 220, 310, 320, 410, 420) con una porción distal (112, 212, 312, 404) con por lo menos un puerto, para aplicar y recibir flujo de un paciente, y un perfil no lineal a lo largo de la porción distal.

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CATÉTER PERMANENTE CON CARACTERÍSTICAS ANTI-COAGULANTES

REFERENCIA CRUZADA A SOLICITUDES RELACIONADAS

La presente solicitud reivindica el beneficio de la Solicitud de Patente Provisional de los Estados Unidos No. 60/819,927 presentada el 11 de julio de 2006, y la Solicitud de Modelo de Utilidad No. 11/528,733 presentada el 27 de septiembre de 2006, las cuales se incorporan en esta especificación por referencia en su totalidad.

ARTE PREVIO

Los pacientes con enfermedad renal en etapa final (ESRD – *end stage renal disease*) rutinariamente tienen que recibir tratamientos de diálisis con el fin de continuar con vida. Los catéteres internos constituyen un método útil de acceso a diálisis para la hemodiálisis debido a que reducen el número de penetraciones venosas necesarias para diálisis repetida. Los catéteres venosos centrales de uso prolongado para diálisis (CVCD - *chronic central venous catheters for dialysis*) constituyen el principal acceso de diálisis a largo plazo para más del 25% de pacientes con enfermedad renal en etapa final (ERSD) o hemodiálisis.

En un sistema estándar de diálisis de flujo directo, los CVCD tienen que ofrecer una primera línea para la extracción de sangre y una segunda línea para el retorno de sangre con un caudal de por lo menos 300 ml/min. Un CVCD para un sistema estándar de diálisis de flujo directo puede formarse insertando dos catéteres separados en la vena yugular en un manera que forme un túnel sobre la clavícula. En esta disposición, las puntas de los catéteres permanecen cerca de la unión de la vena cava superior con la aurícula derecha. La punta del catéter de extracción de sangre, o catéter arterial, se coloca 3-4 cm por encima del catéter de retorno

de sangre descendente, o catéter venoso, con el fin de impedir la mezcla de sangre purificada con la sangre que ingresa al catéter arterial.

Como una alternativa al catéter separado para el sistema estándar de diálisis de flujo directo, puede usarse un catéter de un solo cuerpo con dos luces separadas para acceso de diálisis. En esta disposición, la punta de la luz arterial se coloca 3-4 cm por encima de la punta de la luz venosa. Al igual que la disposición estándar de flujo directo, esta disposición impide también la mezcla de sangre purificada con sangre que ingresa a la luz arterial. Como otra alternativa más, la diálisis puede realizarse además usando un solo catéter con una sola luz. En este caso, la máquina de diálisis entrega una cantidad de sangre no tratada y luego devuelve la sangre tratada en ciclos alternos.

La sangre entra y sale de la luz del catéter a través de puertos u orificios en el catéter. El diseño de estos puertos es sumamente variable, y se emplean conceptos similares tanto en catéteres de una sola luz como en catéteres de dos luces. Un primer ejemplo es una luz de un catéter con un solo puerto en la punta para la entrada o salida de la sangre. Un segundo ejemplo es una luz de un catéter con un puerto de intercambio de sangre localizado en el lado del cuerpo de la luz hacia su punta distal. Otro ejemplo es una luz de un catéter con múltiples puertos de intercambio de sangre, dispuestos axialmente alrededor del lado del cuerpo de la luz hacia su punta distal. Aunque la totalidad de los diseños anteriores de CVCD funcionan, existe un área de mejoramiento en el campo, y se enfrentan problemas con todos los diseños actuales de puerto para los catéteres de diálisis.

Las luces de catéter arterial que contienen únicamente un puerto de intercambio de sangre, sin importar su ubicación, corren el riesgo de obstrucción del puerto por las paredes venosas contiguas, por la coagulación de sangre en el puerto de intercambio y por la formación de una vaina de fibrina alrededor del extremo distal de la luz y el puerto de intercambio. Las luces del catéter venoso que contienen únicamente un puerto de intercambio de sangre, sin importar su ubicación, corren el riesgo

de obstrucción por la coagulación de sangre en el puerto de intercambio y por el desarrollo de una vaina de fibrina alrededor del extremo distal de la luz y el puerto de intercambio. La obstrucción del puerto de intercambio de sangre impide la obtención del caudal deseado de intercambio de sangre de por lo menos 300 ml/min. El grado de obstrucción puede inutilizar el catéter(es) permanente para acceso de diálisis. Por lo tanto, cuando ocurre este nivel de obstrucción, el catéter(es) permanente tiene(n) que cambiarse.

Las luces de catéter arterial, que contienen múltiples puertos de intercambio de sangre alrededor del extremo distal del catéter, reducen la ocurrencia de obstrucción de la vena. Sin embargo, la presencia de múltiples puertos aumenta el riesgo de obstrucción por coágulos de sangre, porque los puertos múltiples permiten que la sangre fluya dentro de la luz cuando no están en uso, la cual puede arrastrar la solución anticoagulante. La presencia disminuida de anticoagulante en el extremo distal del catéter aumenta la cantidad de coagulación de sangre en los puertos y la luz. La obstrucción de los puertos de intercambio de sangre impide obtener el caudal deseado de intercambio de sangre de por lo menos 300 ml/min. El grado de obstrucción puede inutilizar el catéter(es) permanente para acceso de diálisis. En consecuencia, cuando ocurre este nivel de obstrucción, el catéter(es) tiene que cambiarse.

Por lo tanto, existe una necesidad general en la industria de proveer métodos y dispositivos para la prevención de obstrucciones en los puertos de intercambio de sangre de los catéteres y alrededor del extremo distal de los catéteres. Si se desea que estos métodos y dispositivos impidan las obstrucciones de la luz, debidas a coagulación y encapsulamiento por la vaina de fibrina de la punta del catéter, y que mantengan en igual forma la solución de bloqueo anti-coagulante del catéter en el interior de la luz durante períodos inactivos entre diálisis.

SUMARIO

La presente invención se dirige a un catéter permanente. Más

particular, pero no exclusivamente, un aspecto se relaciona con un catéter permanente adaptado para impedir la coagulación y formación de una vaina de fibrina en el extremo distal del catéter. Una aplicación del catéter comprende el uso no exclusivo como catéter para diálisis (CVCD). Igualmente se contemplan otras aplicaciones.

En un aspecto, un catéter incluye un cuerpo alargado con un par de partes de la luz, cada una de las cuales tiene una luz o pasaje para el flujo de líquido a través de él. Cada una de las partes de la luz se extiende entre un extremo distal y uno proximal e incluye un puerto en el extremo distal o adyacente del mismo en comunicación con la luz.

En un aspecto adicional, a lo largo de la porción distal de las partes de la luz, éstas últimas se separan una de otra. Por lo menos una de las partes de la luz se extiende transversalmente al eje longitudinal en una configuración no lineal. En otra incorporación, cada una de las partes de la luz se extiende transversalmente al eje longitudinal y forma un perfil no lineal en relación con él.

En una incorporación, el catéter incluye asimismo un par de obturadores finales y puertos distales, que se abren distalmente en los extremos distales de las respectivas partes de la luz, y un mecanismo accionador en el extremo proximal del catéter. Cada una de los obturadores finales se acopla al mecanismo accionador, extendiéndose por lo menos un miembro accionador en una pared a lo largo del lumen respectivo. El mecanismo accionador es operable para mover independiente y remotamente cada una de los obturadores finales extremos con el respectivo miembro accionador hacia y lejos del puerto de la respectiva parte luz entre posiciones cerradas y abiertas para permitir el flujo de líquido a través del puerto respectivo.

En otra incorporación, las partes de la luz incluyen cada una un

puerto extremo distal, que se abre distalmente en el extremo distal del mismo, y no se proveen obturadores finales o una estructura de válvula para cerrar los puertos extremos distales.

Éstos y otros aspectos se discuten con mayor detalle a continuación.

BREVE DESCRIPCIÓN DE LOS DIBUJOS

Fig. 1 es una vista en planta de un catéter de incorporación.

Fig. 2 es una vista en planta de una porción distal del catéter de Fig. 1, ampliada en relación con Fig. 1.

Fig. 3 es una vista en planta de una porción distal de otro catéter de incorporación.

Fig. 4 es una sección transversal a lo largo de la línea 4-4 de Fig. 1.

Fig. 5 es una vista en planta de otro catéter de incorporación.

Fig. 6 es una vista lateral en alzado de una punta distal del catéter de Fig. 1.

Fig. 7 es una vista superior en planta de la punta de Fig. 6.

Fig. 8 es una vista inferior en planta de la punta de Fig. 6.

Fig. 9 es una vista en planta de una porción distal de otro catéter de incorporación.

Fig. 10 es una vista en planta de otro catéter de incorporación.

Fig. 11 es una vista en perspectiva de una porción del catéter de Fig. 10 con su puerto en estado abierto.

Fig. 12 es una vista en sección longitudinal de la porción de catéter en Fig. 11.

Fig. 13 es una vista en planta de una porción distal de otro catéter de incorporación y una guía metálica.

DESCRIPCIÓN DE LAS INCORPORACIONES ILUSTRADAS

Con el fin de favorecer un entendimiento de los principios de las

invenciones, se hará ahora referencia a las incorporaciones ilustradas en los dibujos y se empleará un lenguaje específico para describir las mismas. Se entenderá sin embargo que, con ello, no se pretende una limitación del ámbito de las invenciones. Cualesquiera alteraciones y modificaciones adicionales de los principios de las invenciones, como se ilustran o describen en esta especificación, se contemplan en la forma en que se le ocurrirían normalmente a una persona experta en el arte, con el cual se relacionan las invenciones.

La presente invención provee un catéter con una configuración no lineal por lo menos a lo largo de una porción distal del mismo, que se implanta en una estructura vascular del paciente. Las aplicaciones del catéter incluyen las que requieren procedimientos de acceso vascular prolongado, incluida hemodiálisis y aféresis. Se contemplan igualmente aplicaciones en procedimientos de corta duración. Los catéteres se insertan percutáneamente en el sistema vascular. Las partes primera y segunda de la luz pueden proveer flujo de salida y de entrada al cuerpo. Tal como se emplea en esta especificación, flujo de entrada al cuerpo se designa asimismo flujo "venoso", y flujo de salida del cuerpo se denomina flujo "arterial".

La porción distal no lineal incluye las partes de la luz primera y segunda, cada una de las cuales comprende por lo menos un puerto para permitir el flujo de líquido a través de él. La configuración no lineal mejora el suministro y retorno del líquido desde la estructura vascular y ayuda a prevenir la formación de una vaina de fibrina, que podría impedir el desempeño del catéter alrededor de la porción distal del catéter y el por lo menos un puerto.

En una incorporación, el por lo menos un puerto puede equiparse con un mecanismo que permita la apertura y el cierre del mismo. El por lo menos un puerto estará en la posición cerrada entre procedimientos de

diálisis para impedir el flujo de sangre a través del puerto y evitar la coagulación en la punta del catéter. Con el por lo menos un puerto cerrado, la solución anti-coagulante inyectada en las partes de la luz se conserva en las luces del catéter.

El catéter puede fabricarse de cualquier material biocompatible apropiado, incluidos silicona, poliuretano, copolímero de poliuretano-policarbonato, o cualquier otro material plástico o polimérico. El catéter puede incluir igualmente un recubrimiento antibacteriano. Del mismo modo, el catéter puede tratarse con un agente anti-infeccioso, tal como azul de metileno, por ejemplo. El catéter puede ser de cualquier tamaño adecuado para posicionamiento en una estructura vascular, incluidos tamaños que varían desde 8 a 15 French. Se contemplan también otros tamaños. La superficie de la pared exterior del catéter, o de las partes de la luz que forman el catéter, puede ser cilíndrica, en forma de D, en forma de doble D, o dividida, por ejemplo. Las partes de la luz pueden incluir además una sola luz o luces múltiples que se extienda(n) en el interior de la pared de la parte de la luz. Las partes de la luz múltiple pueden fijarse unas con otras en toda la longitud del catéter. En una incorporación, las partes de la luz se fijan, a lo largo de una porción sustancial de la longitud, a una bifurcación en las partes de la luz, que se fija en una ubicación entre una porción proximal y distal del catéter. En otra incorporación, las partes de la luz son divisibles para variar la ubicación de la bifurcación en toda la longitud del catéter.

Con referencia a Fig. 1, se ilustra en ella un catéter **100** con un cuerpo alargado que incluye las partes de la luz **110**, **120** las cuales pueden empalmarse entre sí o posicionarse una junto a la otra a lo largo de una porción proximal **102**. La porción proximal **102** puede extenderse distal y proximalmente a lo largo de un eje longitudinal **104**. Como también se muestra en Fig. 2, en un extremo distal del catéter **100** las partes de la luz **110**, **120** configuran una bifurcación **106**, por lo general en forma de Y, que

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separa las dos partes de la luz **110**, **120**. Las partes de la luz separadas **110**, **120** se extienden en una longitud **L** a lo largo del eje longitudinal **104** para posicionamiento en una estructura vascular del paciente. En una incorporación, una de las partes de la luz **110**, **120** puede destinarse para suministro de flujo de líquido al cuerpo del paciente y la otra parte de la luz **110**, **120** puede destinarse a recibir flujo de líquido del cuerpo del paciente. Por ejemplo, la parte de la luz **110** puede suministrar flujo venoso y la parte de la luz **120** puede suministrar flujo arterial.

El catéter **100** incluye una porción de extremo distal **112** que se proyecta distalmente de la bifurcación **106** en toda la longitud axial **L**. La longitud **L** puede ser de alrededor de 6 centímetros, u otra longitud adecuada. La porción de extremo distal **112** tiene un perfil no lineal a lo largo del eje longitudinal **104**. En la incorporación ilustrada, la porción distal **112** forma una configuración de doble curva para excluir la probabilidad de que la porción de extremo distal **112** pueda encapsularse en una vaina de fibrina, formada por el cuerpo del paciente. Por ejemplo, la parte de la luz **110** forma una primera porción **116** que se proyecta de la bifurcación **106** a lo largo de una curva definida por un radio **R1**. La parte de la luz **120** forma una primera porción **126**, que se proyecta de la bifurcación **106**, a lo largo de una curva definida por el radio **R2**. El radio **R1** y el radio **R2** se localizan en el lado de la respectiva parte de la luz **110**, **120** que se aleja del eje longitudinal **104**, de modo que las partes de la luz **110**, **120** se separan y divergen distalmente del eje longitudinal **104** y forman una relación convexa con respecto al eje longitudinal **104**. El radio **R1** y el radio **R2** pueden ser idénticos, o pueden diferir uno del otro.

Asimismo, la parte de la luz **110** incluye una segunda porción **118**, que forma una curva compuesta invertida con una primera porción **116**. La segunda porción **118** se extiende a lo largo de una curva definida por un radio **R3** hacia una punta distal **114**. La parte de la luz **120** incluye igualmente una segunda porción **128** que forma una curva compuesta

invertida con una primera porción **126**. La segunda porción **128** se extiende a lo largo de una curva definida por un radio **R4** hacia una punta distal **124**. El radio **R3** y el radio **R4** se orientan hacia el eje longitudinal **104**, de modo que las segundas porciones **118**, **128** se curvan alejándose del eje longitudinal **104** y forman una relación cóncava, orientada hacia el eje longitudinal **104**.

La longitud de la porción **128** a lo largo del eje **104** es menor que la longitud de la porción **118** a lo largo del eje **104**, de modo que la punta distal **124** se distancia proximalmente de la punta distal **114**. La longitud de la segunda porción **118** y el radio **R3** se dimensionan de tal modo que la segunda porción **118** atraviese el eje longitudinal **104** desde el primer lado al segundo lado del eje longitudinal **104** en una relación transversal al eje longitudinal **104**, y la punta distal **114** se localice por lo menos parcialmente en el segundo lado del eje longitudinal **104**. La longitud de la segunda porción **128** y el radio **R4** se dimensionan de modo que la segunda porción **128** atraviesa el eje longitudinal **104** desde el segundo lado al primer lado del eje **104** en una relación transversal al eje longitudinal **104**, y la punta distal **124** se localiza por lo menos parcialmente en el primer lado del eje longitudinal **104**. Los radios **R1**, **R2**, **R3** y **R4** se indican como ejemplos de la ondulación de las curvas de las partes de la luz **110**, **120**. Cada porción de las partes de la luz **110**, **120** puede extenderse a lo largo de curvas formadas por radios múltiples y regulares o irregulares en su forma. En otra configuración, las curvas incluyen uno o más segmentos lineales o angulares.

La configuración de doble curva de la porción distal **112** ofrece un perfil no lineal, que contribuye a prevenir la formación de una vaina de fibrina que encapsule la porción distal **112** cuando se posiciona en el cuerpo del paciente. La relación divergente y convergente entre las partes de la luz **110**, **112** ofrece un perfil no lineal para las partes de la luz **110**, **120** a lo largo de la porción distal **112**.

Fig. 3 ilustra otra incorporación de una porción distal de un catéter **200**, que es similar al catéter **100** discutido anteriormente, excepto que la parte de la luz **220** del catéter **200** incluye una porción distal con un perfil no lineal con una sola curva. El catéter **200** incluye las partes de la luz **210**, **220** que se proyectan a lo largo del eje longitudinal **204**. La porción distal **212** se proyecta distalmente de una bifurcación **206** a lo largo de una longitud **L**, y es implantable en una estructura vascular. La longitud **L** puede ser alrededor de 6 centímetros, u otra longitud adecuada. Las partes de la luz **210**, **220** se separan una de otra, y la parte de la luz **210** diverge distalmente del eje longitudinal **204** en la bifurcación **206**. Las porciones de las partes de la luz **210**, **220** que se proyectan proximalmente de la bifurcación **206** pueden empalmarse entre sí o posicionarse una junto a la otra a lo largo de una porción proximal **202** del catéter **200**, en una manera similar a la discutida para el catéter **100**. En una incorporación, una de las partes de la luz **210**, **220** puede destinarse suministro de flujo de líquido al cuerpo del paciente y la otra parte de la luz **210**, **220** puede destinarse recibo de flujo de líquido del cuerpo del paciente. Por ejemplo, la parte de la luz **210** puede suministrar flujo venoso y la parte de la luz **220** puede suministrar flujo arterial.

La porción de extremo distal **212** forma una curva doble a lo largo de la parte de la luz **210** y una curva única a lo largo de la parte de la luz **220** para reducir la probabilidad de que la porción de extremo distal **212** pueda encapsularse en una vaina de fibrina, formada por el cuerpo del paciente. Por ejemplo, la parte de la luz **210** forma una primera porción **216** que se proyecta de la bifurcación **206** a lo largo de una curva definida por un radio **R5**. La parte de la luz **220** forma una primera porción **226**, que se extiende linealmente a lo largo y, generalmente, paralela al eje longitudinal **204**. El radio **R5** se localiza en el lado de la parte de la luz **210** alejado del eje longitudinal **204**, de modo que las partes de la luz **210**, **220** se separan, y la parte de la luz **210** diverge distalmente alejándose del eje longitudinal **204**,

y la parte de la luz **210** forma una relación convexa hacia el eje longitudinal **204**.

La parte de la luz **210** incluye asimismo una segunda porción **218**, que forma una curva compuesta invertida con la primera porción **216**, que se extiende a lo largo de una curva, definida por un radio **R6**, a una punta distal **214**. La parte de la luz **220** incluye igualmente una segunda porción **228**, que forma una curva desde la porción lineal **226**, que se extiende a lo largo de una curva, definida por un radio **R7**, a una punta distal **224**. El radio **R6** y el radio **R7** se posicionan hacia el eje longitudinal **204** de modo que las porciones **218**, **228** se curvan alejándose del eje **204** y forman una relación cóncava orientada hacia el eje longitudinal **204**.

La longitud de la segunda porción **228** a lo largo del eje **204** es menor que la longitud de la segunda porción **218** a lo largo del eje **204**, de modo que la punta distal **224** se distancia proximalmente de la punta distal **214**. La longitud de la segunda porción **218** y el radio **R6** se dimensionan de tal modo que la segunda porción **218** atraviese el eje longitudinal **204** desde un primer lado a un segundo lado del eje longitudinal **204** en una relación transversal, y la punta distal **214** se localice por lo menos parcialmente en el segundo lado del eje longitudinal **204**. La longitud de la segunda porción **228** y el radio **R7** se dimensionan de tal modo que la segunda porción **228** atraviese el eje longitudinal **204** desde el segundo lado al primer lado del eje longitudinal **204** en una relación transversal, y la punta distal **224** se localice por lo menos parcialmente en el primer lado. Los radios **R5**, **R6** y **R7** se indican como ejemplos de la ondulación de las curvas de la porción distal **212** de las partes de la luz **210**, **220**. Las ondulaciones de cada una de las partes de la luz **210**, **220** pueden extenderse a lo largo de curvas formadas por radios múltiples y regulares o irregulares en su forma. En otra configuración, las curvas incluyen uno o más segmentos lineales o angulares.

La configuración de doble curva de la porción distal **212** ofrece un perfil no lineal, el cual contribuye a prevenir la formación de una vaina de fibrina que encapsule la porción distal **212**, cuando se posiciona en el cuerpo del paciente. La relación divergente y convergente entre las partes de la luz **210**, **220** ofrece un perfil no lineal para las partes de la luz **210**, **220** a lo largo de la porción distal **212**.

Los catéteres **100**, **200** se han provisto con las respectivas porciones distales **112**, **212** preformadas para ofrecer configuraciones de perfil no lineal, discutidas anteriormente. Se contempla además que puedan proveerse una o más guías metálicas u otros miembros rígidos en la pared de las partes de la luz **110**, **120** o las partes de la luz **210**, **220**, para contribuir a mantener la configuración preformada de perfil no lineal antes de la implantación y después de la implantación.

Fig. 4 es un corte transversal a través del catéter **100** a lo largo de la línea 4-4. La parte de la luz **110** incluye una pared **130** en forma de **D**, que define una luz central o pasaje de flujo **132** que se extiende a través de él. La pared **130** incluye una porción arqueada **134**, y una porción lineal **136** que se extiende entre lados opuestos de la porción arqueada **134**. Análogamente, la parte de la luz **120** incluye una pared **140** en forma de **D**, que define una luz central o pasaje de flujo que se extiende a través de él. La pared **140** incluye una porción arqueada **144**, y una porción lineal **146** que se extiende entre lados opuestos de la porción arqueada **144**. Las partes de la luz **110**, **120** se posicionan con las porciones lineales **136**, **146** en relación paralela a lo largo del eje longitudinal **104**, por lo menos proximalmente de la bifurcación **106**. Las partes de la luz **110** pueden asegurarse una con otra con un adhesivo, técnica de extrusión, fusión, o sujetadores mecánicos.

Las paredes **130**, **140** definen igualmente cada una un par de lúmenes más pequeños en la unión, o adyacentes a ella, de la porción lineal

respectiva **136, 146** con la porción arqueada **134, 144**. La pared **130** incluye elementos rígidos primero y segundo **150a, 150b** en estos lúmenes más pequeños, y la pared **140** incluye elementos rígidos tercero y cuarto **152a, 152b** en estos lúmenes más pequeños. Los elementos rígidos se extienden en toda la longitud **L** de por lo menos la porción distal **112**, y mantienen la porción distal en su configuración no lineal discutida anteriormente. Los elementos rígidos **150a, 150b** y los elementos rígidos **152a, 152b** son elásticos, de modo que cuando la configuración curva a lo largo de la porción distal **112** se endereza, como resultado de las fuerzas de inserción u otras fuerzas al momento del implante, la porción distal **112** se obliga a regresar al perfil no lineal discutido anteriormente, al momento de liberar las fuerzas. En una incorporación, los elementos rígidos **150a, 150b** y los elementos rígidos **152a, 152b** son alambres alargados de material con memoria de forma, tales como aleación de titanio-níquel o acero para resortes. Los elementos rígidos pueden extenderse en toda la longitud de la respectiva parte de la luz **110, 120**, o pueden extenderse a lo largo de tan sólo una porción de la longitud de la respectiva parte de la luz **110, 120**. En otra incorporación, una o ambas partes de la luz se proveen con un solo elemento rígido. En aún otra incorporación, se proveen más de dos elementos rígidos en la pared de una o ambas partes de la luz.

En otra incorporación mostrada en Fig. 5, se provee un catéter **300** con una porción proximal **302** y una porción distal **312**. La porción distal **312** se ilustra en la misma forma que la porción distal **112** del catéter **100**, entendiéndose que podrían proveerse igualmente otras disposiciones de la porción distal. La porción proximal **302** incluye partes de la luz primera y segunda **310, 320** que se configuran al igual que las partes de la luz **110, 120** del catéter **100**. No obstante, la porción proximal **302** incluye una curvatura intermedia **360** que re-orienta un segmento distal **362** de la porción proximal **302** en relación con un segmento proximal **364** de la porción proximal **302**.

El segmento proximal **364** se extiende a lo largo del eje longitudinal **304**, y el segmento distal **362** se extiende a lo largo del eje longitudinal **306**. La curvatura intermedia **360** incluye una forma en U, de modo que los ejes **304**, **306** definen un ángulo **A** entre ellos. Las partes de la luz **310**, **320** pueden preformarse para incluir la curvatura **360**. Los elementos rígidos, al igual que los elementos rígidos **150a**, **150b** y los elementos rígidos **152a**, **152b**, mantienen el catéter **300** con la curvatura **360** durante el embalaje y el despacho, durante el procedimiento de implantación y después de la implantación. La curvatura **360** se arquea a lo largo de un radio con el fin de proporcionar una transición suave entre los segmentos distal y proximal **362**, **364** con el fin de eliminar o evitar la formación de curvas cerradas o torceduras en las partes de la luz **310**, **320**, que podrían restringir o impedir el flujo a través de los pasajes de las mismas.

En una incorporación, el ángulo **A** tiene alrededor de 30 grados. Otras incorporaciones contemplan un ángulo **A** que varía desde 5 grados a 180 grados. En todavía otra incorporación discutida más adelante, la curvatura **360** se extiende en 180 grados, de modo que el eje **306** del segmento distal **362** es paralelo al eje **304** del segmento proximal **364**.

Con referencia nuevamente a Fig. 1, se discutirán detalles asociados con la porción proximal **102** del catéter **100**, entendiéndose que las porciones proximales de las demás incorporaciones del catéter pueden disponerse análogamente o de manera diferente a la porción proximal **102**. La porción proximal **102** incluye un manguito **160** que rodea las partes de la luz **110**, **120**. El manguito **160** provee un soporte para la penetración de tejido en la ubicación donde el catéter **100** penetra en la piel del paciente. El manguito **160** es de fieltro de poliéster en una incorporación. Otras incorporaciones contemplan cualquier otra estructura o material apropiado para el manguito **160**. En otras incorporaciones, el manguito **160** se omite.

La porción proximal **102** del catéter **100** incluye igualmente una

pieza triangular **162** que se conecta a los extremos proximales de las respectivas partes de la luz **110**, **120**. La pieza triangular **162** incluye una aleta **164** que define orificios para alojar suturas que permitan la sujeción del catéter **100** al paciente después de la implantación. La pieza triangular **162** mantiene igualmente la separación de los pasajes **132**, **142** de las partes de la luz **110**, **120**. Los pasajes **132**, **142** están en comunicación fluida con los pasajes respectivos de las conexiones primera y segunda **170**, **180** que se proyectan proximalmente de la pieza triangular **162**. Las conexiones **170**, **180** se fabrican igualmente de tubo flexible, e incluyen adaptadores hembra **172**, **182**, respectivamente, en sus extremos proximales. Los adaptadores macho **174**, **184** se acoplan en forma desmontable a los respectivos adaptadores hembra **172**, **182** para facilitar un obturador, con el fin de mantener la integridad y esterilidad de los adaptadores hembra **172**, **182**. Las conexiones **170**, **180** incluyen además las pinzas **176**, **186**, respectivamente, que cierran en forma liberable la conexión respectiva **170**, **180** para restringir o permitir el flujo de líquido a través de los pasajes **132**, **142** de las partes de la luz **110**, **120**.

Se contemplan varias longitudes del catéter **100**, entendiéndose que las demás incorporaciones del catéter podrían disponerse también con las mismas o con diferentes longitudes. El catéter **100** incluye una dimensión **L1** desde el extremo distal de la pieza triangular **162** al extremo distal de la parte de la luz **110**. El manguito **160** se encuentra distanciado en una dimensión **L2** del extremo distal de la parte de la luz **110**. En una incorporación, la dimensión **L1** varía desde 24 centímetros a 32 centímetros, y la dimensión **L2** varía desde 19 centímetros a 27 centímetros. El catéter **100** incluye una dimensión **L3** desde el extremo distal de la pieza triangular **162** al extremo distal de la parte de la luz **120**. El manguito **160** se encuentra distanciado en una dimensión **L4** del extremo distal de la parte de la luz **120**. En una incorporación, la dimensión **L3** varía desde 21 centímetros a 29 centímetros, y la dimensión **L4** varía desde 16 centímetros a 24 centímetros. Las conexiones **170**, **180** se proyectan proximalmente de

la pieza triangular **162** a lo largo de una dimensión **L5**. En una incorporación, la dimensión **L5** es de alrededor de 3.25 pulgadas. Otras incorporaciones contemplan otras dimensiones para **L1**, **L2**, **L3**, **L4** y **L5**.

Se contemplan varias disposiciones para las puntas distales. En una incorporación, las configuraciones de las respectivas partes de la luz **110**, **120**, mostradas en Fig. 4, se prolongan a través de las puntas distales para constituir un puerto que se abre distalmente. En otra incorporación, mostrada en Figs. 6-8, las puntas distales **114**, **124** incluyen una configuración ahusada distalmente. En Figs. 6-8 se describirá la punta distal **114**, entendiéndose que la punta distal **124** podría disponerse en forma análoga. Específicamente, la pared **130** incluye un primer espesor a lo largo de la parte proximal **190** de la punta **114**. Los elementos rígidos **150a**, **150b** se extienden en el espesor de la pared **130** a una ubicación de extremo distal distanciada proximalmente del extremo distal **192** de la punta **114**. El espesor de la pared **130** disminuye gradualmente a lo largo de una parte distal **194** de la punta distal **114** desde la ubicación de extremo distal de los elementos rígidos **150a**, **150b** hacia el extremo distal **192**, donde el pasaje **132** se abre distalmente. La sección transversal del pasaje **132** permanece constante a través de la punta distal **114** para maximizar el área disponible para flujo. El espesor de pared reducido a lo largo de la parte distal **194** de la punta distal **114** aumenta la flexibilidad de la punta distal y brinda protección adicional a la estructura vascular contra trauma, en el caso de que la punta distal **114** contacte la pared del vaso u otra estructura anatómica.

La punta distal **114** incluye además un puerto lateral **196** que se extiende a lo largo de la pared lineal **136** en la dirección proximal-distal. El puerto lateral **196** forma una abertura alargada que normalmente permanece cerrada, pero que se abre con la aplicación de suficiente presión de líquido para permitir por lo menos que alguna parte de líquido fluya a través de ella. En otra incorporación, se omite el puerto lateral **196** de la punta distal

114. En todavía otra incorporación, se proveen múltiples puertos laterales en la punta distal **114**.

En todavía otra incorporación ilustrada en Fig. 9, un catéter **100'** es similar al catéter **100**, excepto por la punta distal de la parte de la luz arterial **120'**. La punta distal **124'** se dispone de tal modo que el orificio distal se oriente en la dirección de flujo en la estructura vascular. En consecuencia, la punta distal **124'** incluye una pared de extremo distal **125'** que se orienta oblicuamente a la pared **140** de la parte de la luz **120'**. El lado en ángulo agudo **127'** de la pared de extremo distal **125'** se posiciona hacia la parte de la luz **110** y se une a la parte de la luz **110** para mantener el orificio distal orientado en la dirección del flujo de líquido y alejada de la pared del vaso. La disposición del empalme impide que el orificio distal de la punta distal **124'** se obstruya por la pared **130** de la parte de la luz **110** en la estructura vascular.

Figs. 10-12 ilustran otro catéter de incorporación **400**, similar al catéter **100**, excepto que el catéter **400** incluye mecanismos de cierre y apertura, que son operables con un accionador para cerrar y abrir selectivamente los puertos distales de las partes de la luz. Específicamente, el catéter **400** incluye una primera parte de la luz **410** y una segunda parte de la luz **420**, y las partes de la luz **410**, **420** forman una porción proximal **402** del catéter **400** y una porción distal **404**. Las partes de la luz **410**, **420** son sustancialmente idénticas a las partes de la luz **110**, **120** discutidas anteriormente, excepto que los elementos rígidos son también miembros accionadores móviles **450** (Figs. 11-12) provistos en las paredes de las partes de la luz **410**, **420**, que pueden desplazarse longitudinalmente con el accionador **460**. El accionador **460** viene montado en un cono proximal **470** que aloja las partes de la luz **410**, **420** y mantiene sus líneas de flujo separadas a las conexiones **472**, **474**, respectivamente. Los miembros accionadores **450** se acoplan a los respectivos obturadores finales **430**, **440** en el extremo distal de las respectivas partes de la luz **410**, **420** y pueden

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desplazarse longitudinalmente para abrir y cerrar el puerto distal con el respectivo obturador final **430, 440**. Los miembros accionadores **450** proveen igualmente un elemento rígido, como los elementos rígidos **150a, 150b, 152a, 152b**, discutidos anteriormente, para mantener la forma de las partes de la luz **410, 420** y el perfil no lineal a lo largo de la porción distal **404**.

La porción proximal **402** incluye un segmento distal **406** que se extiende a lo largo del eje longitudinal **411** y un segmento proximal **408** que se extiende a lo largo del eje longitudinal **401**. El segmento proximal **408** se conecta con el segmento distal **406** con una curva de 180 grados **414**, de modo que los ejes longitudinales **401, 411** son paralelos entre sí. Otras incorporaciones contemplan otras disposiciones en ángulo entre los ejes **401, 411**, como se discute anteriormente con respecto a los catéteres **100 y 300**.

En Figs. 11-12 se ilustra una parte de la luz **410, 420** en la porción distal **404** del catéter **400**, entendiéndose que las partes de la luz **410, 420** son idénticas a las partes de la luz **110, 120** discutidas anteriormente, excepto lo comentado en contrario en esta especificación. Las partes de la luz **410, 420** incluyen cada una un cuerpo formado por una pared **418** que se extiende alrededor de una luz o pasaje **421**, que permite el flujo de líquido a través de la parte de la luz. La luz **421** se abre en un extremo distal **422** de las partes de la luz **410, 420** para formar un puerto que se abre distalmente **416** para el ingreso y/o egreso de flujo de líquido.

Adicionalmente, el catéter **400** incluye obturadores finales **430, 440** asociados con cada parte respectiva de la luz **410, 420**. Los obturadores finales **430, 440** pueden desplazarse en relación con el extremo distal de la parte de la luz **410, 420** desde una posición abierta, como se muestra en Fig. 11, a una posición cerrada, manipulando los miembros accionadores **450**. El puerto **416** puede abrirse pasando el catéter **400** de su posición cerrada al

desplazar el obturador final **430, 440** distalmente desde su posición cerrada a su posición abierta. En la posición abierta, el obturador **430, 440** se separa del extremo distal **422**, resultando en un cambio de la longitud del catéter **400**, de modo que el puerto **416** se abre para permitir el paso de líquido desde el lumen **421** o al interior del mismo. Los obturadores finales **430, 440** se acoplan a las partes de la luz **410, 420** con uno o más miembros accionadores **450** que se extienden entre las partes de la luz **410, 420** y los obturadores finales **430, 440**. Los miembros accionadores **450** tienen la forma de un alambre de accionamiento en la pared **418** en la unión, o adyacentes a ella, de la porción lineal **419** y la porción convexa redondeada **423**. Cada miembro accionador **450** se posiciona en una luz **451** formada en la pared **418** en toda la longitud de la respectiva parte de la luz **410, 420**. Tal luz **451** destinada a alojar el respectivo miembro accionador **450** podría estar formada por una bobina de alambre plano, de acero inoxidable o un material con memoria de forma. Los miembros accionadores **450** pueden fabricarse asimismo de acero inoxidable, material con memoria de forma, o cualquier material apropiado. Los miembros accionadores **450** y uno o más de otros miembros accionadores o elementos rígidos no móviles pueden localizarse en otras ubicaciones alrededor de la pared **418**.

Los obturadores finales **430, 440** pueden desplazarse a la posición cerrada desde la posición abierta, desplazando axial y proximalmente los obturadores finales **430, 440** hacia el puerto **416** a lo largo del eje longitudinal **411** y en acoplamiento hermético con la respectiva parte de la luz **410, 420**. Los miembros accionadores **450** se acoplan a un mecanismo accionador para permitir el desplazamiento de los miembros accionadores **450** y, por consiguiente, de los obturadores finales **430, 440** acoplados a ellos, proximalmente a lo largo del eje **411** a la posición cerrada, como se indica por las líneas discontinuas en Fig. 12. Para abrir el puerto **416**, los miembros accionadores **450** se desplazan distalmente con el mecanismo accionador para mover el obturador **430, 440** distalmente a lo largo del eje **411** y en relación con puerto **416** de la respectiva parte de la luz **410, 420**.

Los obturadores finales **430**, **440** incluyen una porción proximal, estrechada gradualmente, **432** que puede facilitar el alojamiento por el puerto **416** en la luz **421**. Asimismo, la porción estrechada gradualmente **432** puede permitir que los obturadores finales **430**, **440** se centren automáticamente en relación con el puerto **416** y permitan un acoplamiento hermético con la pared **418** de la respectiva parte de la luz **410**, **420**. En otra incorporación, los obturadores finales **430**, **440** se configuran con un receptáculo que aloja en su interior el extremo de la respectiva parte de la luz en la posición cerrada.

Con referencia nuevamente a Fig. 10, cuando el obturador final **440** de la parte de la luz **420** se abre, contacta la parte de la luz **410** en la porción distal **404** y la desplaza alejándola del eje longitudinal **411**, como se muestra por líneas discontinuas. Esto, a su vez, puede liberar o desprender cualquier vaina de fibrina formada a lo largo de las partes de la luz **410**, **420**. Más aún, al abrir y cerrar los obturadores **430**, **440** se libera o desprende cualquier vaina de fibrina formada en las porciones distales de las partes de la luz **410**, **420**. Adicionalmente, la orientación no lineal de las partes de la luz **410**, **420** y las estructuras de puerto móvil provistas en ellas pueden correr a lo largo de la parte de la luz **410** durante la apertura y cierre del puerto, desplazando y moderando cualquier acumulación de una vaina de fibrina. La orientación transversal de las puntas distales de las partes de la luz **410**, **420** al eje longitudinal **411** orienta los puertos en una relación transversal a la estructura de la vasculatura, mientras que los obturadores finales **430**, **440** desplazan los puertos de las estructuras de la vasculatura, si están en contacto con ellas, e impiden o moderan el bloqueo del flujo de los puertos por la estructura vascular en la cual se encuentran posicionadas las puntas distales.

Fig. 10 muestra además las partes de la luz **410**, **420** acopladas una con la otra en el cono proximal **470**. El cono proximal **470** incluye una configuración que separa las dos partes de la luz **410**, **420** para empalmarlas

a las conexiones **472**, **474**, las cuales pueden configurarse de manera idéntica a las conexiones **170**, **180** discutidas anteriormente para el catéter **100**. En una incorporación, una de las partes de la luz **410**, **420** puede destinarse para suministrar flujo de líquido al cuerpo del paciente y la otra parte de la luz **410**, **420** puede destinarse para recibir flujo de líquido proveniente del cuerpo del paciente, como se indica por las flechas **412**, **413**.

El accionador **460** incluye botones deslizables primero y segundo **462**, **464** asociados con los botones respectivos de las partes de la luz primera y segunda **410**, **420** que se montan o empalman al cono **470**. Los botones deslizables **462**, **464** se mueven longitudinalmente para desplazar uno o más miembros accionadores **450**, acoplados a ellos, para abrir y cerrar los respectivos obturadores finales **430**, **440**. Los botones deslizables **462**, **464** permiten la manipulación remota del movimiento de los miembros accionadores **450** y el obturador final asociado, **440**, de la respectiva parte de la luz **410**, **420** a lo largo de la pared de la parte de la luz. Los botones deslizables separados **462**, **464** pueden moverse axialmente en direcciones proximales o distales, según se desee, para efectuar el correspondiente movimiento independiente y remotamente activado de los obturadores finales **430**, **440**, dependiendo de la parte de la luz **410**, **420** manipulada con el accionador **460**. Tal movimiento posibilita la apertura y cierre selectivo de uno o más puertos para permitir el flujo de líquido a través de ellos.

En Fig. 13 se muestra otra incorporación de la porción distal **404** del catéter **400**, designado como catéter **400'**. El catéter **400'** incluye partes de la luz **410**, **420** pero otro obturador final de incorporación **430'**, **440'** asociado con las respectivas partes de la luz **410**, **420**. Los obturadores finales **430'**, **440'** se empalman a las partes de la luz con los miembros accionadores **450**, pero incluyen los pasajes **431**, **441**, respectivamente, para alojar una guía metálica **500** que facilita la colocación percutánea del catéter **400** en el paciente.

En uso, la guía metálica **500** se posiciona en el sitio de implantación del catéter en el paciente. Los obturadores **430'**, **440'** se mueven a la posición cerrada, y el extremo proximal de la guía metálica **500** se ensarta a través del pasaje longitudinal **431** del obturador final **430'**. Entonces se abre el obturador final **440'** y el extremo proximal de la guía metálica **500** se posiciona a través del pasaje **421** atravesando el extremo proximal de la parte de la luz **420**. Alternativamente, la guía metálica **500** se posiciona a través de un pasaje **441** que se extiende longitudinalmente a través del obturador final **440'**. Entonces el catéter **400'** se guía a lo largo de la guía metálica **500** para ubicar los extremos distales de las partes de la luz **410**, **420** en el sitio de implantación.

En un procedimiento que emplea los catéteres discutidos en esta especificación, el extremo distal de la parte venosa o más larga de la luz se posiciona en la aurícula derecha del corazón, y el extremo distal de la parte arterial o más corta de la luz se posiciona en la unión de la vena cava superior y la aurícula derecha. Otros procedimientos contemplan otros sitios y técnicas de implantación. Por ejemplo, el catéter **100** puede posicionarse al sitio de implantación situando la guía metálica a través del pasaje de una de las partes de la luz **110**, **120** y conduciendo el catéter **100** a lo largo de la guía metálica al sitio de implantación. La porción distal del catéter en la bifurcación puede mantenerse junta con una cinta liberable o sutura para facilitar la inserción. En otro procedimiento, los extremos distales de cualquiera de las incorporaciones del catéter se posicionan en un dispositivo de tunelización para mantener la porción distal no lineal en una configuración más lineal. El catéter se inserta en el paciente en la configuración más lineal, y se libera del dispositivo de tunelización luego de la implantación para volver al perfil no lineal a lo largo de la porción distal. En cualquier procedimiento, el posicionamiento y la colocación de los catéteres puede monitorearse con ultrasonido y fluoroscopia.

Aunque la invención se ha ilustrado y descrito en detalle en los dibujos y la descripción que antecede, la misma tiene que considerarse con carácter ilustrativo y no restrictivo. Por ejemplo, para cualesquiera mecanismos accionadores del catéter de incorporación se contempla que incluyan micro-motores u otros sistemas mecánicos o automáticos para abrir y cerrar los puertos de fluido de líquido. Se desea que se protejan todos los cambios y modificaciones acordes con el espíritu de la invención.

Lo que se reivindica es:

1. Un catéter, que incluye:

una primera parte de la luz y una segunda parte de la luz, que se extienden a lo largo de un eje longitudinal en relación paralela, formando las citadas partes de la luz primera y segunda una porción proximal y una porción distal del catéter, en donde por lo menos un segmento distal de la citada porción proximal se extiende a lo largo del citado eje longitudinal y las citadas partes de la luz primera y segunda se separan una de la otra en una bifurcación entre las citadas porciones distal y proximal, en donde la citada primera parte de la luz se proyecta distalmente de la citada bifurcación e incluye una primera curva, de modo que la citada primera parte de la luz se arquea cóncavamente hacia el citado eje longitudinal en un primer lado del citado eje longitudinal, y la citada segunda parte de la luz se proyecta distalmente de la citada bifurcación e incluye una segunda curva, de modo que la citada segunda parte de la luz se arquea cóncavamente hacia el citado eje longitudinal en un segundo lado del citado eje longitudinal.

2. El catéter de la reivindicación 1, en donde la citada primera parte de la luz y la citada segunda parte de la luz incluye cada una pared en **D** a lo largo de las citadas porciones proximal y distal, definiendo cada una de las citadas paredes en **D** un pasaje central que se extiende a lo largo de la citada parte de la luz respectiva.

3. El catéter de la reivindicación 2, en donde las citadas partes de la luz primera y segunda incluyen cada una un par de elementos rígidos alargados en la citada pared, extendiéndose los citados elementos rígidos alargados a lo largo de las citadas porciones proximal y distal del catéter.

4. El catéter de la reivindicación 3, en donde las citadas partes de la luz primera y segunda definen cada una un puerto, que se abre distalmente en su extremo distal, y comprenden además un obturador en el citado extremo

distal de cada una de las citadas partes de la luz primera y segunda, en donde los citados elementos rígidos se acoplan a los citados obturadores respectivos y se pueden mover en la citada pared de la citada parte de la luz respectiva para desplazar el citado obturador respectivo desde una posición abierta, a una distancia del citado extremo distal de la citada parte de la luz respectiva, a una posición cerrada, acoplada al citado extremo distal de la citada parte de la luz respectiva, para cerrar el citado pasaje de la misma.

5. El catéter de la reivindicación 4, en donde los citados elementos rígidos de cada una de las citadas partes de la luz primera y segunda se acoplan con un accionador adyacente a un extremo proximal de las citadas partes de la luz primera y segunda, siendo el citado accionador operable para mover selectivamente cada uno de los citados obturadores entre las citadas posiciones abierta y cerrada.

6. El catéter de la reivindicación 1, en donde la citada primera parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado segundo lado del citado eje longitudinal.

7. El catéter de la reivindicación 6, en donde la citada segunda parte de la luz es curva, de modo que un extremo distal se localiza en el citado primer lado del citado eje longitudinal.

8. El catéter de la reivindicación 1, en donde la citada primera parte de la luz tiene una longitud a lo largo del citado eje longitudinal que es mayor que una longitud de la citada segunda parte de la luz a lo largo del citado eje longitudinal, de modo que un extremo distal de la citada primera parte de la luz se distancia distalmente de un extremo distal de la citada segunda parte de la luz a lo largo del citado eje longitudinal.

9. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda parte incluyen un segmento

distal de cada una de las citadas partes de la luz primera y segunda, en donde los citados elementos rígidos se acoplan a los citados obturadores respectivos y se pueden mover en la citada pared de la citada parte de la luz respectiva para desplazar el citado obturador respectivo desde una posición abierta, a una distancia del citado extremo distal de la citada parte de la luz respectiva, a una posición cerrada, acoplada al citado extremo distal de la citada parte de la luz respectiva, para cerrar el citado pasaje de la misma.

5. El catéter de la reivindicación 4, en donde los citados elementos rígidos de cada una de las citadas partes de la luz primera y segunda se acoplan con un accionador adyacente a un extremo proximal de las citadas partes de la luz primera y segunda, siendo el citado accionador operable para mover selectivamente cada uno de los citados obturadores entre las citadas posiciones abierta y cerrada.

6. El catéter de la reivindicación 1, en donde la citada primera parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado segundo lado del citado eje longitudinal.

7. El catéter de la reivindicación 6, en donde la citada segunda parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado primer lado del citado eje longitudinal.

8. El catéter de la reivindicación 1, en donde la citada primera parte de la luz tiene una longitud a lo largo del citado eje longitudinal que es mayor que una longitud de la citada segunda parte de la luz a lo largo del citado eje longitudinal, de modo que un extremo distal de la citada primera parte de la luz se distancia distalmente de un extremo distal de la citada segunda parte de la luz a lo largo del citado eje longitudinal.

9. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda parte incluyen un segmento

proximal que se extiende a lo largo de un segundo eje longitudinal y una curva que conecta el citado segmento proximal y el citado segmento distal, en donde los citados ejes longitudinal forman un ángulo de alrededor de 30 grados.

10. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda incluyen un segmento proximal, que se extiende a lo largo de un segundo eje longitudinal, y una curva que conecta el citado segmento proximal y el citado segmento distal, en donde los citados ejes longitudinales son paralelos entre sí.

11. El catéter de la reivindicación 1, en donde:

la citada primera parte de la luz forma una tercera curva en la citada bifurcación y la citada primera curva es distal de la citada tercera curva, formando las citadas curvas primera y tercera una curva compuesta invertida a lo largo de la citada primera parte de la luz; y

la citada segunda parte de la luz forma una cuarta curva en la citada bifurcación y la citada segunda curva es distal de la citada segunda curva, formando las citadas curvas segunda y cuarta una curva compuesta invertida a lo largo de la citada segunda parte de la luz.

12. El catéter de la reivindicación 1, en donde por lo menos una de las citadas partes de la luz primera y segunda incluye una punta distal y la citada punta distal incluye una parte proximal con un primer espesor de pared y por lo menos un elemento rígido, que se extiende el citado primer espesor de pared, terminando el citado por lo menos un elemento rígido en la citada parte proximal e incluyendo la citada punta distal una parte distal y el citado espesor de pared disminuye gradualmente, distalmente de la citada parte proximal, a lo largo de la citada parte distal a un extremo distal de la citada punta distal.

13. El catéter de la reivindicación 1, en donde la citada primera parte de

proximal que se extiende a lo largo de un segundo eje longitudinal y una curva que conecta el citado segmento proximal y el citado segmento distal, en donde los citados ejes longitudinal forman un ángulo de alrededor de 30 grados.

10. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda incluyen un segmento proximal, que se extiende a lo largo de un segundo eje longitudinal, y una curva que conecta el citado segmento proximal y el citado segmento distal, en donde los citados ejes longitudinales son paralelos entre sí.

11. El catéter de la reivindicación 1, en donde:

la citada primera parte de la luz forma una tercera curva en la citada bifurcación y la citada primera curva es distal de la citada tercera curva, formando las citadas curvas primera y tercera una curva compuesta invertida a lo largo de la citada primera parte de la luz; y

la citada segunda parte de la luz forma una cuarta curva en la citada bifurcación y la citada segunda curva es distal de la citada cuarta curva, formando las citadas curvas segunda y cuarta una curva compuesta invertida a lo largo de la citada segunda parte de la luz..

12. El catéter de la reivindicación 1, en donde por lo menos una de las citadas partes de la luz primera y segunda incluye una punta distal y la citada punta distal incluye una parte proximal con un primer espesor de pared y por lo menos un elemento rígido, que se extiende el citado primer espesor de pared, terminando el citado por lo menos un elemento rígido en la citada parte proximal e incluyendo la citada punta distal una parte distal y el citado espesor de pared disminuye gradualmente, distalmente de la citada parte proximal, a lo largo de la citada parte distal a un extremo distal de la citada punta distal.

13. El catéter de la reivindicación 1, en donde la citada primera parte de

la luz se extiende distalmente más allá de una punta distal de la citada segunda parte de la luz, y la citada punta distal de la citada segunda parte de la luz incluye una pared de extremo distal orientada oblicuamente a una pared de la citada segunda parte de la luz en la citada punta distal, en donde la citada punta distal de la citada segunda parte de la luz se asegura a una pared de la citada primera parte de la luz.

14. Un catéter, que incluye:

un cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado cuerpo una pared que define por lo menos una luz para fluido de líquido a través del mismo, en donde el citado cuerpo incluye por lo menos un puerto en el citado extremo distal del citado cuerpo alargado en comunicación con la citada por lo menos una luz, y que comprende además un obturador final en el citado extremo distal y un mecanismo accionador en el citado extremo proximal, acoplándose el citado obturador final al citado mecanismo accionador, el cual es operable para mover remotamente el citado obturador final alejándolo del citado puerto a una posición abierta y permitir el flujo de líquido a través del citado puerto y para mover remotamente el citado obturador final hacia el citado extremo distal a una posición cerrada para impedir el flujo de líquido a través del citado puerto, en donde el citado obturador final incluye un pasaje que se extiende a través del mismo y que comprende además una guía metálica que se puede posicionar a través del citado pasaje y a lo largo del citado cuerpo alargado fuera de la citada luz.

15. El catéter de la reivindicación 14, que comprende además un segundo cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado segundo cuerpo una segunda pared que define por lo menos una luz para flujo de líquido a través del mismo y por lo menos un segundo puerto en el citado extremo distal del citado segundo cuerpo en comunicación con la citada por lo menos una luz del mismo, y que comprende además un segundo obturador final en el citado extremo

la luz se extiende distalmente más allá de una punta distal de la citada segunda parte de la luz, y la citada punta distal de la citada segunda parte de la luz incluye una pared de extremo distal orientada oblicuamente a una pared de la citada segunda parte de la luz en la citada punta distal, en donde la citada punta distal de la citada segunda parte de la luz se asegura a una pared de la citada primera parte de la luz en la citada pared de extremo distal.

14. Un catéter, que incluye:

un cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado cuerpo una pared que define por lo menos una luz para fluido de líquido a través del mismo, en donde el citado cuerpo incluye por lo menos un puerto en el citado extremo distal del citado cuerpo alargado en comunicación con la citada por lo menos una luz, y que comprende además un obturador final en el citado extremo distal y un mecanismo accionador en el citado extremo proximal, acoplándose el citado obturador final al citado mecanismo accionador, el cual es operable para mover remotamente el citado obturador final alejándolo del citado puerto a una posición abierta y permitir el flujo de líquido a través del citado puerto y para mover remotamente el citado obturador final hacia el citado extremo distal a una posición cerrada para impedir el flujo de líquido a través del citado puerto, en donde el citado obturador final incluye un pasaje que se extiende a través del mismo y que comprende además una guía metálica que se puede posicionar a través del citado pasaje y a lo largo del citado cuerpo alargado fuera de la citada luz.

15. El catéter de la reivindicación 14, que comprende además un segundo cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado segundo cuerpo una segunda pared que define por lo menos una luz para flujo de líquido a través del mismo y por lo menos un segundo puerto en el citado extremo distal del citado segundo cuerpo en comunicación con la citada por lo menos una luz del mismo, y que comprende además un segundo obturador final en el citado extremo

distal, acoplándose el citado segundo obturador final al citado mecanismo accionador, el cual es operable para mover remotamente el citado segundo obturador final alejándolo del citado segundo puerto a una posición abierta y permitir el flujo de líquido a través del citado segundo puerto y mover remotamente el citado segundo obturador final hacia el citado extremo distal a una posición cerrada para impedir el flujo de líquido a través del citado segundo puerto, en donde, con el citado segundo obturador final en la citada posición abierta, la citada guía metálica se puede posicionar a través de la citada por lo menos una luz del citado segundo cuerpo alargado a través del citado extremo proximal del citado segundo cuerpo alargado.

16. El catéter de la reivindicación 15, en donde el citado segundo obturador final incluye un pasaje que se extiende a través de él y la citada guía metálica se puede posicionar a través del citado pasaje del citado segundo obturador final en la citada por lo menos una luz del citado segundo cuerpo alargado.

17. El catéter de la reivindicación 15, en donde las citadas paredes de los citados cuerpos alargados primero y segundo se aseguran mutuamente a lo largo de una porción proximal del catéter y los citados cuerpos alargados primero y segundo se separan uno del otro en una bifurcación para formar una porción distal del catéter que se proyecta distalmente de la bifurcación, en donde la porción distal incluye un perfil no lineal a lo largo del eje longitudinal.

18. Un catéter, que incluye:

una primera parte de la luz y una segunda parte de la luz que se extienden a lo largo de un eje longitudinal en una relación paralela, formando las citadas partes de la luz primera y segunda una porción proximal y una porción distal del catéter, en donde por lo menos un segmento distal de la citada porción proximal se extiende a lo largo del citado eje longitudinal y las citadas partes de la luz primera y segunda se

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separan una de la otra en una bifurcación entre las citadas porciones distal y proximal, en donde la citada primera parte de la luz se proyecta distalmente de la citada bifurcación a lo largo de una primera curva, de modo que la citada primera parte de la luz se arquea cóncavamente en relación con el citado eje longitudinal en un primer lado del citado eje longitudinal y la citada segunda parte de la luz se proyecta lineal y distalmente de la citada bifurcación a lo largo de un segundo lado del citado eje longitudinal a una segunda curva que se arquea para ubicar una punta distal de la citada segunda parte de la luz en el citado primer lado del citado eje longitudinal.

19. El catéter de la reivindicación 18, en donde la citada primera curva de la citada primera parte de la luz se arquea para ubicar un extremo distal de la citada primera parte de la luz en el citado segundo lado del citado eje longitudinal.

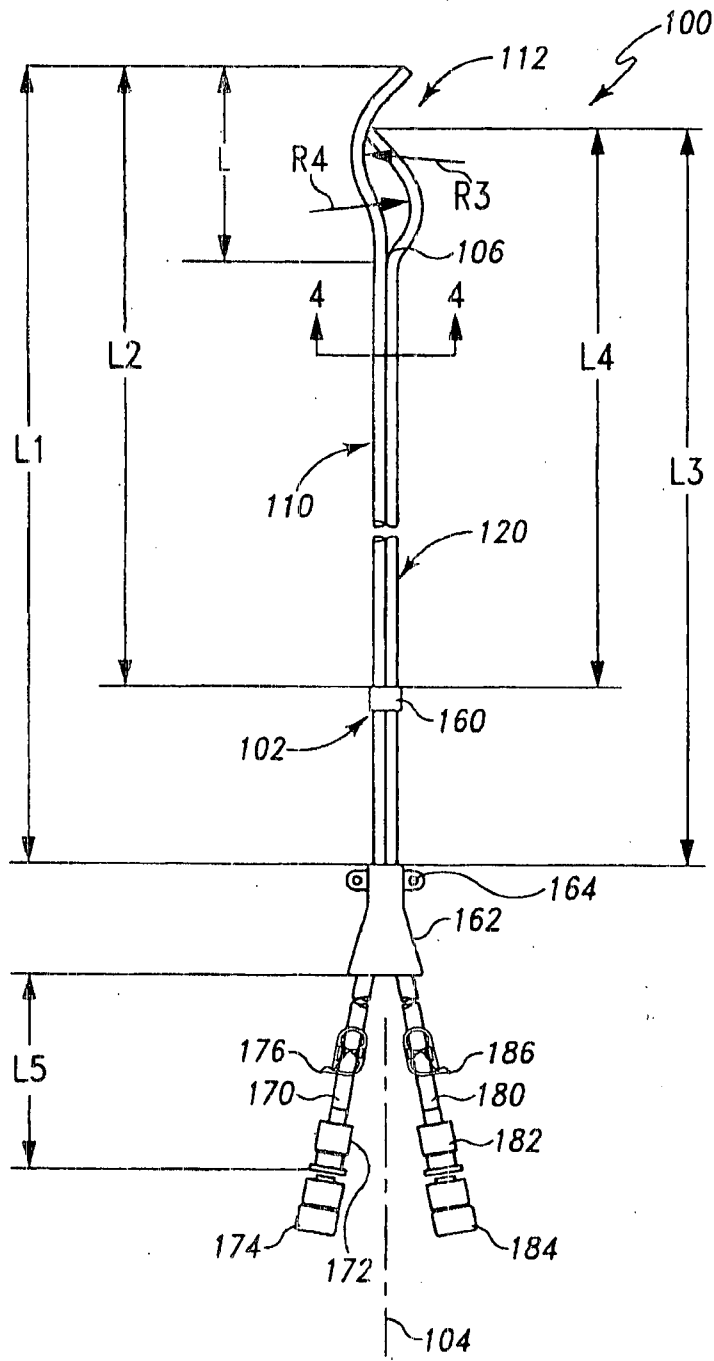


Fig. 1

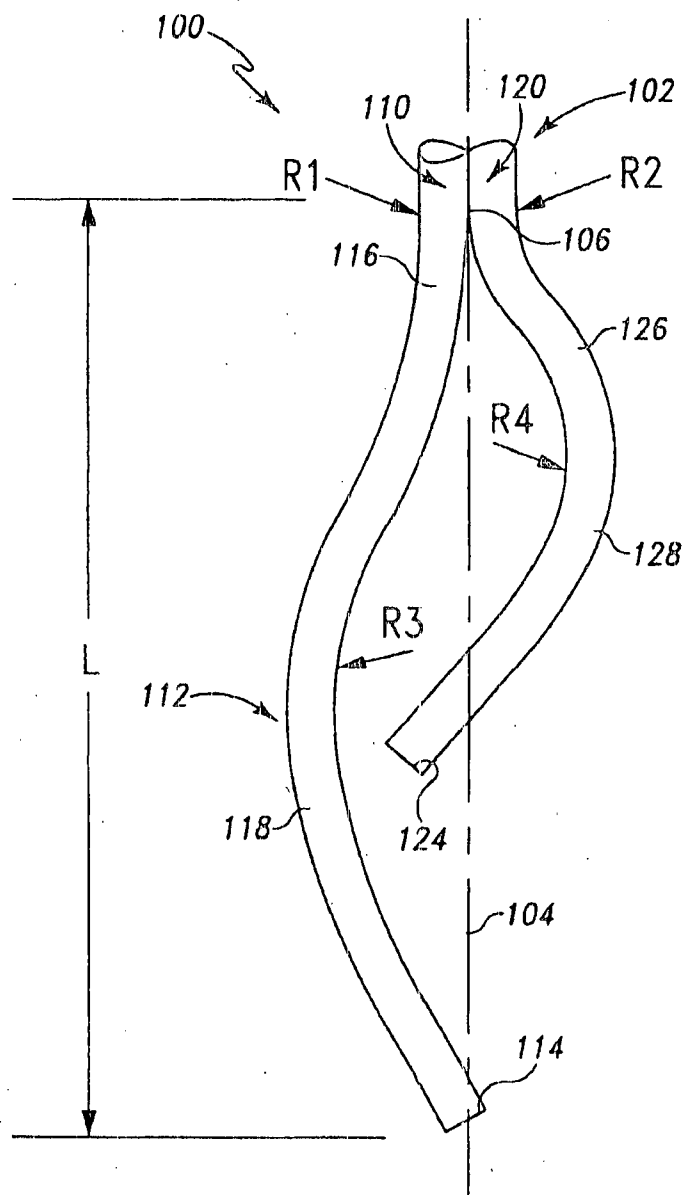


Fig. 2

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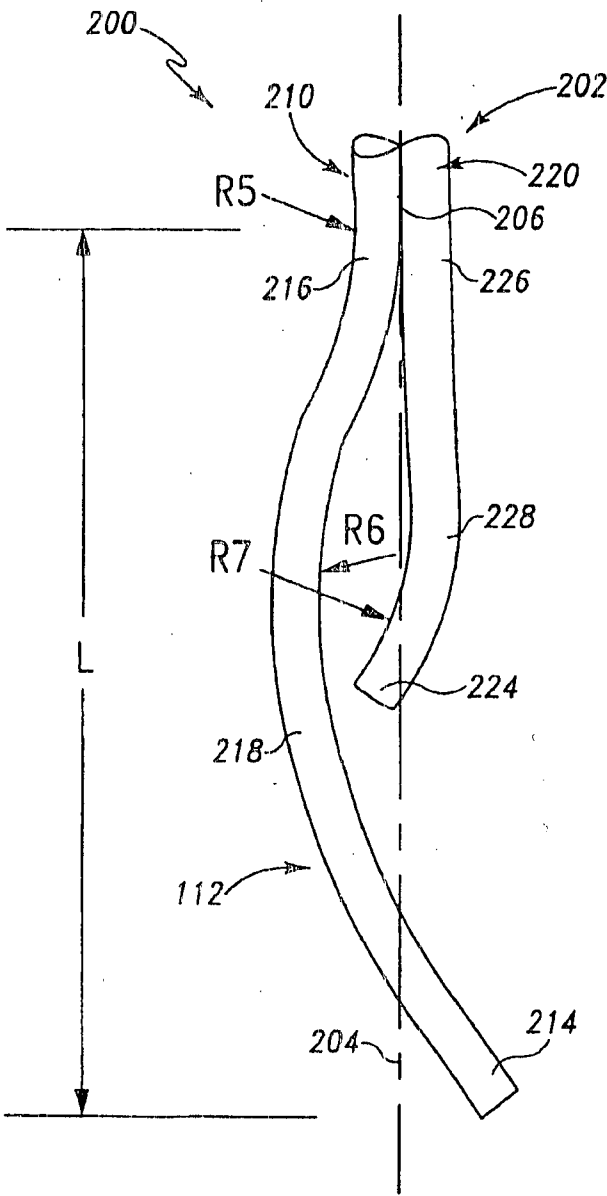


Fig. 3

80

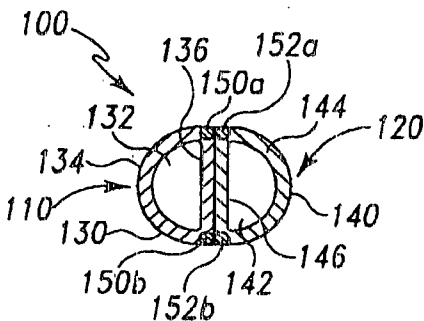


Fig. 4

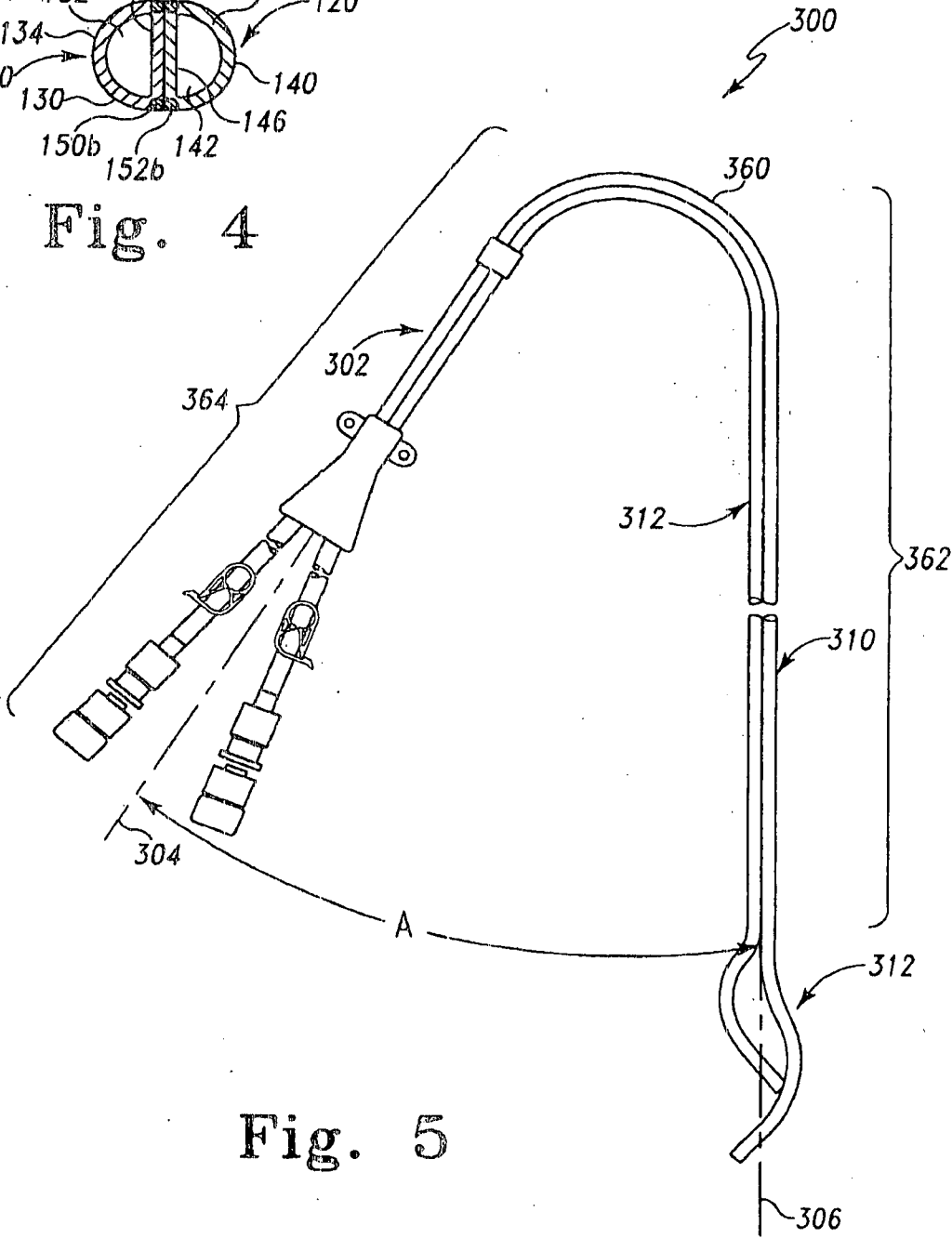


Fig. 5

81

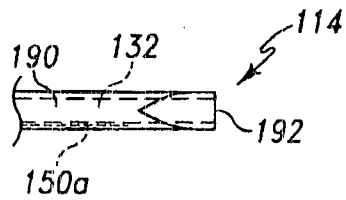


Fig. 6

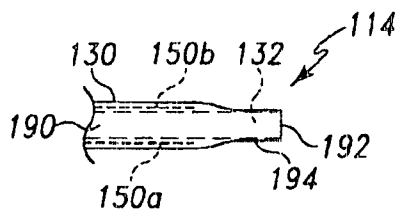


Fig. 7

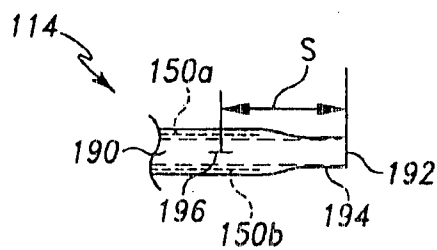


Fig. 8

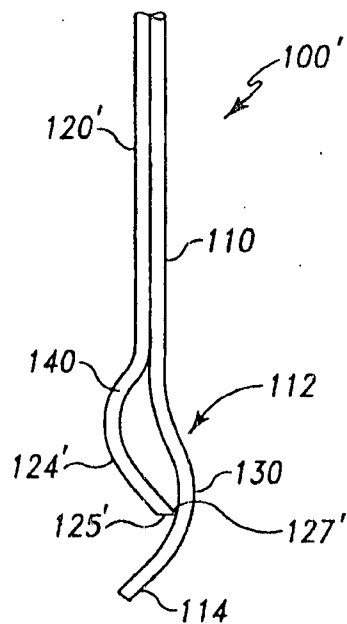


Fig. 9

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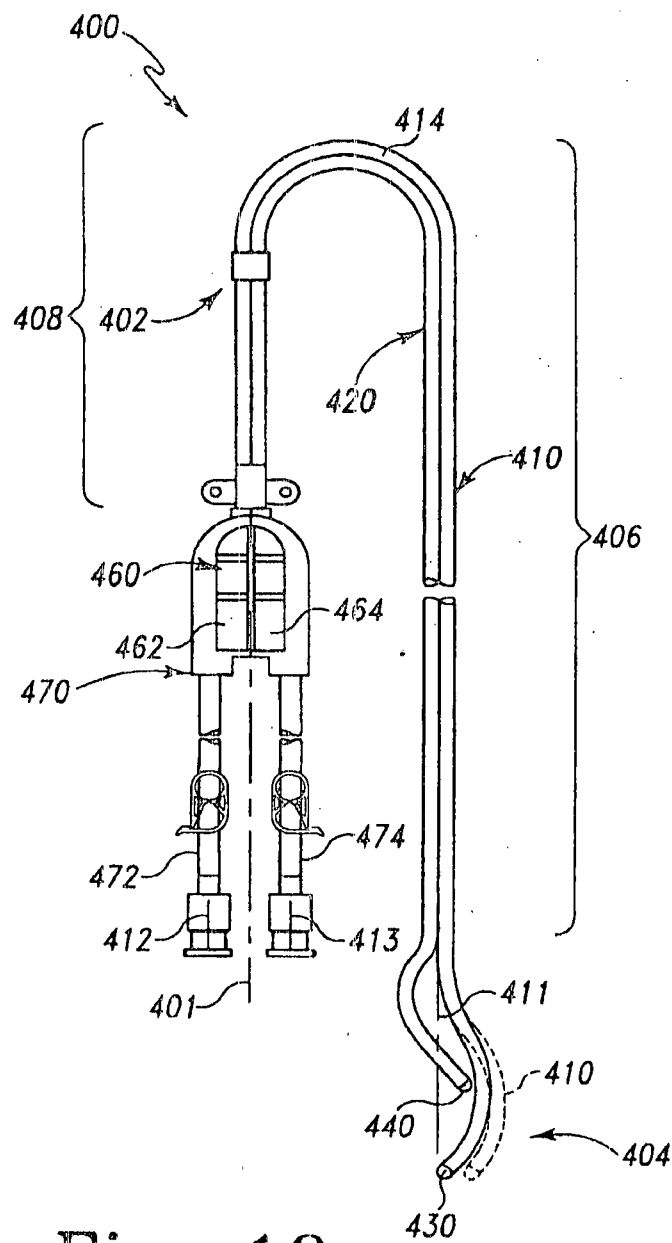


Fig. 10

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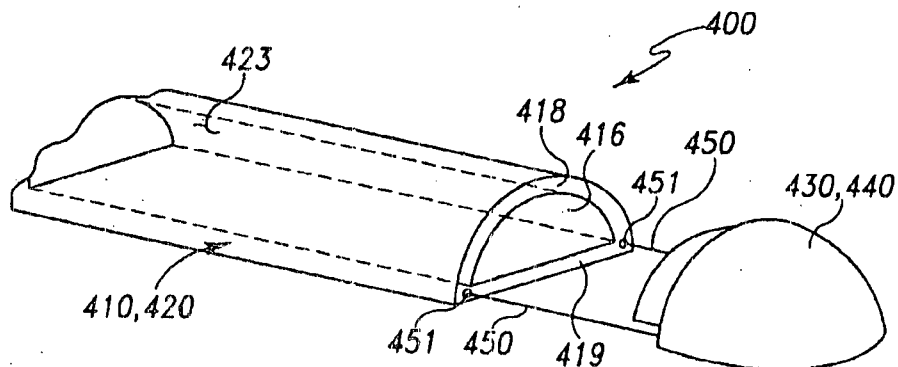


Fig. 11

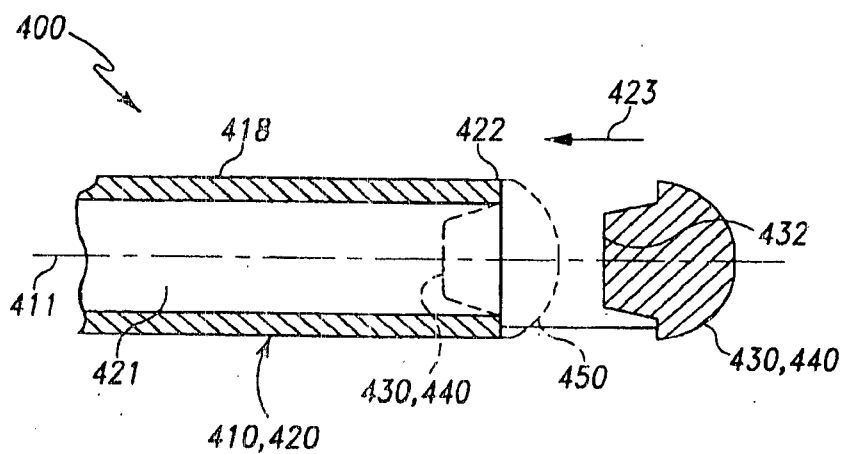


Fig. 12

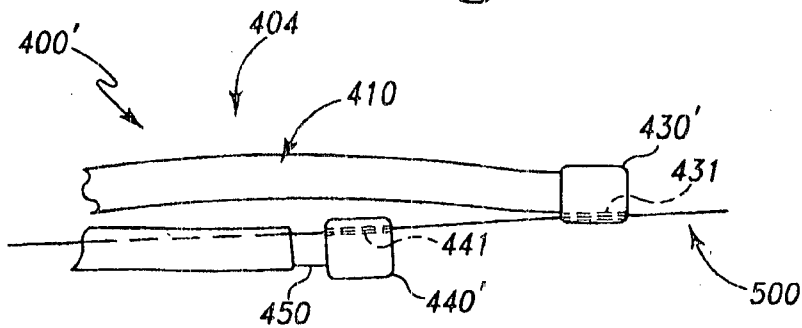


Fig. 13

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GREGORY B. COY
KRIEG DEVAULT LLP
ONE INDIANA SQUARE
SUITE 2800
INDIANAPOLIS, IN 46217-2079

PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year)

02 DEC 2008

Applicant's or agent's file reference

AATI-67

REPLY DUE

within 2 months/days from
the above date of mailing

International application No.

PCT/US07/15283

International filing date (day/month/year)

09 July 2007 (09.07.2007)

Priority date (day/month/year)

11 July 2006 (11.07.2006)

International Patent Classification (IPC) or both national classification and IPC

IPC: Please See Continuation Sheet

USPC: 604/264,27,284,43,48,523,524,93.01

Applicant

ASH ACCESS TECHNOLOGY, INC.

1. ☒ The written opinion established by the International Searching Authority:

☒ is ☐ is not

considered to be a written opinion of the International Preliminary Examining Authority.

2. This second (first, etc.) opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 11 November 2008 (11.11.2008)

Name and mailing address of the IPEA/ US

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Commissioner for Patents
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RPT: 1-5-08

DUE: 1

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Box No. I Basis of the opinion

1. With regard to the language, this opinion had been established on the basis of:
- ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the elements of the international application, this opinion has been established on the basis of *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed.")*:
- ☐ the international application as originally filed/furnished
 - ☒ the description:
 - pages 1-17 and 23 as originally filed/furnished
 - pages NONE received by this Authority on _____
 - pages NONE received by this Authority on _____
 - ☒ the claims:
 - pages 18, 21 and 22 as originally filed/furnished
 - pages NONE as amended (together with any statement) under Article 19
 - pages 19 and 20 received by this Authority on 09 October 2008 (09.10.2008)
 - pages NONE received by this Authority on _____
 - ☒ the drawings:
 - pages 1/7-7/7 as originally filed/furnished
 - pages NONE received by this Authority on _____
 - pages NONE received by this Authority on _____
 - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to the sequence listing (*specify*): _____
4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to the sequence listing (*specify*): _____
5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 66.1(*d-bis*))

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Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement			
Novelty (N)	Claims	<u>3-5, 9, 10, 12, 14-17</u>	YES
	Claims	<u>1, 2, 6-8, 11, 13, 18, 19</u>	NO
Inventive Step (IS)	Claims	<u>NONE</u>	YES
	Claims	<u>1-19</u>	NO
Industrial Applicability (IA)	Claims	<u>1-19</u>	YES
	Claims	<u>NONE</u>	NO

2. Citations and Explanations:
Please See Continuation Sheet

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(To be used when the space in any of the preceding boxes is not sufficient.)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended, 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Report on Patentability (Chapter II of the Patent Cooperation Treaty).

Continuation of IPC:

A61M 1/00(2006.01),3/00(2006.01),5/00(2006.01),25/00(2006.01),31/00(2006.01),37/00(2006.01)

V. 2. Citations and Explanations:

NOVELTY

Claims 1, 6-8, 11, 13, 18, and 19 lack novelty under PCT Article 33(2) as being anticipated by Tovey (US 5,527,330):

In regards to claim 1, Tovey teaches a catheter (Figures 6A-6C, instrument [110]) comprising: a first lumen part (suction tube [118]) and a second lumen part (irrigation tube [116]) extending along a longitudinal axis in side-by-side relation (Figures 6A-6C), said first and second lumen parts [118][116] forming a proximal portion and a distal portion (distal portions [126][120]) of the catheter [110] (Figure 6A), wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts [118][116] separate from one another at a bifurcation between said distal and proximal portions (Figure 6A), wherein said first lumen part [118] extends distally from said bifurcation and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part [116] extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis (Figure 6A).

In regards to claim 6, Tovey teaches that said first lumen part [118] is curved so that a distal end (flange [128]) thereof is located on said second side of said longitudinal axis (Figure 6B).

In regards to claim 7, Tovey teaches that said second lumen part [116] is curved so that a distal end (nozzle [124]) thereof is located on said first side of said longitudinal axis (Figure 6B).

In regards to claim 8, Tovey teaches said first lumen part [118] has a length along said longitudinal axis that is greater than a length of said second lumen part [116] along said longitudinal axis so that a distal end [128] of said first lumen part is spaced distally of a distal end [124] of said second lumen part along said longitudinal axis (Figures 6A-6B).

In regards to claim 11, Tovey further teaches that said first lumen part [118] forms a third bend at said bifurcation and said first bend is distal of said third bend, said first and third bends forming a reverse compound curve along said first lumen part (Figure 6A), and

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said second lumen part [116] forms a fourth bend at said bifurcation and said second bend is distal of said fourth bend, said second and fourth bends forming a reverse compound curve along said second lumen part (Figure 6A).

In regards to claim 13, Tovey teaches that said first lumen part [118] extends distally beyond a distal tip [124] of said second lumen part [116], and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part [118] at said distal end wall (Figure 6B).

In regards to claim 19, Tovey teaches a catheter (Figures 6A-6C, instrument [110]) comprising: a first lumen part (suction tube [118]) and a second lumen part (irrigation tube [116]) extending along a longitudinal axis in side-by-side relation (Figures 6A-6C), said first and second lumen parts [118][116] forming a proximal portion and a distal portion (distal portions [126][120]) of the catheter [110] (Figure 6A), wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts [118][116] separate from one another at a bifurcation between said distal and proximal portions (Figure 6A), wherein said first lumen part [118] extends distally from said bifurcation along a first bend so that said first lumen part is concavely curved relative to said longitudinal axis on a first side of said longitudinal axis (Figure 6A) and said second lumen part [116] extends linearly and distally from said bifurcation along a second side of said longitudinal axis to a second bend that is curved to locate a distal tip (nozzle [124]) of said second lumen part on said first side of said longitudinal axis (Figure 6B).

In regards to claim 20, Tovey teaches that said first bend of said first lumen part [118] is curved to locate a distal end (flange [128]) of said first lumen part on said second side of said longitudinal axis (Figure 6B).

Claims 1, 2, 6-8, 11, 13, 18, and 19 lack novelty under PCT Article 33(2) as being anticipated by Anand (US 2005/0277862):

In regards to claim 1, Anand teaches a catheter (Figure 7A) comprising: a first lumen part (lumen [40]) and a second lumen part (lumen [30]) extending along a longitudinal axis in side-by-side relation (Figures 7A), said first and second lumen parts [40][30] forming a proximal portion and a distal portion (distal portions [42][32]) of the catheter (Figure 7A), wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts [40][30] separate from one another at a bifurcation (gap [93]) between said distal and proximal portions (Figure 7A), wherein said first lumen part [40] extends distally from said bifurcation [93] and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part [30] extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis (Figure 7A).

In regards to claim 2, Anand teaches that said first lumen part [40] and said second lumen part [30] each include a D-shaped wall along said proximal and distal portions, each of said D-shaped walls defining a central passage extending along said respective lumen part (paragraph [0047]).

In regards to claim 6, Anand teaches that said first lumen part [40] is curved so that a distal end thereof is located on said second side of said longitudinal axis (Figure 7A).

In regards to claim 7, Anand teaches that said second lumen part [30] is curved so that a distal end thereof is located on said first side of said longitudinal axis (Figure 7A).

In regards to claim 8, Anand teaches said first lumen part [40] has a length along said longitudinal axis that is greater than a length of said second lumen part [30] along said longitudinal axis so that a distal end of said first lumen part is spaced distally of a distal end of said second lumen part along said longitudinal axis (Figure 7A).

In regards to claim 11, Anand further teaches that said first lumen part [40] forms a third bend at said bifurcation [93] and said first bend is distal of said third bend, said first and third bends forming a reverse compound curve along said first lumen part (Figure 7A), and said second lumen part [30] forms a fourth bend at said bifurcation and said second bend is distal of said fourth bend, said second and fourth bends forming a reverse compound curve along said second lumen part (Figure 7A).

In regards to claim 13, Anand teaches that said first lumen part [40] extends distally beyond a distal tip of said second lumen part [30], and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part at said distal end wall (Figure 7A) (paragraph [0062]).

In regards to claim 18, Anand teaches a catheter (Figures 6A-6C, instrument [110]) comprising: a first lumen part (lumen [40]) and a second lumen part (lumen [30]) extending along a longitudinal axis in side-by-side relation (Figure 7A), said first and second lumen parts [40][30] forming a proximal portion and a distal portion (distal portions [42][32]) of the catheter (Figure 7A), wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts [40][30] separate from one another at a bifurcation (gap [93]) between said distal and proximal portions (Figure 7A), wherein said first lumen part [40] extends distally from said bifurcation along a first bend so that said first lumen part is concavely curved relative to said longitudinal axis on a first side of said longitudinal axis (Figure 7A) and said second lumen part [30] extends linearly and distally from said bifurcation along a second side of said longitudinal axis to a second bend that is curved to locate a distal tip of said second lumen part on said first side of said longitudinal axis (Figure 7A).

In regards to claim 19, Anand teaches that said first bend of said first lumen part [40] is curved to locate a distal end of said first lumen part on said second side of said longitudinal axis (Figure 7A).

INVENTIVE STEP

Claim 2 lacks an inventive step under PCT Article 33(3) as being obvious over Tovey, in view of Anand, as applied to claim 1 above:

In regards to claim 2, Tovey teaches that both the first lumen part [118] and the second lumen part [116] have a central passage extending therethrough (column 4, lines 57-59); however, Tovey does not teach that said first lumen part [118] and said second lumen

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part [116] include a D-shaped wall along said proximal and distal portions. Anand teaches a catheter (Figure 7A) comprising a first lumen part (lumen [40]) and a second lumen part (lumen [30]), wherein both lumen parts include a D-shaped wall along their proximal and distal portions (paragraph [0047]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the first and second lumen parts, of the catheter of Tovey, with D-shaped walls, as taught by Anand, as a preferential design choice to the user, since both the lumen parts can have a variety of cross-sectional shapes and sizes, the D-shaped wall being one of them (paragraph [0047]).

Claims 3-5 lack an inventive step under PCT Article 33(3) as being obvious over Tovey and Anand, in view of Wise et al (US 6,270,489), as applied to claim 2 above:

In regards to claim 3, in a modified catheter of Tovey and Anand, neither Tovey nor Anand teaches that said first and second lumen parts [118][116] each include a pair of elongated stiffening elements in said wall, said elongated stiffening elements extending along said proximal and distal portions of the catheter [110]. Wise teaches a catheter (Figure 7) comprising first and second lumen parts (lumens [20][24]) that each include an elongated stiffening element (hollow stem [74]) in their walls (Figure 7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify both the first and second lumen parts, of the modified catheter of Tovey and Anand, with an elongated stiffening element, as taught by Wise et al, as each stiffening element within each lumen part will facilitate the correct positioning of the distal end of the catheter within the patient (column 6, lines 33-41). However, Wise et al does not overcome the deficiency that each lumen part must have a pair of elongated stiffening elements, as Wise et al only teaches one stiffening element for each lumen part (Figure 7). Though, since both stiffening elements of a pair of stiffening elements perform the same function of providing rigidity and guiding the catheter, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a second stiffening element into each of the lumen parts, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

In regards to claims 4 and 5, in a modified catheter of Tovey, Anand, and Wise et al, Tovey teaches that said first and second lumen parts [118][116] each define a distally opening port in a distal end thereof (Figure 6A) (column 4, lines 57-59); however, Tovey does not teach that each of the first and second lumen parts comprises a cap at their respective distal ends, wherein an actuator and stiffening elements are coupled to each of said caps to move the caps from an open position to a closed position. Wise et al teaches first and second lumen parts [20][24] that each has a cap (internal balloon [76]) at their distal ends. Stiffening elements (hollow stems [74]) and an actuator (syringe [80]) are coupled to each of said caps [76] to selectively move each of said caps between an open position and a closed position (Figure 7) (column 5, lines 8-24)(column 5, lines 38-57). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the first and second lumen parts, of the modified catheter of Tovey, Anand, and Wise et al, with caps, stiffening elements, and an actuator, as taught by Wise et al, as the ability to close the distal ends of each of the lumen parts with caps will substantially preclude entry and clotting of blood at the distal ends of the indwelling catheter when flow therein is not occurring (Abstract)(column 5, lines 54-57).

Claims 3-5 lack an inventive step under PCT Article 33(3) as being obvious over Anand, in view of Wise et al, as applied to claim 2 above:

In regards to claim 3, Anand does not teach that said first and second lumen parts [40][30] each include a pair of elongated stiffening elements in said wall, said elongated stiffening elements extending along said proximal and distal portions of the catheter. Wise teaches a catheter (Figure 7) comprising first and second lumen parts (lumens [20][24]) that each include an elongated stiffening element (hollow stem [74]) in their walls (Figure 7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify both the first and second lumen parts, of the catheter of Anand, with an elongated stiffening element, as taught by Wise et al, as each stiffening element within each lumen part will facilitate the correct positioning of the distal end of the catheter within the patient (column 6, lines 33-41). However, Wise et al does not overcome the deficiency that each lumen part must have a pair of elongated stiffening elements, as Wise et al only teaches one stiffening element for each lumen part (Figure 7). Though, since both stiffening elements of a pair of stiffening elements perform the same function of providing rigidity and guiding the catheter, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a second stiffening element into each of the lumen parts, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

In regards to claims 4 and 5, in a modified catheter of Anand and Wise et al, Anand teaches that said first and second lumen parts [40][30] each define a distally opening port in a distal end thereof (paragraph [0043]); however, Anand does not teach that each of the first and second lumen parts comprises a cap at their respective distal ends, wherein an actuator and stiffening elements are coupled to each of said caps to move the caps from an open position to a closed position. Wise et al teaches first and second lumen parts [20][24] that each has a cap (internal balloon [76]) at their distal ends. Stiffening elements (hollow stems [74]) and an actuator (syringe [80]) are coupled to each of said caps [76] to selectively move each of said caps between an open position and a closed position (Figure 7) (column 5, lines 8-24)(column 5, lines 38-57). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the first and second lumen parts, of the modified catheter of Anand and Wise et al, with caps, stiffening elements, and an actuator, as taught by Wise et al, as the ability to close the distal ends of each of the lumen parts with caps will substantially preclude entry and clotting of blood at the distal ends of the indwelling catheter when flow therein is not occurring (Abstract)(column 5, lines 54-57).

Claims 3 and 12 lack an inventive step under PCT Article 33(3) as being obvious over Tovey and Anand, in view of Mahurkar (US 5,374,245), as applied to claims 1 and 2 above:

In regards to claim 3, in a modified catheter of Tovey and Anand, neither Tovey nor Anand teaches that said first and second

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lumen parts [118][116] each include a pair of elongated stiffening elements in said wall, said elongated stiffening elements extending along said proximal and distal portions of the catheter [110]. Mahurkar teaches a catheter (Figures 13, 14, 16) with two lumens [13][14] that are reinforced by two stiffening elements (reinforcing strips [50]) within the wall, as can be seen in Figure 16 (column 6, lines 32-42). Though Mahurkar does not teach a pair of stiffening elements for each lumen part and only a pair of stiffening elements for both lumen parts, such is simply a duplication of parts that would provide an additional reinforcement to the catheter if both lumen parts had their own pair of reinforcing elements. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a pair of stiffening elements for each lumen part, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Also, based on the teachings of Mahurkar, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate stiffening elements, as taught by Mahurkar, into both the lumen parts of the modified catheter of Tovey and Anand, as the material of the stiffening elements, being stiffer than that of the catheter, will allow the catheter to be advanced against resistance by the application of force to the proximal end of the catheter (column 6, lines 35-39).

In regards to claim 12, in a modified catheter of Tovey and Anand, Tovey teaches that at least one of said first and second lumen parts [118][116] includes a distal tip [124] and said distal tip includes a proximal part with a first wall thickness and a distal part, wherein said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip (Figures 6A-6B). However, Tovey does not teach at least one stiffening element extending in said first wall thickness. Mahurkar teaches a catheter (Figure 14) having a distal tip (tapered conical tip [15]) and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element [50] extending in said first wall thickness, said at least one stiffening element terminating in said proximal part and said distal tip [15] including a distal part (column 5, lines 31-33) (column 6, lines 35-39). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal tip, of the modified catheter of Tovey and Anand, with a stiffening element, as taught by Mahurkar, as the material of the stiffening element, being stiffer than that of the catheter, will allow the catheter to be advanced against resistance by the application of force to the proximal end of the catheter (column 6, lines 35-39).

Claims 3 and 12 an inventive step under PCT Article 33(3) as being obvious over Anand, in view of Mahurkar, as applied to claims 1 and 2 above:

In regards to claim 3, Anand does not teach that said first and second lumen parts [118][116] each include a pair of elongated stiffening elements in said wall, said elongated stiffening elements extending along said proximal and distal portions of the catheter [110]. Mahurkar teaches a catheter (Figures 13, 14, 16) with two lumens [13][14] that are reinforced by two stiffening elements (reinforcing strips [50]) within the wall, as can be seen in Figure 16 (column 6, lines 32-42). Though Mahurkar does not teach a pair of stiffening elements for each lumen part and only a pair of stiffening elements for both lumen parts, such is simply a duplication of parts that would provide an additional reinforcement to the catheter if both lumen parts had their own pair of reinforcing elements. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a pair of stiffening elements for each lumen part, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Also, based on the teachings of Mahurkar, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate stiffening elements, as taught by Mahurkar, into both the lumen parts, of the catheter of Anand, as the material of the stiffening elements, being stiffer than that of the catheter, will allow the catheter to be advanced against resistance by the application of force to the proximal end of the catheter (column 6, lines 35-39).

In regards to claim 12, Anand teaches that at least one of said first and second lumen parts [40][30] includes a distal tip, and said distal tip includes a proximal part with a first wall thickness and a distal part (Figure 7A); however, Anand does not teach at least one stiffening element extending in said first wall thickness and said wall thickness tapering distally from said proximal part along said distal part to a distal end of said distal tip. Mahurkar teaches a catheter (Figure 14) having a distal tip (tapered conical tip [15]) and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element [50] extending in said first wall thickness, said at least one stiffening element terminating in said proximal part and said distal tip [15] including a distal part and said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip (column 5, lines 31-33) (column 6, lines 35-39). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal tip, of the catheter of Anand, to be distally tapered, as taught by Mahurkar, as a tapered tip is more easily insertable into a vessel based on its smaller diameter. Also, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a stiffening element, as taught by Mahurkar, into the catheter of Anand, as the material of the stiffening element, being stiffer than that of the catheter, will allow the catheter to be advanced against resistance by the application of force to the proximal end of the catheter (column 6, lines 35-39).

Claims 9 and 10 lack an inventive step under PCT Article 33(3) as being obvious over Tovey, as applied to claim 1 above:

In regards to claims 9 and 10, Tovey teaches that said proximal portion of said first and second lumen parts [118][116] include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment (Figures 6A-6C); however, Tovey is silent about whether said longitudinal axes form an angle of about 30 degrees or about 180 degrees (i.e. parallel to one another). Regardless, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the bend angle between proximal segment and the distal segment to be either 30 degrees or 180 degrees, since it has been held that discovering the optimum value of a result effective variable (bend angle) involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 9 and 10 lack an inventive step under PCT Article 33(3) as being obvious over Anand, as applied to claim 1 above:

In regards to claims 9 and 10, Anand teaches that said proximal portion of said first and second lumen parts [40][30] include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment

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(Figures 7A); however, Anand is silent about whether said longitudinal axes form an angle of about 30 degrees or about 180 degrees (i.e. parallel to one another). Regardless, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the bend angle between proximal segment and the distal segment to be either 30 degrees or 180 degrees, since it has been held that discovering the optimum value of a result effective variable (bend angle) involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 14-16 lack an inventive step under PCT Article 33(3) as being obvious over Wise et al, in view of Chee et al (US 6,315,757):

In regards to claim 14, Wise et al teaches a catheter (Figure 7, dual lumen catheter [26]) comprising: an elongate body (portion of catheter [26] with lumen [20]) extending between a distal end and a proximal end, said body including a wall defining at least one lumen (lumen [20]) for fluid flow therethrough, wherein said body includes at least one port (opening at distal end [34]) at said distal end of said elongate body in communication with said at least one lumen [20], and further comprising an end cap (balloon [76]) at said distal end and an actuating mechanism (hollow stem [74] with syringe [80]) at said proximal end, said end cap [76] being coupled to said actuating mechanism [74][80] which is operable to remotely move said end cap away from said port to an open position and permit fluid flow through said port and to remotely move said end cap toward said distal end to a closed position to prevent fluid flow through said port (column 5, lines 8-24)(column 5, lines 38-57). Though not stated by Wise et al, the end cap [76] naturally includes a passage extending therethrough, since the end cap extends about and around the hollow stem [74]. However, Wise et al does not teach a guidewire positionable through said passage and along said elongate body [26] outside said lumen [20]. Chee et al teaches a catheter (Figure 7) comprising an end cap (tip [250]) with a passage extending therethrough, wherein a guidewire (guidewire [246]) is positionable through said passage and along the elongate body of the catheter outside the lumen (lumen [244]) of the catheter (Figure 7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter, of Wise et al, with a guidewire, as taught by Chee et al, as the guidewire will guide and manipulate the elongate body of the catheter along complicated and tortuous pathways typically in the human vasculature to a target site within the body (column 4, lines 41-47).

In regards to claims 15 and 16, in a modified catheter of Wise et al and Chee et al, Wise et al teaches that the catheter [26] further comprises: a second elongate body (portion of catheter [26] with lumen [24]) extending between a distal end and a proximal end (Figure 7), said second body including a second wall defining at least one lumen (lumen [24]) for fluid flow therethrough and at least one second port (opening at distal end [36]) at said distal end of said second body in communication with said at least one lumen thereof, and further comprising a second end cap (balloon [76]) at said distal end, said second end cap being coupled to said actuating mechanism (hollow stem [74] with syringe [80]) which is operable to remotely move said second end cap away from said second port to an open position and permit fluid flow through said second port and to remotely move said second end cap toward said distal end to a closed position to prevent fluid flow through said second port (column 5, lines 8-24)(column 5, lines 38-57). Though not stated by Wise et al, the end cap [76] naturally includes a passage extending therethrough, since the end cap extends about and around the hollow stem [74]. However, Wise et al does not teach a guidewire positionable through said passage into said lumen [24] of said second elongate body. Chee et al teaches a catheter (Figure 7) comprising an end cap (tip [250]) with a passage extending therethrough, wherein a guidewire (guidewire [246]) is positionable through said passage and along the elongate body of the catheter outside the lumen (lumen [244]) of the catheter (Figure 7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the modified catheter, of Wise et al and Chee et al, with a guidewire, as taught by Chee et al, as the guidewire will guide and manipulate the second elongate body of the catheter along complicated and tortuous pathways typically in the human vasculature to a target site within the body (column 4, lines 41-47).

Claim 17 lacks an inventive step under PCT Article 33(3) as being obvious over Wise et al and Chee et al, in view of Tovey, as applied to claim 15 above:

In regards to claim 17, in a modified catheter of Wise et al and Chee et al, Wise et al teaches that said walls of said first and second elongate bodies are secured to one another along a proximal portion of the catheter [26] and said first and second elongate bodies separate from one another at a bifurcation to form a distal portion of the catheter extending distally from the bifurcation (Figure 7); however, Wise et al is silent about whether the distal portion includes a non-linear profile along the longitudinal axis. Tovey teaches a catheter (Figures 6A-6C, instrument [110]) wherein first and second elongate bodies (tubes [116][118]) of the catheter separate from one another at a bifurcation to form a distal portion of the catheter extending distally from the bifurcation, wherein the distal portion includes a non-linear profile along the longitudinal axis (Figures 6A-6B). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the first and second elongate bodies, of the modified catheter of Wise et al and Chee et al, to have a non-linear profile at the distal portion, as taught by Tovey, as the non-linear profile will facilitate flexing of the first and second elongate bodies towards one another in the case that the catheter is introduced through a trocar cannula. The non-linear profile will efficiently flex the catheter into a more compact structure to be easily inserted into the inner diameter of the trocar cannula (column 4, lines 17-22).

Claim 17 lacks an inventive step under PCT Article 33(3) as being obvious over Wise et al and Chee et al, in view of Tovey, as applied to claim 15 above:

In regards to claim 17, in a modified catheter of Wise et al and Chee et al, Wise et al teaches that said walls of said first and second elongate bodies are secured to one another along a proximal portion of the catheter [26] and said first and second elongate bodies separate from one another at a bifurcation to form a distal portion of the catheter extending distally from the bifurcation (Figure 7); however, Wise et al is silent about whether the distal portion includes a non-linear profile along the longitudinal axis. Anand teaches a catheter (Figure 7A) wherein first and second elongate bodies (lumens [30][40]) of the catheter separate from one another at a bifurcation (gap [93]) to form a distal portion of the catheter extending distally from the bifurcation, wherein the distal portion includes a non-linear profile along the longitudinal axis (Figure 7A). It would have been obvious to a person having ordinary skill in the art at the time the

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/US07/15283

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1a2

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient.)

invention was made to modify the first and second elongate bodies, of the modified catheter of Wise et al and Chee et al, to have a non-linear profile at the distal portion, as taught by Anand, as the non-linear profile will facilitate the insertion of the catheter into the body. The first and second elongate bodies, being adhesively joined, in the non-linear profile, will allow for an efficient insertion of the catheter into the body, since the first and second elongate bodies will be guided into the body together. The user will not have to individually insert each of the elongate bodies into the body of the patient (paragraph [0062]).

INDUSTRIAL APPLICABILITY

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

US 5,527,330 (TOVEY) 18 June 1996, see Figures 6A-6C and column 4, lines 57-59.

US 6,270,489 B1 (WISE et al) 07 August 2001, see Figure 7.

US 6,315,757 B1 (CHEE et al) 13 November 2001, see Figure 7.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GREGORY B. COY
KRIEG DEVAULT LLP
ONE INDIANA SQUARE
SUITE 2800
INDIANAPOLIS, IN 46217-2079

PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year) 02 DEC 2008

Applicant's or agent's file reference

AATI-67

REPLY DUE

within 2 months/days from
the above date of mailing

International application No.

PCT/US07/15283

International filing date (day/month/year)

09 July 2007 (09.07.2007)

Priority date (day/month/year)

11 July 2006 (11.07.2006)

International Patent Classification (IPC) or both national classification and IPC

IPC: Please See Continuation Sheet

USPC: 604/264,27,284,43,48,523,524,93.01

Applicant

ASH ACCESS TECHNOLOGY, INC.

1. ☒ The written opinion established by the International Searching Authority:

☒ is ☐ is not

considered to be a written opinion of the International Preliminary Examining Authority.

2. This second (first, etc.) opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
☐ Box No. II Priority
☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐ Box No. IV Lack of unity of invention
☒ Box No. V Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐ Box No. VI Certain documents cited
☐ Box No. VII Certain defects in the international application
☐ Box No. VIII Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 11 November 2008 (11.11.2008)

Name and mailing address of the IPEA/ US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

SHEFALI D. PATEL

Telephone No. (571) 272-3700

PATENT COOPERATION TREATY

AATI-67
GBC

94

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DOUGLAS A. COLLIER
KRIEG DEVAULT LLP
ONE INDIANA SQUARE
SUITE 2800
INDIANAPOLIS, IN 46204-2079

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year) **11 JUL 2008**

Applicant's or agent's file reference
AATI-67

FOR FURTHER ACTION Sec paragraphs 1 and 4 below

International application No.
PCT/US07/15283

International filing date
(day/month/year) 09 July 2007 (09.07.2007)

Applicant
ASH ACCESS TECHNOLOGY, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:**

☐ the protest together with the decision hereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer

Kevin C Simons

Telephone No. (571) 272-3700

RECEIVED

IP DOCKETING

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

JUL 17 2008

DOCKETED BY: DM
RPT: 8-17-2008
DUE: 10-17-2008

(Corrected Wm)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference AATI-67	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below	
International application No. PCT/US07/15283	International filing date (day/month/year) 09 July 2007 (09.07.2007)	(Earliest) Priority Date (day/month/year) 11 July 2006 (11.07.2006)
Applicant ASH ACCESS TECHNOLOGY, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the **language**, the international search was carried out on the basis of:

☒

the international application in the language in which it was filed.

☐

a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 Rule 43.6 *bis(a)*

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable**(See Box No. II)

3. ☐ **Unity of invention is lacking**(See Box No. III)

4. With regard to the **title**,

☒

the text is approved as submitted by the applicant.

☐

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒

the text is approved as submitted by the applicant.

☐

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒

as suggested by the applicant.

☐

as selected by this Authority, because the applicant failed to suggest a figure.

☐

as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US07/15283

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61M 5/00(2006.01),25/00(2006.01),31/00(2006.01)

USPC: 604/93.01,264,284,523,524,525,526

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/93.01,264,284,523,524,525,526

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,916,313 B2 (CUNNINGHAM) 12 July 2005 (12.07.2005), Figures 1-2, column 5, lines 22-39, column 8, lines 1-5, column 6, lines 5-19, column 7, lines 58-60.	1,2,6-11,13,17-19
Y	US 5,374,245 (MAHURKAR) 20 December 1994 (20.12.1994), Figures 13, 14, 16, column 6, lines 32-42, column 5, lines 31-33.	3,12
Y	US 5,827,305 (GORDON) 27 October 1998 (27.10.1998), Figures 1-3, Figures 8-10, column 8, lines 30-31.	14-17
A	US 5,533,980 (SWEENEY et al) 9 July 1996 (09.07.1996).	14-16
A	US 2005/0277862 A1 (ANAND) 15 December 2005 (15.12.2005).	1
A	US 5,542,937 (CHEE et al) 6 August 1996 (06.08.1996).	3

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

28 May 2008 (28.05.2008)

Date of mailing of the international search report

11 JUL 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

Kevin C Simons

Telephone No. (571) 272-3700

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
DOUGLAS A. COLLIER
KRJEG DEVAULT LLP
ONE INDIANA SQUARE
SUITE 2800
INDIANAPOLIS, IN 46204-2079

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference AATI-67		Date of mailing (day/month/year) 11 JUL 2008
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US07/15283	International filing date (day/month/year) 09 July 2007 (09.07.2007)	Priority date (day/month/year) 11 July 2006 (11.07.2006)
International Patent Classification (IPC) or both national classification and IPC IPC: A61M 5/00(2006.01),25/00(2006.01),31/00(2006.01) USPC: 604/93.01,264,284,523,524,525,526		
Applicant ASH ACCESS TECHNOLOGY, INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 28 May 2008 (28.05.2008)	Authorized officer Shefali D. Patel /Kevin C Simons/
--	--	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US07/15283

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/15283

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>4,5</u>	YES
	Claims <u>1,2,6-11,13,18,19</u>	NO
Inventive step (IS)	Claims <u>4,5</u>	YES
	Claims <u>1-3,6-19</u>	NO
Industrial applicability (IA)	Claims <u>1-19</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

100

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US07/15283

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 12 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:

In regards to claim 12, in the limitation "said second lumen part...", the statement that "said second bend is distal of said second bend..." should be corrected as "said second bend is distal of said **fourth** bend...", based on the Examiner's understanding of the claim.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/15283

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

NOVELTY

Claims 4 and 5:

Claims 4 and 5 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest movable stiffening elements coupled to end caps that move the end caps from an open position to a closed position.

Claims 1, 2, 6-11, 13, 18, and 19:

Claims 1, 2, 6-11, 13, 18, and 19 lack novelty under PCT Article 33(2) as being anticipated by Cunningham (US 6,916,313):

In regards to claims 1 and 18, Cunningham teaches a catheter (Figures 1-2, catheter assembly [10]) comprising:

- a. a first lumen part (lumen [12b] of catheter [12]) and a second lumen part (lumen [14b] of catheter [14]) extending along a longitudinal axis in side-by-side relation (Figures 1-2)
- b. said first and second lumen parts forming a proximal portion and a distal portion (*labeled in Figure 1 below*) of the catheter
- c. wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts separate from one another at a bifurcation (splitting point [S]) between said distal and proximal portions
- d. wherein said first lumen part extends distally from said bifurcation and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis.
- i. Cunningham teaches connecting means [40A][40B][40C][40D][40E] that connect the first lumen part [12] to the second lumen part [14]. Generally, Cunningham teaches that if an outer connecting means, such as [40C] is connected, all intervening connecting means [40A][40B] are also connected (column 5, lines 22-39); however, Cunningham teaches that this is **generally** the practice for the connecting means. That being said, the connecting means [40C], for example, can be connected without connecting the intervening connecting means [40A][40B]. If an outer connecting means, such as [40E] is connected without connecting the intervening connecting means [40A][40B][40C][40D], then the concavely curved inward first bend of the first lumen part and the concavely curved inward second bend of the second lumen part, as described by the Applicant's invention, will be created, since both lumen parts [12][14] are made of a flexible, bendable material (column 8, lines 1-5).

In regards to claim 2, Cunningham teaches that said first lumen part [12] and said second lumen part [14] each include a D-shaped wall (Figure 5, walls [36]) along said proximal and distal portions, each of said D-shaped walls defining a central passage (interior flow cavities [38]) extending along said respective lumen part (column 6, lines 5-19).

In regards to claims 6, 7, and 19, as shown above with claim 1, the structure of the lumen parts of the catheter of Cunningham is

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/15283

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

capable of concavely curving inward by the connection of a connecting means [40E], for example, since both lumen parts [12][14] are made of a flexible, bendable material (column 8, lines 1-5). Therefore, it naturally follows that the flexibility of the lumen parts will allow the distal end of the first lumen part to be located on the second side of the longitudinal axis and the distal end of the second lumen part to be located on the first side of the longitudinal axis.

In regards to claim 8, Cunningham teaches that said first lumen part [12] has a length along said longitudinal axis that is greater than a length of said second lumen part [14] along said longitudinal axis (Figure 1)(column 7, lines 58-60).

In regards to claims 9 and 10, though not stated by Cunningham that the distal portion and the proximal portion of the catheter form a bend angle of 30 degrees (claim 10) or 180 degrees (parallel, as in claim 11), the structure of the catheter of Cunningham is capable of forming different bend angles since the catheter is made of a flexible, bendable material that is easily conformable to the shape of an area to be catheterized (column 8, lines 1-5). Such is illustrated by the different bend angles between the distal portion and the proximal portion, as seen in Figure 1 and 6, based on the shape of the area to be catheterized.

In regards to claim 11, as shown above with claim 1, the structure of the lumen parts of the catheter of Cunningham is capable of concavely curving inward by the connection of a connecting means [40E], for example, since both lumen parts [12][14] are made of a flexible, bendable material (column 8, lines 1-5). Therefore, it naturally follows that said first lumen part [12] forms a third bend at said bifurcation [S] and said first bend is distal of said third bend. Said second lumen part [14] forms a fourth bend at said bifurcation [S] and said second bend is distal of said fourth bend (Figure 2).

In regards to claim 13, Cunningham teaches that said first lumen part [12] extends distally beyond a distal tip of said second lumen part [14] (Figure 1)(column 7, lines 58-60) and said distal tip of said second lumen part [14] is secured to a wall [34] of said first lumen part [12] by connecting means [40] (column 5, lines 22-28). Also, as shown above with claim 1, the structure of the lumen parts of the catheter of Cunningham is capable of concavely curving inward by the connection of a connecting means [40E], for example, since both lumen parts [12][14] are made of a flexible, bendable material (column 8, lines 1-5). Therefore, it naturally follows that the distal end wall of the second lumen part [14] will be obliquely oriented to the distal tip wall of the second lumen part [14] based on the second and fourth bends.

INVENTIVE STEP

Claims 4 and 5:

Claims 4 and 5 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest movable stiffening elements coupled to end caps that move the end caps from an open position to a closed position.

Claims 1-3 and 6-19:

Claims 1, 2, 6-11, 13, 18, and 19 lack an inventive step under PCT Article 33(3) as being obvious over Cunningham, as shown above with respect to novelty.

Claims 3 and 12 lack an inventive step under PCT Article 33(3) as being obvious over Cunningham, in view of Mahurkar (US 5,374,245):

In regards to claim 3, Cunningham does not teach that said first and second lumen parts each include a pair of elongated stiffening elements in said wall. Mahurkar teaches a catheter (Figures 13, 14, 16) with two lumens [13][14] that are reinforced by two stiffening elements (reinforcing strips [50]) within the wall, as can be seen in Figure 16 (column 6, lines 32-42). Though Mahurkar does not teach a pair of stiffening elements for each lumen part and only a pair of stiffening elements for both lumen parts, such is simply a duplication of parts that would provide an additional reinforcement to the catheter if both lumen parts had their own pair of reinforcing elements. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a pair of stiffening elements for each lumen part, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. Also, based on the teachings of Mahurkar, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate stiffening elements, as taught by Mahurkar, into the lumen parts of the catheter of Cunningham, as the material of the stiffening elements, being stiffer than that of the catheter, will allow the catheter to be advanced against resistance by the application of force to the proximal end of the catheter (column 6, lines 35-39).

In regards to claim 12, Cunningham teaches that at least one of said first [12] and second [14] lumen parts includes a distal tip (Figure 1); however, Cunningham does not teach a stiffening element extending through said distal tip and that the distal tip is tapered. Mahurkar teaches a catheter (Figure 14) having a distal tip (tapered conical tip [15]) and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element [50] extending in said first wall thickness, said at least one stiffening element terminating in said proximal part and said distal tip [15] including a distal part and said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip column 5, lines 31-33) (column 6, lines 35-39). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal tip of Cunningham to be tapered as taught by Mahurkar, as a tapered tip is more easily insertable into a vessel based on its smaller diameter. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a stiffening element, as taught by Mahurkar, into the catheter of Cunningham, as the material of the stiffening element, being stiffer than that of the catheter, will allow the catheter to be advanced against resistance by the application of force to the proximal end of the catheter (column 6, lines 35-39).

Claims 14-16 lack an inventive step under PCT Article 33(3) as being obvious over Gordon (US 5,827,305):

In regards to claim 14, Gordon teaches a catheter (Figure 1-3, catheter [10]) comprising:

- a. an elongate body [10] extending between a distal end and a proximal end
- b. said body including a wall defining at least one lumen (first lumen [20]) for fluid flow therethrough

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/15283

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

c. wherein said body includes at least one port (Figure 2) at said distal end (distal end [14]) of said elongate body in communication with said at least one lumen

d. an end cap (cap [16]) at said distal end and an actuating mechanism (cam [32] with sheath [34]) at said proximal end

e. said end cap [16] being coupled to said actuating mechanism [32][34] which is operable to remotely move said end cap [16] away from said port to an open position (Figure 2) and permit fluid flow through said port and to remotely move said end cap toward said distal end to a closed position (Figure 3) to prevent fluid flow through said port

Gordon does not state a guidewire for use with the catheter; however, Gordon does teach that the catheter can be a guide catheter.

Guidewires are commonly used with guide catheters. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a guidewire into the catheter of Gordon, as the guidewire will facilitate in the proper placement and positioning of the catheter within a vessel.

In the current embodiment (Figures 1-3) of Gordon, Gordon does not teach that the end cap has a passage extending therethrough.

In a further embodiment (Figures 8-10), Gordon teaches an end cap [116] with a passage (channel [117]) therethrough (column 8, lines 30-31). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the end cap of Gordon (Figures 1-3) with the passage, as taught by Gordon (Figures 8-10), as the passage within the channel will deflect fluid flowing distally within the catheter while the cap is in the closed position (column 8, lines 30-31).

In regards to claims 15 and 16, Gordon does not teach a second elongate body; however, the claim limitations teach of a second elongate body with the exact same limitations of the elongate body of claim 15. Also, claims 16 and 17 do not cite an association between the elongate body, of claim 15, and the second elongate body, as claimed. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a second elongate body into the catheter of Gordon, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

Claim 17 lacks an inventive step under PCT Article 33(3) as being obvious over Gordon, in view of Cunningham:

In regards to claim 17, Gordon does not teach of a second elongate body. Cunningham teaches a catheter wherein the first [12] and second [14] elongate bodies are secured to one another along a proximal portion of the catheter (Figure 1 above) and said first [12] and second [14] elongate bodies separate from one another at a bifurcation [S] to form a distal portion of the catheter extending distally from the bifurcation (Figure 1 above), wherein the distal portion includes a non-linear profile along the longitudinal axis, *as described above with respect to claims 1, 6, 7, and 19*. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gordon with the teachings of Cunningham, as the multi-lumen catheter structure will allow a fluid to be removed from the body from one lumen part and another fluid to be introduced into the body through another lumen part, for example (column 2, lines 5-12).

INDUSTRIAL APPLICABILITY

Claims 1-19 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should, however, be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

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NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DOUGLAS A. COLLIER
KRIEG DEVAULT LLP
ONE INDIANA SQUARE
SUITE 2800
INDIANAPOLIS, IN 46204-2079

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	
Applicant's or agent's file reference AATI-67	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US07/15283	International filing date (day/month/year) 09 July 2007 (09.07.2007)
Applicant ASH ACCESS TECHNOLOGY, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally twomonths from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision hereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Kevin C Simmons  Telephone No. (571) 272-3700 
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PCT application of:)
 Ash Access Technology, Inc.)

Authorized Officer:
 Kevin C. Sirmons

International Application)
 No. PCT/US07/15283)

File Ref. AATI-67

International Filing Date)
 9 July 2007)

Mailing Date:
 9 October 2008

Title of Invention)
 INDWELLING CATHETER)
 WITH ANTI-CLOTTING)
 FEATURES)

I hereby certify that this
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 VA 22313-1450 on:

09 October 2008

Date of Transmission

Gregory B. Coy

Name of Registered Representative

Gregory B. Coy

Signature

09 October 2008

Date of Signature

AMENDMENT UNDER PCT ARTICLE 34

Mail Stop PCT, Attn: IPEA/US
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Pursuant to Article 34 and without prejudice to their reintroduction, we wish to
 replace claim pages 19 and 20 with the enclosed Replacement Page 19 and Replacement Page
 20. A marked copy of each pertinent claim page is enclosed to make clearer the changes
 made to pages 19 and 20.

Kindly continue to review the application in view of these amendments and
 Applicant's remarks.

Respectfully submitted,

Gregory B. Coy

Gregory B. Coy, Reg. No. 40,967

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second lumen parts, said actuator being operable to selectively move each of said caps between said open and closed positions.

6. The catheter of claim 1, wherein said first lumen part is curved so that a distal end thereof is located on said second side of said longitudinal axis.

7. The catheter of claim 6, wherein said second lumen part is curved so that a distal end thereof located on said first side of said longitudinal axis.

8. The catheter of claim 1, wherein said first lumen part has a length along said longitudinal axis that is greater than a length of said second lumen part along said longitudinal axis so that a distal end of said first lumen part is spaced distally of a distal end of said second lumen part along said longitudinal axis.

9. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes form an angle of about 30 degrees.

10. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes are parallel to one another.

11. The catheter of claim 1, wherein:

said first lumen part forms a third bend at said bifurcation and said first bend is distal of said third bend, said first and third bends forming a reverse compound curve along said first lumen part; and

said second lumen part forms a fourth bend at said bifurcation and said second bend is distal of said fourth bend, said second and fourth bends forming a reverse compound curve along said second lumen part.

12. The catheter of claim 1, wherein at least one of said first and second lumen parts includes a distal tip and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element extending in said first wall thickness, said at least one stiffening element terminating in said proximal part and said distal tip including a distal part and said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip.

13. The catheter of claim 1, wherein said first lumen part extends distally beyond a distal tip of said second lumen part, and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part at said distal end wall.

14. A catheter, comprising:

an elongate body extending between a distal end and a proximal end, said body including a wall defining at least one lumen for fluid flow therethrough, wherein said body includes at least one port at said distal end of said elongate body in communication with said at least one lumen, and further comprising an end cap at said distal end and an actuating mechanism at said proximal end, said end cap being coupled to said actuating mechanism which is operable to remotely move said end cap away from said port to an open position and permit fluid flow through said port and to remotely move said end cap toward said distal end to a closed position to prevent fluid flow through said port, wherein said end cap includes a passage extending therethrough and further comprising a guidewire positionable through said passage and along said elongate body outside said lumen.

15. The catheter of claim 14, further comprising a second elongate body extending between a distal end and a proximal end, said second body including a second wall defining at least one lumen for fluid flow therethrough and at least one second port at said distal end of said second body in communication with said at least one lumen thereof, and

second lumen parts, said actuator being operable to selectively move each of said caps between said open and closed positions.

6. The catheter of claim 1, wherein said first lumen part is curved so that a distal end thereof is located on said second side of said longitudinal axis.

7. The catheter of claim 6, wherein said second lumen part is curved so that a distal end ~~there of~~ thereof located on said first side of said longitudinal axis.

8. The catheter of claim 1, wherein said first lumen part has a length along said longitudinal axis that is greater than a length of said second lumen part along said longitudinal axis so that a distal end of said first lumen part is spaced distally of a distal end of said second lumen part along said longitudinal axis.

9. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes form an angle of about 30 degrees.

10. The catheter of claim 1, wherein said proximal portion of said first and second lumen parts include a proximal segment extending along a second longitudinal axis and a bend connecting said proximal segment and said distal segment, wherein said longitudinal axes are parallel to one another.

11. The catheter of claim 1, wherein:
 said first lumen part forms a third bend at said bifurcation and said first bend is distal of said third bend, said first and third bends forming a reverse compound curve along said first lumen part; and
 said second lumen part forms a fourth bend at said bifurcation and said second bend is distal of said fourth ~~second~~ bend, said second and fourth bends forming a reverse compound curve along said second lumen part.

12. The catheter of claim 1, wherein at least one of said first and second lumen parts includes a distal tip and said distal tip includes a proximal part with a first wall thickness and at least one stiffening element extending in said first wall thickness, said at least one
5 stiffening element terminating in said proximal part and said distal tip including a distal part and said wall thickness tapers distally from said proximal part along said distal part to a distal end of said distal tip.

13. The catheter of claim 1, wherein said first lumen part extends distally beyond a
10 distal tip of said second lumen part, and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part at said distal end wall.

14. A catheter, comprising:

an elongate body extending between a distal end and a proximal end, said body including a wall defining at least one lumen for fluid flow therethrough, wherein said body includes at least one port at said distal end of said elongate body in communication with said at least one lumen, and further comprising an end cap at said distal end and an
20 actuating mechanism at said proximal end, said end cap being coupled to said actuating mechanism which is operable to remotely move said end cap away from said port to an open position and permit fluid flow through said port and to remotely move said end cap toward said distal end to a closed position to prevent fluid flow through said port, wherein said end cap includes a passage extending therethrough and further comprising a
25 guidewire positionable through said passage and along said elongate body outside said lumen.

15. The catheter of claim 14, further comprising a second elongate body extending between a distal end and a proximal end, said second body including a second wall
30 defining at least one lumen for fluid flow therethrough and at least one second port at said distal end of said second body in communication with said at least one lumen thereof, and

segunda, siendo el citado accionador operable para mover selectivamente cada uno de los citados obturadores entre las citadas posiciones abierta y cerrada.

6. El catéter de la reivindicación 1, en donde la citada primera parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado segundo lado del citado eje longitudinal.

7. El catéter de la reivindicación 6, en donde la citada segunda parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado primer lado del citado eje longitudinal.

8. El catéter de la reivindicación 1, en donde la citada primera parte de la luz tiene una longitud a lo largo del citado eje longitudinal que es mayor que una longitud de la citada segunda parte de la luz a lo largo del citado eje longitudinal, de modo que un extremo distal de la citada primera parte de la luz se distancia distalmente de un extremo distal de la citada segunda parte de la luz a lo largo del citado eje longitudinal.

9. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda parte incluyen un segmento proximal que se extiende a lo largo de un segundo eje longitudinal y una curva que conecta el citado segmento proximal y el citado segmento distal, en donde los citados ejes longitudinal forman un ángulo de alrededor de 30 grados.

10. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda incluyen un segmento proximal, que se extiende a lo largo de un segundo eje longitudinal, y una curva que conecta el citado segmento proximal y el citado segmento distal,

en donde los citados ejes longitudinales son paralelos entre sí.

11. El catéter de la reivindicación 1, en donde:

la citada primera parte de la luz forma una tercera curva en la citada bifurcación y la citada primera curva es distal de la citada tercera curva, formando las citadas curvas primera y tercera una curva compuesta invertida a lo largo de la citada primera parte de la luz; y

la citada segunda parte de la luz forma una cuarta curva en la citada bifurcación y la citada segunda curva es distal de la citada cuarta curva, formando las citadas curvas segunda y cuarta una curva compuesta invertida a lo largo de la citada segunda parte de la luz.

12. El catéter de la reivindicación 1, en donde por lo menos una de las citadas partes de la luz primera y segunda incluye una punta distal y la citada punta distal incluye una parte proximal con un primer espesor de pared y por lo menos un elemento rígido, que se extiende el citado primer espesor de pared, terminando el citado por lo menos un elemento rígido en la citada parte proximal e incluyendo la citada punta distal una parte distal y el citado espesor de pared disminuye gradualmente, distalmente de la citada parte proximal, a lo largo de la citada parte distal a un extremo distal de la citada punta distal.

13. El catéter de la reivindicación 1, en donde la citada primera parte de la luz se extiende distalmente más allá de una punta distal de la citada segunda parte de la luz, y la citada punta distal de la citada segunda parte de la luz incluye una pared de extremo distal orientada oblicuamente a una pared de la citada segunda parte de la luz en la citada punta distal, en donde la citada punta distal de la citada segunda parte de la luz se asegura a una pared de la citada primera parte de la luz en la citada pared de extremo distal.

14. Un catéter, que incluye:

un cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado cuerpo una pared que define por lo menos una luz para fluido de líquido a través del mismo, en donde el citado cuerpo incluye por lo menos un puerto en el citado extremo distal del citado cuerpo alargado en comunicación con la citada por lo menos una luz, y que comprende además un obturador final en el citado extremo distal y un mecanismo accionador en el citado extremo proximal, acoplándose el citado obturador final al citado mecanismo accionador, el cual es operable para mover remotamente el citado obturador final alejándolo del citado puerto a una posición abierta y permitir el flujo de líquido a través del

citado puerto y para mover remotamente el citado obturador final hacia el citado extremo distal a una posición cerrada para impedir el flujo de líquido a través del citado puerto, en donde el citado obturador final incluye un pasaje que se extiende a través del mismo y que comprende además una guía metálica que se puede posicionar a través del citado pasaje y a lo largo del citado cuerpo alargado fuera de la citada luz.

15. El catéter de la reivindicación 14, que comprende además un segundo cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado segundo cuerpo una segunda pared que define por lo menos una luz para flujo de líquido a través del mismo y por lo menos un segundo puerto en el citado extremo distal del citado segundo cuerpo en comunicación con la citada por lo menos una luz del mismo, y

segunda, siendo el citado accionador operable para mover selectivamente cada uno de los citados obturadores entre las citadas posiciones abierta y cerrada.

6. El catéter de la reivindicación 1, en donde la citada primera parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado segundo lado del citado eje longitudinal.

7. El catéter de la reivindicación 6, en donde la citada segunda parte de la luz es curva, de modo que un extremo distal de la misma se localiza en el citado primer lado del citado eje longitudinal.

8. El catéter de la reivindicación 1, en donde la citada primera parte de la luz tiene una longitud a lo largo del citado eje longitudinal que es mayor que una longitud de la citada segunda parte de la luz a lo largo del citado eje longitudinal, de modo que un extremo distal de la citada primera parte de la luz se distancia distalmente de un extremo distal de la citada segunda parte de la luz a lo largo del citado eje longitudinal.

9. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda parte incluyen un segmento proximal que se extiende a lo largo de un segundo eje longitudinal y una curva que conecta el citado segmento proximal y el citado segmento distal, en donde los citados ejes longitudinal forman un ángulo de alrededor de 30 grados.

10. El catéter de la reivindicación 1, en donde la citada porción proximal de las citadas partes de la luz primera y segunda incluyen un segmento proximal, que se extiende a lo largo de un segundo eje longitudinal, y una curva que conecta el citado segmento proximal y el citado segmento distal,

en donde los citados ejes longitudinales son paralelos entre sí.

11. El catéter de la reivindicación 1, en donde:

la citada primera parte de la luz forma una tercera curva en la citada bifurcación y la citada primera curva es distal de la citada tercera curva, formando las citadas curvas primera y tercera una curva compuesta invertida a lo largo de la citada primera parte de la luz; y

la citada segunda parte de la luz forma una cuarta curva en la citada bifurcación y la citada segunda curva es distal de la citada cuarta curva, formando las citadas curvas segunda y cuarta una curva compuesta invertida a lo largo de la citada segunda parte de la luz..

12. El catéter de la reivindicación 1, en donde por lo menos una de las citadas partes de la luz primera y segunda incluye una punta distal y la citada punta distal incluye una parte proximal con un primer espesor de pared y por lo menos un elemento rígido, que se extiende el citado primer espesor de pared, terminando el citado por lo menos un elemento rígido en la citada parte proximal e incluyendo la citada punta distal una parte distal y el citado espesor de pared disminuye gradualmente, distalmente de la citada parte proximal, a lo largo de la citada parte distal a un extremo distal de la citada punta distal.

13. El catéter de la reivindicación 1, en donde la citada primera parte de la luz se extiende distalmente más allá de una punta distal de la citada segunda parte de la luz, y la citada punta distal de la citada segunda parte de la luz incluye una pared de extremo distal orientada oblicuamente a una pared de la citada segunda parte de la luz en la citada punta distal, en donde la citada punta distal de la citada segunda parte de la luz se asegura a una pared de la citada primera parte de la luz en la citada pared de extremo distal.

14. Un catéter, que incluye:

un cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado cuerpo una pared que define por lo menos una luz para fluido de líquido a través del mismo, en donde el citado cuerpo incluye por lo menos un puerto en el citado extremo distal del citado cuerpo alargado en comunicación con la citada por lo menos una luz, y que comprende además un obturador final en el citado extremo distal y un mecanismo accionador en el citado extremo proximal, acoplándose el citado obturador final al citado mecanismo accionador, el cual es operable para mover remotamente el citado obturador final alejándolo del citado puerto a una posición abierta y permitir el flujo de líquido a través del

citado puerto y para mover remotamente el citado obturador final hacia el citado extremo distal a una posición cerrada para impedir el flujo de líquido a través del citado puerto, en donde el citado obturador final incluye un pasaje que se extiende a través del mismo y que comprende además una guía metálica que se puede posicionar a través del citado pasaje y a lo largo del citado cuerpo alargado fuera de la citada luz.

15. El catéter de la reivindicación 14, que comprende además un segundo cuerpo alargado que se extiende entre un extremo distal y un extremo proximal, incluyendo el citado segundo cuerpo una segunda pared que define por lo menos una luz para flujo de líquido a través del mismo y por lo menos un segundo puerto en el citado extremo distal del citado segundo cuerpo en comunicación con la citada por lo menos una luz del mismo, y

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PCT application of:	)	Authorized Officer:
Ash Access Technology, Inc.	)	Kevin C. Sirmons
	)	
International Application	)	File Ref. AATI-67
No. PCT/US07/15283	)	
	)	
International Filing Date	)	Mailing Date:
9 July 2007	)	9 October 2008
	)	
Title of Invention	)	
INDWELLING CATHETER	)	
WITH ANTI-CLOTTING	)	
FEATURES	)	

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**REMARKS IN RESPONSE TO WRITTEN OPINION
OF THE INTERNATIONAL SEARCHING AUTHORITY**

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Written Opinion of the International Searching Authority mailed on 11 July 2008, please consider the following remarks. Submitted herewith is an Amendment Under PCT Article 34, by which Applicant has amended claims 7, 11 and 13 to improve the clarity thereof or to correct clerical errors. Also submitted herewith are a PCT Demand and payment of the fee for same. Consideration of the remarks that follow and further consideration of the subject application, as amended and including claims 1-19, are hereby requested.

In the Written Opinion of the International Searching Authority dated 11 July 2008 (hereafter "Written Opinion"), claims 1-19 were pending. The Written Opinion acknowledges that claims 1-19 have industrial applicability because the subject matter claimed can be made or used in industry, and therefore meet the criteria set out in PCT Article 33(4). In addition, the Written Opinion indicates that claims 4 and 5 satisfy the

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novelty and inventive step requirements, and therefore meet the criteria set out in PCT Article 33(2)-(3). Claims 1-3 and 6-19, however, are indicated in the Written Opinion to lack novelty and/or inventive step. For the reasons set forth below, Applicant submits that claims 1-3 and 6-19, as amended, do not lack novelty or inventive step, and respectfully request an indication that all pending claims, as amended, satisfy the novelty and inventive step requirements of PCT Article 33(2)-(3).

In claim 11 (mistakenly referred to as claim 12 in Box No. VII of the Written Opinion) the wording "said second bend is distal of said second bend" was objected to under PCT Rule 66.2(a)(iii) as containing a defect. The claim has been corrected in a non-narrowing manner as suggested in the Written Opinion to recite "said second bend is distal of said fourth bend." Withdrawal of the objection to claim 11 is respectfully requested.

The Written Opinion asserts that claims 1, 2, 6-11, 13, 18 and 19 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,916,313 to Cunningham. Cunningham discloses "[a] multiple lumen catheter assembly having at least two catheters separate and independent from each other along at least a portion of their lengths, and that can be selectively joined together to change the separation distances between the catheters by of [sic] a connecting means." (Abstract). Cunningham states the following at column 5, lines 22-26:

There can be any number of connecting means 40 located along the facing walls 34 of the at least two catheters 12, 14. However, for ease of use, and to decrease the number of possible clotting or coagulation sites, the use of one or two connecting means 40 is preferred.

The Written Opinion states that if one of the connecting means [40] in the device described in Cunningham is connected without connecting the intervening connecting means, "then the concavely curved inward first bend of the first lumen part and the concavely curved inward second bend of the second lumen part, as described by the Applicant's invention, will be created, since both lumen parts [12][14] are made of a flexible, bendable material." It appears that the Written Opinion is advancing an argument that, even though Cunningham does not describe a device having the features recited in claim 1, it describes a device having an orientation of components that could be manipulated to arrive at the subject matter of claim 1. Applicant submits, however, that

this is not proper grounds for asserting that a claim lacks novelty. It appears that Applicant's specification has been used as a template for modifying the Cunningham disclosure to support this assertion. Applicant submits that Cunningham does not anticipate the subject matter of claim 1.

It is well settled that a claim lacks novelty only if each and every element as set forth in the claim is found in a single prior art reference, and every element of the claimed invention must be literally present, arranged as in the claim. Applicant submits that the rationale advanced in the Written Opinion does not negate the novelty of claim 1 because Cunningham does not expressly and literally describe every element of claim 1, arranged as in claim 1. In addition to other features, claim 1 recites the following:

said first lumen part extends distally from said bifurcation and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis

Cunningham fails to disclose a catheter that includes a "first lumen part...concavely curved toward said longitudinal axis on a first side of said longitudinal axis" and a "second lumen part...concavely curved toward said longitudinal axis on a second side of said longitudinal axis" as recited in claim 1. Notably, none of the Figures in Cunningham depict such an arrangement, and no description in Cunningham describes any embodiment that includes an arrangement of lumen parts as recited in claim 1. Moreover, the novelty analysis in the Written Opinion relies upon a modification of the Cunningham device and asserts that the modified form of the disclosed device anticipates the subject claims. This reliance on a modification of Cunningham in the Written Opinion supports Applicant's position that there is no express or literal disclosure present in Cunningham that anticipates claim 1.

In view of the above, the novelty analysis set forth in the Written Opinion relies upon subject matter that is missing from Cunningham, but that is suggested to be inherent in Cunningham (hereafter the "missing descriptive matter"). For the sake of those PCT member countries in which the issue of inherency is considered, Applicant submits that Cunningham cannot be properly considered to inherently disclose the subject matter of claim 1, and does not inherently negate the novelty of claim 1. Moreover, if the

International Preliminary Examining Authority ("IPEA") bases any subsequent novelty analysis upon a theory of inherency, Applicant respectfully requests that the IPEA clearly indicate that reliance is made upon an inherency theory so that the same can be properly considered by the respective National Patent Offices examining this application in the National Stage.

The missing descriptive matter discussed in the Written Opinion is not an inherent feature of the Cunningham device because the missing descriptive matter is not necessarily present in the device, and would not be recognized by persons of ordinary skill in the art to be necessarily present in the device. Moreover, it is improper to assert that a claim lacks novelty over a reference on the grounds that elements in the reference could be modified and used other than as described in the reference and for a different function. The mere fact that a certain structural orientation of a prior art device could possibly result from a possible set of undisclosed circumstances does not negate the novelty of a claim.

In the present case, the missing descriptive material relied upon in the Written Opinion is an arrangement in which

said first lumen part extends distally from said bifurcation and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis

This arrangement is not necessarily present in the device described in Cunningham and does not necessarily flow from the teachings of Cunningham. As an initial point, Cunningham discloses that the purpose of connecting means [40A], [40B], [40C], [40D], [40E] depicted in Fig. 2 is to give a practitioner the ability to adjust the distance between the distal tips of the catheter and to adjust the "separated length" between the separated lumen catheters. More particularly, Cunningham discloses that the distance between the distal tips and the separated length can be incrementally reduced by joining additional connecting means, moving from the proximal connecting means (i.e., connecting means [40A]) toward the distal connecting means (i.e., connecting means [40E]). (See, e.g., column 2, lines 43-48 ("As more sections of the catheters are joined, the distance

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between the distal tips of the catheters is decreased. In many cases, the joining of sections of the at least two catheters allows the practitioner to control the distance between the tips at the distal ends of the catheters.”); column 3, lines 13-16 (“the practitioner can join the at least two catheters together along the facing walls of the at least two catheters using the joinable means to reduce the separation distance to the desired or required distance.”); column 4, line 67 to column 5, line 4 (“The joining of more portions of the at least two catheters 12, 14 will decrease distance D between the tips 16, 18 of the at least two catheters 12, 14, as well as the separated length L between the separated lumens catheters [sic] 12, 14.”); etc.). The adjustment between the distal tips of the catheter and of the separated length between the separated lumen catheters is described in Cunningham to be accomplished by “joining more portions of the at least two catheters” (Column 4, line 67 to column 5, line 1). As stated at column 5, lines 8-16 of Cunningham, “if the practitioner needs the tips 16, 18 at the distal end 20 of the at least two catheters 12, 14 to be closer, the practitioner can join more sections along the walls 34 of the at least two catheters 12, 14 by using connecting means 40. Contrastingly, if the practitioner wants to maintain an increased distance D and/or length L at the distal end 20 between the at least two catheters 12, 14, the practitioner will not join as many sections of the least two catheters 12, 14.”

Cunningham does not disclose the use of the connecting means in any manner where one or more distally positioned connecting means would be joined while leaving other more proximal connecting means unjoined. Moreover, given the stated purpose of the connecting means, i.e., to adjust the distance between the distal tips of the catheter and to adjust the separated length between the separated lumen catheters, a person of ordinary skill in the art would have recognized that (1) the Cunningham device is used by joining consecutive connecting means moving from the most proximal connecting means, toward one or more distal connecting means, if present, and (2) the modified configuration described in the Written Opinion is not contemplated in the Cunningham disclosure. Moreover, the disclosure of Cunningham would not have motivated a person of ordinary skill in the art to make such a modification because to do so would not operate to achieve the desired result described in Cunningham, that is, to increase the

distance between the distal tips of the catheter or to adjust the length between the separated lumen catheters.

In addition to the above, even assuming *arguendo* that the modification proposed in the Written Opinion were to be made to the Cunningham device, i.e., if connecting means [40C] were to be connected without connecting the intervening connecting means [40A], [40B], there is no disclosure or teaching in Cunningham that lumen parts [12], [14] would necessarily assume the configuration recited in claim 1, and Applicant submits that the configuration recited in claim 1 indeed is not the necessary result of this modification. For example, Cunningham discloses that Figure 1 is a perspective view of the catheter assembly [10] in an unstressed configuration. (See col. 4, lines 7-9.). In this configuration, lumen part [12] is *convexly* curved in relation to the longitudinal axis. This is opposite the subject matter recited in claim 1 of the present application, which recites that the "first lumen part is *concavely* curved toward said longitudinal axis on a first side of said longitudinal axis" and that the "second lumen part is *concavely* curved toward said longitudinal axis on a second side of said longitudinal axis." (emphasis added). There is no teaching or reasonable determination that can be made, nor would one of ordinary skill in the art expect that lumen part [12] necessarily assumes a configuration that is opposite its unstressed configuration if intervening connecting means are disengaged.

Also, as acknowledged in the Written Opinion, Cunningham discloses that lumen parts [12], [14] are made of a flexible, bendable material. Therefore, a modification to the Cunningham device as proposed in the Written Opinion to join connecting means [40C] without joining the intervening connecting means [40A], [40B] would be understood by a person of ordinary skill in the art to be at least as likely, if not more likely, to result in deformation of the walls of lumen parts [12], [14], and therefore deformation of the lumens therein, than to result in a concave bending of the first and second lumen parts as asserted in the Written Opinion. Another possible result of this modification would be a kinking of lumen parts [12], [14] at the location of unjoined, connecting means rather than producing a concavely curved lumen part. Therefore, Cunningham cannot be found to inherently anticipate the subject matter of claim 1 because, even if the modification proposed in the Written Opinion were to be made, the

“missing descriptive material” relied upon in the Written Opinion is not the necessary result of the modification, and therefore is not necessarily or inherently present in the device described in Cunningham.

For the above reasons, Applicant respectfully submits that the subject matter of claim 1 is novel, and Applicant respectfully requests a positive indication regarding the novelty of claim 1 over Cunningham.

Claims 2, 6-11, 13, 18 and 19 depend from claim 1 and satisfy the novelty requirement at least for the reasons claim 1 is novel and for other reasons. For example, claim 7 recites “wherein said first lumen part is curved so that a distal end thereof is located on said second side of said longitudinal axis” and claim 8 depends from claim 7 and recites “wherein said second lumen part is curved so that a distal end thereof is located on said first side of said longitudinal axis.” A review of Cunningham finds no disclosure that the distal ends of catheters [12], [14] are located on opposite sides of the longitudinal axis along which catheters [12], [14] extend at their bifurcation. The Written Opinion asserts that the flexibility of catheters [12], [14] will allow the distal end to be so positioned, but there is no disclosure of this arrangement of elements in Cunningham. Therefore, Cunningham cannot be properly considered to disclose the subject matter of claims 7 and 8, and an indication that these claims satisfy the novelty requirement is respectfully requested.

Furthermore, amended claim 13 recites “wherein said first lumen part extends distally beyond a distal tip of said second lumen part, and said distal tip of said second lumen part includes a distal end wall obliquely oriented to a wall of said second lumen part at said distal tip, wherein said distal tip of said second lumen part is secured to a wall of said first lumen part at said distal end wall of said distal tip.” Support for the amendment to claim 13 may be found, for example, at page 12, lines 30 to page 13, line 7 and Figure 9 of the present application. Cunningham fails to disclose the distal tip of catheter [12] is secured to a wall of catheter [14] at a distal end wall of the distal tip of catheter [12]. As clearly shown in Figures 1-4 of Cunningham, the connecting means is located well proximally of the distal end wall of the distal tip of catheter [12]. Therefore, even if the distal-most connecting means [40] were secured, it does not disclose the connection arrangement recited in claim

13. Therefore, Applicant respectfully requests an indication that claim 13 satisfies the novelty requirement.

Claim 18 is an independent claim that recites, among other features, wherein at least a distal segment of said proximal portion extends along said longitudinal axis and said first and second lumen parts separate from one another at a bifurcation between said distal and proximal portions, wherein said first lumen part extends distally from said bifurcation along a first bend so that said first lumen part is concavely curved relative to said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends linearly and distally from said bifurcation along a second side of said longitudinal axis to a second bend that is curved to locate a distal tip of said second lumen part on said first side of said longitudinal axis.

As discussed above with respect to claim 1, Cunningham fails to disclose this arrangement of elements, and therefore does not anticipate claim 18.

Claim 19 depends from claim 18 and is novel at least for the reasons claim 18 is novel and also for the reasons claim 7 is novel as discussed above. Applicant therefore respectfully requests an indication that claim 19 satisfies the novelty requirement.

The Written Opinion also asserts that claims 1, 2, 6-11, 13, 18 and 19 lack an inventive step under PCT Article 33(3) as being "obvious over Cunningham as shown above with respect to novelty." In reply, Applicant submits that the subject claims satisfy the inventive step requirement because a person skilled in the art would find no motivation in Cunningham or any other reference of record to modify the Cunningham device to arrive at the subject matter recited in the subject claims. Moreover, Applicant submits that Cunningham teaches away from such a modification. As discussed above, Cunningham discloses that the purpose of connecting means [40A], [40B], [40C], [40D], [40E] is to give a practitioner the ability to adjust the distance between the distal tips of the catheter and to adjust the "separated length" between the separated lumen catheters. More particularly, Cunningham discloses that the distance between the distal tips and the separated length can be incrementally reduced by joining additional connecting means, moving from the proximal connecting means (i.e., connecting means [40A]) toward the distal connecting means. (i.e., connecting means [40E]). As stated at column 5, lines 8-16

of Cunningham, "if the practitioner needs the tips 16, 18 at the distal end 20 of the at least two catheters 12, 14 to be closer, the practitioner can join more sections along the walls 34 of the at least two catheters 12, 14 by using connecting means 40.

Contrastingly, if the practitioner wants to maintain an increased distance D and/or length L at the distal end 20 between the at least two catheters 12, 14, the practitioner will not join as many sections of the least two catheters 12, 14."

A person skilled in the art, upon reading Cunningham, would find no motivation to modify the Cunningham device in a manner whereby one or more distally positioned connecting means would be joined while leaving other more proximal connecting means unjoined because such a modification would not operate to achieve the express purpose of the connecting means, i.e., to adjust the distance between the distal tips of the catheter and to adjust the separated length between the separated lumen catheters. Moreover, Applicant also submits that, for the reasons discussed hereinabove, even such a modification would not necessarily result in the subject matter recited in claim 1, which recites a device in which, "said first lumen part extends distally from said bifurcation and includes a first bend so that said first lumen part is concavely curved toward said longitudinal axis on a first side of said longitudinal axis and said second lumen part extends distally from said bifurcation and includes a second bend so that said second lumen part is concavely curved toward said longitudinal axis on a second side of said longitudinal axis."

For the above reasons, Applicant submits that claims 1, 2, 6-11, 13, 18 and 19 satisfy the inventive step requirement of PCT Article 33(3), and request a positive indication of same.

The Written Opinion also asserts that claims 3 and 12 lack an inventive step under PCT Article 33(3) as being unpatentable over Cunningham in view of U.S. Patent No. 5,374,245 to Mahurkar. Claims 3 and 12 depend directly or indirectly from claim 1, and satisfy the inventive step requirement at least for the reasons claim 1 satisfies the inventive step requirement. Applicant therefore respectfully requests an indication that claims 3 and 12 satisfy the inventive step requirement of PCT Article 33(3).

The Written Opinion also asserts that claims 14-16 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 5,827,305 to Gordon.

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In rejecting claims 14, the Office Action asserts that the embodiment in Figures 8-10 of Gordon teaches an end cap [116] with a passage (channel [117]) therethrough as discussed at col. 8, lines 30-31. It is respectfully submitted that Gordon fails to teach any end cap "wherein said end cap includes a passage extending therethrough and further comprising a guidewire positionable through said passage and along said elongate body outside said lumen" as recited in claim 14. Rather, Gordon teaches a catheter [110] with a distal end [114] that "is closed with a cap 116.... The cap 116 preferably comprises a channel 117 formed therein so as to deflect fluid flow distally within the second lumen into the first lumen such that it urges any tissue samples contained within first lumen 120 proximally." See col. 8, lines 7-34. Accordingly, a guidewire is not positionable through channel [117] since Gordon teaches channel [117] is closed to deflect the fluid flow from second lumen [122] into first lumen [120]. Furthermore, Gordon teaches away from a passage through cap [116] to allow passage of a guidewire therethrough since it teaches a closed channel for deflection of fluid flow. Therefore, Gordon fails to teach or suggest all the elements recited in claim 14, and teaches away from modifying it to arrive at claim 14. For these reasons, Applicant respectfully requests an indication that claim 14 satisfies the inventive step requirement.

Claims 15-16 depend from claim 14 and distinguish Gordon at least for the reasons claim 15 does and for other reasons. Claims 15 and 16 were rejected as being a mere duplication of essential working parts of a device. However, claim 16 recites "wherein said second end cap includes a passage extending therethrough and said guidewire is positionable through said passage of said second end cap into said at least one lumen of said second elongate body." Claim 14 recites an arrangement where the guidewire positionable through the passage of the end cap of the other elongate body and along the other elongate body outside its lumen. There is no teaching or suggestion in Gordon of any arrangement that includes a guidewire positionable through a passage of an end cap of one elongate body outside of its lumen and through the passage of the end cap of the other body and into the lumen of the other body. Therefore, Gordon fails to teach or suggest all the elements arranged in the manner recited in claim 16. Applicant

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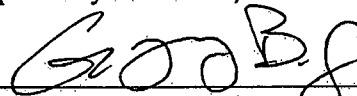
therefore respectfully requests an indication that claims 15 and 16 satisfy the inventive step requirement.

The Written Opinion also asserts that claim 17 lacks an inventive step under PCT Article 33(3) as being obvious over Gordon, in view of Cunningham. Claim 17 depends indirectly from claim 14, and satisfies the inventive step requirement at least for the reasons claim 14 satisfies the inventive step requirement. Applicant therefore respectfully requests an indication that claim 17 satisfies the inventive step requirement.

In view of the above amendments and remarks, Applicant submits that claims 1-19 satisfy the requirements of novelty, inventive step and industrial applicability, and respectfully requests an indication of same.

Kindly continue to review the application in view of these amendments and Applicant's remarks.

Respectfully submitted,



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From the INTERNATIONAL BUREAU

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NOTIFICATION CONCERNING
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International application No. PCT/US2007/015283	International filing date (day/month/year) 09 July 2007 (09.07.2007)		
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 11 July 2006 (11.07.2006)		
Applicant ASH ACCESS TECHNOLOGY, INC. et al			

- By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- (If applicable) The letters "NR" appearing in the right-hand column denote a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- (If applicable) An asterisk (*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b) (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
11 July 2006 (11.07.2006)	60/819,927	US	02 September 2007 (02.09.2007)
27 September 2006 (27.09.2006)	11/528,733	US	02 September 2007 (02.09.2007)

RECEIVED
IP DOCKETING

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Signature: <u>S. P. B.</u> RPT: <u>11/15/07</u> Telephone No. +41 22 338 9111
Facsimile No. +41 22 338 82 70 Form PCT/IB/304 (October 2005)	Stamp: OCT 15 2007 Signature: <u>S. P. B.</u> RPT: <u>11/15/07</u> Telephone No. +41 22 338 9111

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) AATI-67

Box-No. I	TITLE OF INVENTION	
INDWELLING CATHETER WITH ANTI-CLOTTING FEATURES		
Box No. II	APPLICANT	☐ This person is also inventor
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)		Telephone No.
ASH ACCESS TECHNOLOGY, INC. 3601 Sagamore Parkway North Suite B Lafayette, Indiana 47904 United States of America		Facsimile No.
		Applicant's registration No. with the Office
State (that is, country) of nationality: US		State (that is, country) of residence: US
This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box		
Box No. III	FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.		
Box No. IV	AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:		☒ agent ☐ common representative
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)		Telephone No.
COLLIER, DOUGLAS A. Krieg DeVault LLP One Indiana Square Suite 2800 Indianapolis, Indiana 46204-2079 United States of America		(317) 636-4341
		Facsimile No.
		(317) 636-1507
		Agent's registration No. with the Office
		43,556
☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.		

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
ASH, STEPHEN R. 2514 Mar Ruth Drive Lafayette, Indiana 47905 United States of America	
This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
BROWN, KENNETH E. 3641 Chesterfield Way West Lafayette, Indiana 47906 United States of America	
This person is: ☐ applicant only ☒ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
This person is: ☐ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
This person is: ☐ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
This person is: ☐ applicant only ☐ applicant and inventor ☐ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.	

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Supplemental Box

If the Supplemental Box is not used, this sheet should not be included in the request.

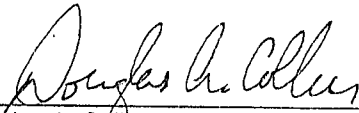
1. If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No." (indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:
 - (i) if more than one person is to be indicated as applicant and/or inventor and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;
 - (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;
 - (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;
 - (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;
 - (v) if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.
2. If the applicant intends to make an indication of the wish that the international application be treated, in certain designated States, as an application for a patent of addition, certificate of addition, inventor's certificate of addition or utility certificate of addition: in such a case, write the name or two-letter code of each designated State concerned and the indication "patent of addition," "certificate of addition," "inventor's certificate of addition" or "utility certificate of addition," the number of the parent application or parent patent or other parent grant and the date of grant of the parent patent or other parent grant or the date of filing of the parent application (Rules 4.11(a)(iii) and 49bis.1(a) or (b)).
3. If the applicant intends to make an indication of the wish that the international application be treated, in the United States of America, as a continuation or continuation-in-part of an earlier application: in such a case, write "United States of America" or "US" and the indication "continuation" or "continuation-in-part" and the number and the filing date of the parent application (Rules 4.11(a)(iv) and 49bis.1(d)).

Continuation of Box IV:

John H. Allie, Reg. No. 39,088; Clifford W. Browning, Reg. No. 32,201; Gregory B. Coy, Reg. No. 40,967; Douglas A. Collier, Reg. No. 43,556; Jason A. Houdek, Reg. No. 54,620; Kevin J. Huser, Reg. No. 56,379; David A. Lundy, Reg. No. 22,162; L. Scott Paynter, Reg. No. 39,797; Jason A. Penninger, Reg. No. 58,687; Brad A. Schepers, Reg. No. 45,431; Dean E. McConnell, Reg. No. 44,916; Brion G. St. Amour, Reg. No. 55,640; Mark T. Stephenson, Reg. No. 60,530; Arthur J. Usher, IV, Reg. No. 41,359; and Alastair J. Warr, Reg. No. 47,166, KRIEG DeVAULT LLP, One Indiana Square, Suite 2800, Indianapolis, Indiana 46204-2079, Telephone: (317) 636-4341, Facsimile: (317) 636-1507, Email: ipdocketing@kdlegal.com

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Box No. V DESIGNATIONS				
The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents. However, ☐ DE Germany is not designated for any kind of national protection ☐ JP Japan is not designated for any kind of national protection ☐ KR Republic of Korea is not designated for any kind of national protection ☐ RU Russian Federation is not designated for any kind of national protection <i>(The check-boxes above may only be used to exclude (irrevocably) the designations concerned if, at the time of filing or subsequently under Rule 26bis.1, the international application contains in Box No. VI a priority claim to an earlier national application filed in the particular State concerned, in order to avoid the ceasing of the effect, under the national law, of this earlier national application.)</i>				
Box No. VI PRIORITY CLAIM				
The priority of the following earlier application(s) is hereby claimed:				
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application: regional Office	international application: receiving Office
item (1) 11 July 2006	60/819,927	US		
item (2) 27 September 2006	11/528,733	US		
item (3)				
☐ Further priority claims are indicated in the Supplemental Box.				
Transmit certified copy: the receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) <i>(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)</i> identified above as: ☒ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box				
Restore the right of priority: the receiving Office is requested to restore the right of priority for the earlier application(s) identified above or in the Supplemental Box as item(s) (). <i>(See also the Notes to Box No. VI; further information must be provided to support a request to restore the right of priority.)</i>				
Incorporation by reference: where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.				
Box No. VII INTERNATIONAL SEARCHING AUTHORITY				
Choice of International Searching Authority (ISA) <i>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</i> ISA / US				
Request to use results of earlier search; reference to that search <i>(if an earlier search has been carried out by or requested from the International Searching Authority):</i> Date (day/month/year) Number Country (or regional Office)				
Box No. VIII DECLARATIONS				
The following declarations are contained in Boxes Nos. VIII (i) to (v) <i>(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration):</i>				Number of declarations
☐ Box No. VIII (i)	Declaration as to the identity of the inventor			:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent			:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application			:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)			:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty			:

Box No. IX CHECK LIST; LANGUAGE OF FILING			
This international application contains:		This international application is accompanied by the following item(s) (mark the applicable check-boxes below and indicate in right column the number of each item):	Number of items
(a) on paper, the following number of sheets:		1. ☒ fee calculation sheet	1
request (including declaration and supplemental sheets)	5	2. ☐ original separate power of attorney	
description (excluding sequence listing and/or tables related thereto)	17	3. ☐ original general power of attorney	
claims	5	4. ☐ copy of general power of attorney; reference number, if any:	
abstract	1	5. ☐ statement explaining lack of signature	
drawings	7	6. ☐ priority document(s) identified in Box No. VI as item(s):	
Sub-total number of sheets	35	7. ☐ translation of international application into (language):	
sequence listing		8. ☐ separate indications concerning deposited microorganism or other biological material	
tables related thereto		9. ☐ sequence listing in electronic form (indicate type and number of carriers)	
(for both, actual number of sheets if filed on paper, whether or not also filed in electronic form; see (c) below)		(i) ☐ copy submitted for the purposes of international search under Rule 13ter only (and not as part of the international application):	
Total number of sheets	35	(ii) ☐ (only where check-box (b)(i) or (c)(i) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Rule 13ter	
(b) ☐ only in electronic form (Section 801(a)(i))		(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing mentioned in left column	
(i) ☐ sequence listing		10. ☐ tables in electronic form related to sequence listing (indicate type and number of carriers)	
(ii) ☐ tables related thereto		(i) ☐ copy submitted for the purposes of international search under Section 802(b-quater) only (and not as part of the international application)	
(c) ☐ also in electronic form (Section 801(a)(ii))		(ii) ☐ (only where check-box (b)(ii) or (c)(ii) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Section 802(b-quater)	
(i) ☐ sequence listing		(iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column	
(ii) ☐ tables related thereto		11. ☒ other (specify): Credit Card Payment Form	1
Type and number of carriers (diskette, CD-ROM, CD-R or other) on which are contained the			
☐ sequence listing:			
☐ tables related thereto:			
(additional copies to be indicated under items 9(ii) and/or 10(ii), in right column)			
Figure of the drawings which should accompany the abstract:	1	Language of filing of the international application:	English
Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE			
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).			
			
Douglas A. Collier, Reg. No. 43,556			

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid
For International Bureau use only	
Date of receipt of the record copy by the International Bureau:	



11/11-71
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAY 30, 2007

PTAS

KRIEG DEVAULT LLP
ONE INDIANA SQUARE, SUITE 2800
INDIANAPOLIS, IN 46204-2079

CORRECTED
NOTICE

RECEIVED
IP DOCKETING

JUN 04 2007

KRIEG DEVAULT LLP

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF
THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS
AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER
REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE
INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA
PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD
FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY
CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 571-272-3350.
PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE,
MAIL STOP: ASSIGNMENT SERVICES BRANCH, P.O. BOX 1450, ALEXANDRIA, VA 22313.

RECORDATION DATE: 09/27/2006

REEL/FRAME: 018359/0876
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

ASH, STEPHEN R.

DOC DATE: 09/27/2006

ASSIGNOR:

BROWN, KENNETH E.

DOC DATE: 09/26/2006

ASSIGNEE:

ASH ACCESS TECHNOLOGY, INC.
3601 SAGAMORE PARKWAY NORTH, SUITE
B
WEST LAFAYETTE, INDIANA 47904

SERIAL NUMBER: 11528733

FILING DATE: 09/27/2006

PATENT NUMBER:

ISSUE DATE:

TITLE: INDWELLING CATHETER WITH ANTI-CLOTTING FEATURES

ENTERED

By: pm
Rpt: 7-4-2007
Due: _____

TONYA LEE, EXAMINER
ASSIGNMENT SERVICES BRANCH
PUBLIC RECORDS DIVISION

ASSIGNMENT

WHEREAS, Stephen R. Ash of 2514 Mar Ruth Drive, Lafayette, Indiana 47905 and Kenneth E. Brown of 3641 Chesterfield Way, West Lafayette, Indiana 47906, hereinafter referred to as Assignors, have made a new and useful Invention in an **INDWELLING CATHETER WITH ANTI-CLOTTING FEATURES** for which Assignors have made or will make application for Letters Patent of the United States; and

WHEREAS, Ash Access Technology, Inc., hereinafter referred to as Assignee, a corporation of the State of Indiana, having a principal place of business at 3601 Sagamore Parkway North, Suite B, West Lafayette, Indiana 47904, desires to acquire all of the entire right, title, and interest in, to and under said Invention disclosed, described and/or claimed, or intended so to be in said application, and in, to and under said application, and in, to and under any and all Letters Patent, United States and foreign, which may be obtained therefor and thereon;

NOW, THEREFORE, To All Whom It May Concern, be it known that for and in consideration of the sum of One Dollar (\$1.00) and other good, valuable and sufficient considerations to Assignors in hand paid, the receipt of which is hereby acknowledged, Assignors have sold, assigned and transferred, and by these presents do sell, assign and transfer unto Assignee, all of the entire right, title and interest in, to and under said invention disclosed, described and claimed or intended so to be in said application, and in, to and under said application for United States Letters Patent, and any and all other applications thereon and arising therefrom, including any and all divisions and continuations thereof, and any and all patents to be issued and obtained therefor and thereon, United States and foreign, including all reissues and extensions thereof.

Assignors hereby authorize and request the firm of Krieg DeVault LLP of 2800 One Indiana Square, Indianapolis, IN 46204-2079 to insert here in parentheses (Serial No. _____, Filed _____) the date and serial number of said application when officially known, and Assignors hereby authorize and request the Honorable Commissioner of Patents to issue said Letters Patent to Assignee, its assigns and legal representatives.

Assignors agree to sign and execute any and all other papers necessary or desirable for the procurement of Letters Patent on said Inventions in this and all foreign countries for the use of Assignee.

WITNESS Assignor's hand this 27th day of September, 2006.

Stephen R. Ash
Stephen R. Ash

STATE OF INDIANA)
) : SS
COUNTY OF TIPPECANOE)

Before me, a Notary Public, in and for said County and State, personally appeared Stephen R. Ash, who, being first duly sworn upon his oath, acknowledged the execution of the foregoing "Assignment" as his voluntary act and deed.

WITNESS my hand and Notarial Seal this 27th day of September, 2006.

Heike Hartwich
Notary Public

Printed: Heike Hartwich

Resident of Warren County

My Commission Expires:

April 20, 2007

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WITNESS Assignor's hand this 26 day of SEPTEMBER, 2006.

Kenneth E. Brown
Kenneth E. Brown

STATE OF INDIANA)
) : SS
COUNTY OF TIPPECANOE)

Before me, a Notary Public, in and for said County and State, personally appeared Kenneth E. Brown, who, being first duly sworn upon his oath, acknowledged the execution of the foregoing "Assignment" as his voluntary act and deed.

WITNESS my hand and Notarial Seal this 26th day of September, 2006.

Heike Hartwich
Notary Public

Printed: Heike Hartwich

Resident of Warren County

My Commission Expires:

April 20, 2007

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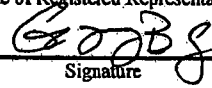
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PCT application of:)
Ash Access Technology, Inc.)
International Application)
No. PCT/US07/15283)
International Filing Date)
9 July 2007)
Title of Invention)
INDWELLING CATHETER)
WITH ANTI-CLOTTING)
FEATURES)

Authorized Officer:
Kevin C. Sirmons

File Ref. AATI-67

Mailing Date:
9 October 2008

I hereby certify that this correspondence is being transmitted via First Class United States Mail to the Mail Stop PCT, Attn: IPEA/US, United States Patent and Trademark Office at P.O. Box 1450, Alexandria, VA 22313-1450 on:	
09 October 2008	Date of Transmission
Gregory B. Coy	Name of Registered Representative
	Signature
09 October 2008	Date of Signature

TRANSMITTAL LETTER

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

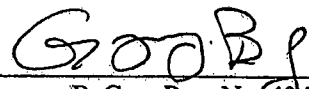
Sir:

Enclosed for consideration are the following documents:

- PCT Demand
- Amendment Under PCT Article 34
- Remarks in Response to Written Opinion of the International Searching Authority
- Credit Card Payment Form

Please continue to review the application in view of these documents.

Respectfully submitted,


Gregory B. Coy, Reg. No. 40967
KRIEG DEVAULT LLP
One Indiana Square, Suite 2800
Indianapolis, IN 46204-2079
United States of America
Tel.: (317) 238-6323
Fax: (317) 636-1507
Email: gcoy@kdlegal.com

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The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only			
Identification of IPEA		Date of receipt of DEMAND	
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference AATI-67	
International application No. PCT/US07/15283	International filing date (day/month/year) 9 July 2007	(Earliest) Priority date (day/month/year) 11 July 2006	
Title of invention INDWELLING CATHETER WITH ANTI-CLOTTING FEATURES			
Box No. II APPLICANT(S)			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) ASH ACCESS TECHNOLOGY, INC. 3601 Sagamore Parkway North Suite B Lafayette, Indiana 47904 United States of America		Telephone No.	
		Facsimile No.	
		Applicant's registration No. with the Office	
☐ E-mail authorization: Marking this check-box authorizes the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, if the Authority so wishes, advance copies of notifications in respect of this international application. (See also the Notes to Box No. II.)		E-mail address	
State (that is, country) of nationality: US		State (that is, country) of residence: US	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) ASH, STEPHEN R. 2514 Mar Ruth Drive Lafayette, Indiana 47905 United States of America			
State (that is, country) of nationality: US		State (that is, country) of residence: US	
☒ Further applicants are indicated on a continuation sheet.			

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Sheet No. 2.

International application No.
CT/US07/15283

Continuation of Box No. II APPLICANT(S)	
<i>If none of the following sub-boxes is used, this sheet should not be included in the demand.</i>	
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i> BROWN, KENNETH E. 3641 Chesterfield Way West Lafayette, Indiana 47906 United States of America	
State <i>(that is, country)</i> of nationality: US	State <i>(that is, country)</i> of residence: US
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
State <i>(that is, country)</i> of nationality:	State <i>(that is, country)</i> of residence:
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
State <i>(that is, country)</i> of nationality:	State <i>(that is, country)</i> of residence:
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)</i>	
State <i>(that is, country)</i> of nationality:	State <i>(that is, country)</i> of residence:
☐ Further applicants are indicated on another continuation sheet.	

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCEThe following person is ☒ agent ☐ common representativeand ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.Name and address: (Family name followed by given name; for a legal entity, full official designation.
The address must include postal code and name of country.)

COY, GREGORY B.

Krieg DeVault LLP

One Indiana Square

Suite 2800

Indianapolis, Indiana 46217-2079

United States of America

Telephone No.

(317) 238-6323

Facsimile No.

(317) 636-1507

Agent's registration No. with the Office

40,967

☒ **E-mail authorization:** Marking this check-box authorizes the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, if the Authority so wishes, advance copies of notifications in respect of this international application. (See also the Notes to Box No. II.)

E-mail address

ipdocketing@kdlegal.com

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.**Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION****Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

☐ the international application as originally filedthe description ☒ as originally filed☐ as amended under Article 34the claims ☐ as originally filed☐ as amended under Article 19 (together with any accompanying statement)☒ as amended under Article 34the drawings ☒ as originally filed☐ as amended under Article 342. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ Where the IPEA wishes to start the international preliminary examination at the same time as the international search in accordance with Rule 69.1(b), the applicant requests the IPEA to postpone the start of the international preliminary examination until the expiration of the applicable time limit under Rule 69.1(d).4. ☐ The applicant expressly wishes the international preliminary examination to start earlier than at the expiration of the applicable time limit under Rule 54bis.1(a).

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English☒ which is the language in which the international application was filed.☐ which is the language of a translation furnished for the purposes of international search.☐ which is the language of publication of the international application.☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.**Box No. V ELECTION OF STATES**

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT.

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Sheet No. 4

International application No.
PCT/US07/15283

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | | |
|--|---|----|--------|
| 1. translation of international application | : | | sheets |
| 2. amendments under Article 34 | : | 5 | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | | sheets |
| 5. letter | : | 1 | sheets |
| 6. other (specify) Remarks in Response to Written Opinion of the ISA | : | 11 | sheets |

For International Preliminary Examining Authority use only

received not received

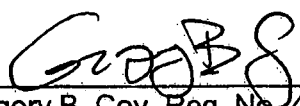
- | | |
|--------------------------|--------------------------|
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |

The demand is also accompanied by the item(s) marked below:

- | | |
|--|---|
| 1. ☒ fee calculation sheet | 5. ☐ statement explaining lack of signature |
| 2. ☐ original separate power of attorney | 6. ☐ sequence listing in electronic form |
| 3. ☐ original general power of attorney | 7. ☐ tables in electronic form related to a sequence listing |
| 4. ☐ copy of general power of attorney; reference number, if any: | 8. ☒ other (specify): Credit Card Payment Form |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).


Gregory B. Coy, Reg. No. 40,967

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

- | | |
|--|--|
| 3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.
☐ The applicant has been informed accordingly. | 6. ☐ The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8, below, does not apply. |
| 4. ☐ The date of receipt of the demand is WITHIN the time limit of 19 months from the priority date as extended by virtue of Rule 80.5. | 7. ☐ The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5. |
| 5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82. | 8. ☐ Although the date of receipt of the demand is after the expiration of the time limit under Rule 54bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82. |

For International Bureau use only

Demand received from IPEA on:

CHAPTER II

PCT

FEE CALCULATION SHEET

Annex to the Demand

International application No. PCT/US07/15283		For International Preliminary Examining Authority use only
Applicant's or agent's file reference AATI-67		
Applicant ASH ACCESS TECHNOLOGY, INC.		Date stamp of the IPEA
CALCULATION OF PRESCRIBED FEES		
1. Preliminary examination fee	600.00 P	
2. Handling fee (<i>Applicants from certain States are entitled to a reduction of 90% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 10% of the handling fee.</i>)	171.00 H	
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box.....	771.00	
TOTAL		
MODE OF PAYMENT (Not all modes of payment may be available at all IPEAs)		
☒ authorization to charge deposit account with the IPEA (see below)	☐ cash	
☐ cheque	☐ revenue stamps	
☐ postal money order	☐ coupons	
☐ bank draft	☒ other (specify): Credit Card Payment Form	
AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT (This mode of payment may not be available at all IPEAs)		
☐ Authorization to charge the total fees indicated above.	IPEA/ US	
☒ (This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit) Authorization to charge any deficiency or credit any overpayment in the total fees indicated above.	Deposit Account No.: 12-2424	
	Date: 09 October 2008	
	Name: Gregory B. Coy	
	Signature: Gregory B. Coy	

15.1057.04 -147

Brigard & Castro
BOGOTÁ - COLOMBIA

PODER

Yo (nosotros), **ASH ACCESS TECHNOLOGY, INC.**

domiciliado(s) en, 3601 Sagamore Parkway North, Suite B,
West Lafayette, IN 47904, Estados Unidos de América

Nombro(amos) a: **JUAN PABLO CADENA SARMIENTO**
y/o **CARLOS H. PALACIO EASTMAN** y/o **MARTIN E. TORRES CARDOZO**, de Bogotá, Colombia, apoderados verdaderos y legales con poder especial, amplio y suficiente, para recabar de las oficinas y autoridades colombianas administrativas, judiciales y de policía, en cualquier instancia o recurso, la obtención de patentes de invención, registros de marcas, diseños industriales, modelos de utilidad, depósitos de nombres comerciales, lemas comerciales y enseññas, registros de derechos de autor y contratos sobre los mismos, obtención de certificados de obtentor de variedades vegetales, así como sus prórrogas, renovaciones, anotaciones de traspaso, cambios de nombre, domicilio y/o dirección; elaborar, tramitar y registrar contratos de licencia y licencias de cualesquiera clases; intervenir como demandante o como demandado en cualquier instancia y recurso ante cualquier juez, corporación, funcionario público o autoridad en acciones judiciales, administrativas y de policía tales como: oposiciones al registro de marcas; acciones de caducidad, cancelación y nulidad; acciones reivindicatorias, acciones derivadas de la obtención o explotación de licencias; acciones de competencia desleal; demandas penales; acciones de indemnización de perjuicios, reclamos y observaciones a solicitudes de patentes, diseños industriales, modelos de utilidad, en el ejercicio de medidas cautelares y en otras acciones o medidas similares.

A este efecto, lo(s) faculto(amos) para elevar solicitudes, formular descripciones, enmiendas, protestas, declaraciones, oposiciones, cancelaciones, nulidades, apelaciones y reclamos; pagar impuestos, cuotas y gravámenes prescritos por la ley; renunciar o desistir a derechos concedidos o en curso de concesión; recibir toda clase de documentos y valores, dando el descargo respectivo, y, en general, para dar ante dichas autoridades todos los pasos necesarios al efecto indicado y tomar todas las medidas que creyeren conducentes al resguardo de mis (nuestros intereses), con todas las demás facultades legales necesarias.

Este poder comprende la facultad de ratificar o confirmar en mi (nuestro) nombre lo actuado así como la facultad de desistir, transigir, comprometer, y la de sustituirlo en todo o en parte y revocar sustituciones. Asimismo nombro(amos) a: **JUAN PABLO CADENA SARMIENTO** y/o **CARLOS H. PALACIO EASTMAN** y/o **MARTIN E. TORRES CARDOZO**, domiciliado(s) en la Carrera 7 No. 71-21, Torre B, Piso 4, mis (nuestros) apoderados en Colombia, con facultades para recibir notificaciones y designar apoderados judiciales o extrajudiciales.

Otorgado y firmado en

hoy de de 200_

Firma

Nombre
Cargo

POWER OF ATTORNEY

I (We), **ASH ACCESS TECHNOLOGY, INC.**

domiciled in, 3601 Sagamore Parkway North, Suite B,
West Lafayette, IN 47904, United States of America

Hereby appoints **JUAN PABLO CADENA SARMIENTO** and/or **CARLOS H. PALACIO EASTMAN** and/or **MARTIN E. TORRES CARDOZO**, of Bogotá, Colombia, my (our) true and lawful attorneys with special, ample and sufficient power to obtain from the Colombian administrative, judicial and police offices and authorities, in any instance, privileges of patents of invention, registration of trademarks, industrial designs and utility models; registration of commercial names, slogans and emblems, registration of copyright and contracts related thereto, certificates of obtainers of vegetables varieties, as well as extensions, renewals and recordal of assignments and changes of name, domicile and/or address related to the above; to prepare, prosecute and register licenses of any kind; to act as plaintiff or defendant in any instance or recourse, and before any judge, corporation, public official or authority in judicial, administrative and police actions, such as: oppositions to the registration of trademarks; caducity, cancellation and nullity actions; claim actions derived from the obtaining or exploitation of licenses, action of unfair competition; criminal proceedings, actions for payment of damages; claims or observations on patent applications, models, industrial designs and utility models; in the exercise of preventive measures and in other actions or similar proceedings.

To that effect they hereby empowered to file applications, formulate descriptions, amendments, protests, declarations, oppositions, cancellations, nullities, appeals and claims; to pay taxes, quotas and assessments prescribed by law, renounce or waive the rights granted or in the process of granting; to receive all kinds of documents and valuables, giving the respective release of receipt, and, in general, to take before said authorities the necessary steps to such effect, and any measures that they may deem pertinent to the safeguard of my (our) interest(s) with all the other necessary legal powers.

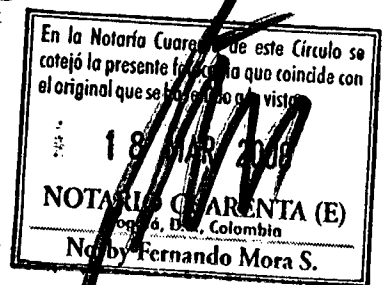
This power includes the faculty to ratify or confirm desist, settle and compromise on my (our) behalf, and to substitute this power in whole or in part and to revoke substitutions. At the same time I (We) hereby appoint **JUAN PABLO CADENA SARMIENTO** and/or **CARLOS H. PALACIO EASTMAN** and/or **MARTIN E. TORRES CARDOZO**, domiciled in Carrera 7 No. 71-21, Torre B, Piso 4, my (our) attorney(s) in fact, with powers to receive notifications and to designate judicial and extrajudicial attorneys.

Granted and signed in

this 16th day Nov. of 2007

Signature

Name **Robert B. Truitt**
Title **President**





Todd Rokita
Secretary of State

SECRETARY OF STATE
STATE OF INDIANA

APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. Country: United States of America
2. This public document has been signed by *Heike Hartwich*
3. acting in the capacity of notary public in & for *Warren County*
4. and bears the seal/stamp of notary public in & for the State of Indiana
- Certified**
5. at Indianapolis, Indiana
6. this *Twenty-seventh* day of *November*, 2007
7. by Secretary of State of Indiana
8. No. A2007 - 016549

9. Seal/Stamp:



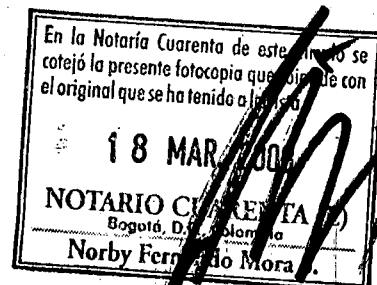
10. Signature:

Todd Rokita

Todd Rokita
Indiana Secretary of State

*Effective May 1, 2003 all apostilles from the Indiana Secretary of State will have an electronically printed seal.

taove



CERTIFICADO NOTARIAL (SOCIEDAD)

NOTARIAL CERTIFICATE (CORPORATION)

Hoy de
personalmente compareció ante mí

On this 16th day of NOVEMBER of 2007 personally
appeared before me ROBERT B. TRUITT

a quien conozco, y de quien me consta que firmó el anterior
documento, debidamente juramentado declaró y dijo que él
(ella) es

to me known, and known to me to be the person who
signed the foregoing instrument who being by me duly
sworn did depose and say that he (she) is the

PRESIDENT & CEO

de, ASH ACCESS TECHNOLOGY, INC.

of, ASH ACCESS TECHNOLOGY, INC.

Sociedad legalmente constituida para un período de
duración que aún no ha terminado; que el declarante está
autorizado por dicha compañía para conferir este poder; que
el sello estampado por él al pie de tal poder, en nombre y
representación de la expresada compañía, es el sello oficial
de ella; y que el objeto para el cual se confiere este
instrumento está comprendido dentro del objeto social de la
sociedad.

Which is legally constituted for a term not yet expired, that
deponent is authorized by said Company to confer this
Power of Attorney: that the seal affixed hereunto by the
deponent in the name and on behalf of said Corporation is
the corporate seal thereof; and that the purpose for which
this instrument is granted is included within the corporate
purpose of company.

El suscrito Notario hace constar que tuvo a la vista las
pruebas de la existencia de la sociedad.

The undersigned Notary Public attests that he has seen the
documents that prove the existence of the company.

Estado de
con fecha

State of INDIANA
under date of

y que quien confiere el presente poder es su representante.

and that he (she) who grants the present power of attorney
is its Representative.

Notario Público (sello)

Public Notary (Seal)

CERTIFICADO NOTARIAL PERSONA NATURAL

NOTARIAL CERTIFICATE NATURAL PERSON

Hoy de de , compareció(eron) ante mí

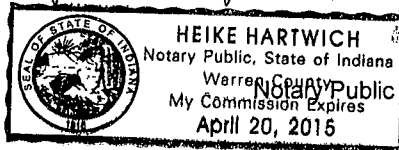
On this 16th day of NOVEMBER 2007,
personally appeared before me

ROBERT B. TRUITT

a quien (es) conozco y me consta que es(son) la(s)
persona(s) firmante(s) del documento que precede y
quien(es) declara(n) que otorgan el mismo para los fines y
propósitos que en él se expresan.

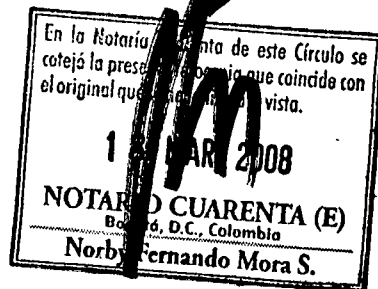
who is(are) known to me and who I attest executed the
foregoing document and he (they) declared he (they)
grant(s) the document for the uses and purposes therein
expressed.

Notario Público (sello)



LEGALIZACIÓN POR APOSTILLA ES REQUERIDA.

LEGALIZATION BY APOSTILLE IS REQUIRED



HRT

TRADUCCIÓN AL ESPAÑOL del documento de poder otorgado por **ASH ACCESS TECHNOLOGY, INC.**, con domicilio en 3601 Sagamore Parkway North, Suite B, West Lafayette, IN 47904, Estados Unidos de América.

SECRETARIO DE ESTADO
ESTADO DE INDIANA

Todd Rokita
Secretario de Estado

APOSTILLA

(Convención de La Haya del 5 de Julio de 1961)

1. País: Estados Unidos de América
2. Este documento público ha sido firmado por Heinke Hartwich
3. actuando en capacidad de notario público en y para Condado de Warren
4. lleva el sello/timbre de notario público en y para el Estado de Indiana

CERTIFICADO

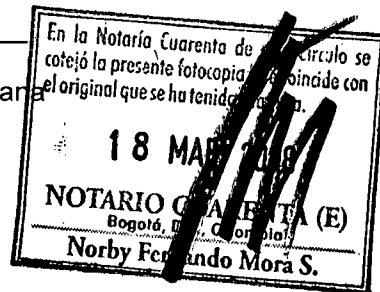
5. en Indianapolis, Indiana
6. este vigésimo séptimo día de Noviembre, 2007
7. por el Secretario de Estado de Indiana
8. No. A2007 - 016549
9. Sello/timbre
10. Firma

SELLO DEL ESTADO DE INDIANA
1816

(FIRMA)
Todd Rokita
Secretario de Estado de Indiana

Hay un sello que dice:

HEINKE HARTWICH
Notario Público, Estado de Indiana
Condado de Warren
Mi Comisión Vence
Abril 20, 2015



REQUISITOS MINIMOS PARA ADMISION A TRAMITE
PCT

PATENTE DE INVENCION []

MODELO DE UTILIDAD []

- ◆ Indicación de que se solicita la concesión de una patente []
- ◆ Datos de identificación del solicitante o de la persona que presenta la solicitud []
- ◆ Descripción de la invención []
- ◆ Dibujos de ser estos pertinentes []
- ◆ Comprobante de pago de las tasas establecidas []

COMPLETA []

INCOMPLETA []

DISEÑO INDUSTRIAL []

- ◆ Indicación de que se solicita el registro de Diseño Industrial []
- ◆ Datos de identificación del solicitante o de la persona que presenta la solicitud []
- ◆ Representación gráfica y fotográfica del Diseño Industrial o muestra del material que incorpora el diseño []
- ◆ Comprobante de pago de las tasas establecidas []

COMPLETA []

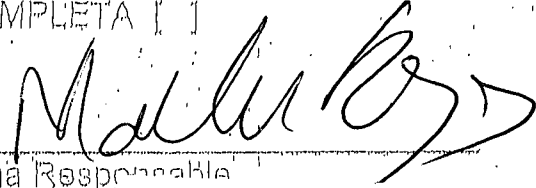
INCOMPLETA []

ESQUEMA DE TRAZADO []

- ◆ Indicación de que se solicita el registro de un Esquema de Trazado []
- ◆ Datos de identificación del solicitante o de la persona que presenta la solicitud []
- ◆ Representación gráfica del esquema trazado []
- ◆ Comprobante de pago de las tasas establecidas []

COMPLETA []

INCOMPLETA []


Firma Responsable

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 09-011070- -00000-0000

Fecha: 2009-02-05 16:55:00 Dep. 2020 NUECREACIONII
Tra. 11 PATENTEIYII Eve: 379 FASENACIONALII
Act. 411 PRESENTACION Folios: 148

Fecha _____

arrera 13 No. 27-00 Piso 6, 7 y 10

Corregidor 3 82 08 40

Fax: 350 52 20

E-mail: info@slc.gov.co

www.slc.gov.co

Bogotá, D.C., Colombia

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Bogotá,
2020

Doctor(a)
CADENA SARMIENTO JUAN PABLO
Apoderado(a) y/o Representante de
ASH ACCESS TECHNOLOGY INC

REFERENCIA	Radicación No.	9 11070
	Solicitud internacional	PCT/US2007/015283
	Fecha inicio fase nacional	11/02/2009
	Trámite	11
	Evento	379
	Actuación	430
	Oficio No.	2263

Como resultado del examen de forma, realizado con fundamento en el artículo 38 de la Decisión 486 de la Comisión de la Comunidad Andina, artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la Superintendencia de Industria y Comercio, se le comunica que:

1. Si fuere el caso, el solicitante debe adjuntar la traducción de los anexos del reporte de examen preliminar internacional (Art. 36.2.b) del tratado PCT.

2. La solicitud no contiene la copia del documento en que consta la cesión del derecho a la patente del inventor al solicitante o a su causante, conforme a lo establecido por el artículo 26 literal k) de la Decisión 486 de la Comisión de la Comunidad Andina. Cuando se trate de documentos otorgados en el extranjero, estos deberán legalizarse de conformidad con lo dispuesto por los artículos 259 y 260 del Código de Procedimiento Civil. Cuando se trate de las declaraciones a que hace referencia la Regla 4.17 ii) del Tratado de Cooperación en Materia de Patentes PCT., el alcance de las tales declaraciones se determinará según indiquen claramente una cesión de derechos del inventor al solicitante o su causante, de conformidad con lo dispuesto en el numeral 5.2.15 del Capítulo Quinto, Título X de la Circular Única de Superintendencia de Industria y Comercio.

En cumplimiento de lo dispuesto por el artículo 39 de la Decisión 486, se le requiere para que dentro del término de dos meses siguientes a la fecha de notificación del presente oficio, complete los requisitos anteriormente enunciados. En caso de no dar cumplimiento al presente requerimiento, la solicitud se considerará abandonada y perderá su prelación.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No.10 de 2001.

Continúa en la página siguiente...

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Radicación No.: 9 11070



DORIS ELENA POLO CORDOBA
Jefe de la división de Nuevas Creaciones (E)

El anterior requerimiento fue notificado por fijación en lista de
fecha 27 FEB. 2009
adpall