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Clarke, Modet & Cº

COLOMBIA

P-3769

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

E. S. D.

Ref.: Expediente No. 13.124.623

Solicitud de Patente a nombre de

DEPUY SYNTHES PRODUCTS, LLC

Yo, SILVANA MARIA LÓPEZ DIAZ, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad **DEPUY SYNTHES PRODUCTS, LLC** domiciliada en Massachusetts, Estados Unidos de América, solicitante de la patente de la referencia, atentamente me permito presentar copia certificada de la solicitud de Patente número 13/478,487 de 23 de mayo de 2012, con la debida traducción de lo pertinente.

Señor Superintendente,

SILVANA MARIA LÓPEZ DÍAZ

C.C. 22.468.787 de Barranquilla

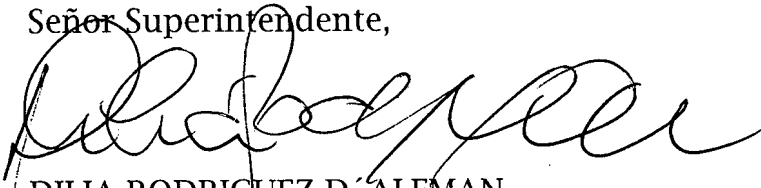
T.P. 147463 del CSJ

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432

Yo, **DILIA RODRÍGUEZ D' ALEMAN**, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 No. 86-53 Piso 6, Edificio Segovia Bogotá, Colombia, atentamente informo a usted que sustituyo el poder con que obro a la doctora **SILVANA MARÍA LÓPEZ DÍAZ**, domiciliada en Bogotá, identificada con la Cédula de Ciudadanía No. 22.468.787 y portadora de la tarjeta profesional No. 147.463 del CSJ, con las mismas facultades con que me fueron conferidas para este caso.

Señor Superintendente,



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Acepto sustitución

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PRESENTACION PERSONAL

El anterior escrito fue presentado ante el
NOTARIO ONCE DEL CIRCULO DE BOGOTA, D.C.
personalmente por D. JULIA RODRIGUEZ
D. VALENZUELA
quien exhibió la c.c. 14634882 BOGOTA
y Tarjeta Profesional No. 20324
Fecha 11.8 JUN 2013

Guillermo Chávez Cristancho
NOTARIO



P-3769

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Mayo 22 de 2013

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: **13/478,487**

Fecha de Presentación: Mayo 23 de 2012

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, PARA SER USADA EN LA PRESENTACIÓN EXTRANJERA BAJO EL CONVENIO DE PARÍS ES **US 13/478,487**

Por la autoridad de
Bajo el Secretario de Comercio para la Propiedad Intelectual y el Director de la Oficina de Patentes y Marcas de los Estados Unidos de América

(fdo) **P.R. GRANT**

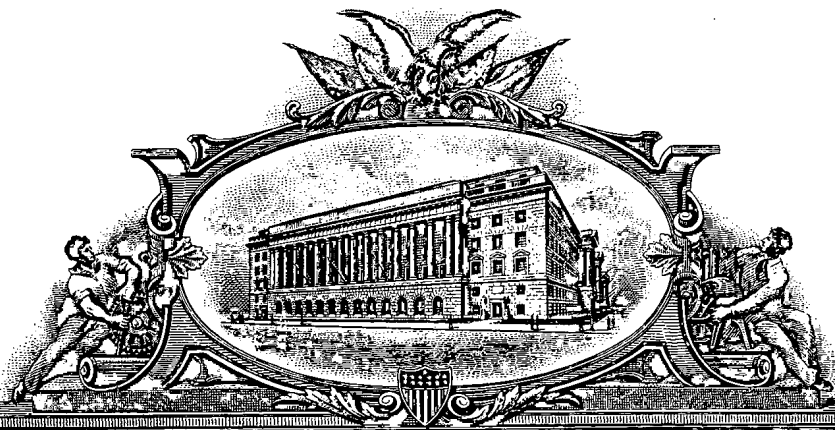
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May 22, 2013

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 13/478,487

FILING DATE: May 23, 2012

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US13/478,487

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

P. R. GRANT
Certifying Officer



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Electronic Acknowledgement Receipt	
EFS ID:	12845943
Application Number:	13478487
International Application Number:	
Confirmation Number:	8012
Title of Invention:	CATHETER CURVATURE BRACES AND METHODS OF USING SAME
First Named Inventor/Applicant Name:	ALAN DEXTRADEUR
Customer Number:	27777
Filer:	Eugene L Szczecina/Crystal Washington
Filer Authorized By:	Eugene L Szczecina
Attorney Docket Number:	COD5293USNP
Receipt Date:	23-MAY-2012
Filing Date:	
Time Stamp:	14:19:01
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 1500
RAM confirmation Number	664
Deposit Account	100750
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

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Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ADS_COD5293USNP.pdf	899045 83584df91cf24078701d98e2489f99bac01c1efa	no	4
Warnings:					
Information:					
2	Drawings-only black and white line drawings	FIGURES1-7_COD5293USNP.pdf	62426 28859f3a27b9e8db80c05b3d6788341ab18dae1b	no	3
Warnings:					
Information:					
3	Specification	SPECIFICATION_COD5293USNP.pdf	244793 ef5df0e1da39adcc51eb624f69f0e89ec608e975	no	13
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	36662 746328a940f0453dcd04f899cd0a9bc6fe9ad85a	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1242926		

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Electronic Acknowledgement Receipt	
EFS ID:	12847654
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Attorney Docket Number:	COD5293USNP
Receipt Date:	23-MAY-2012
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Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Codman_Aneurysm_clips.pdf	221667 60d6aa938ffaba111911492068567aba3903b1fe3	no	8
Warnings:					
Information:					

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Information Disclosure Statement (IDS)
Form (SB08)

IDS_COD5293USNP.pdf

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Warnings:

Information:

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Non Patent Literature

LIND_CathPlacment_Clin_Neuroscience.pdf

63685

07bcd2de08a3c34cc1108d624080be8ac388044a

no

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Warnings:

Information:

Total Files Size (in bytes):

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Catheter Curvature Braces and Methods of Using Same
BACKGROUND OF THE INVENTION

1. Field of the Invention

5 [0001] The invention relates to a device and methods for ensuring proper curvature for a catheter placed in a patient and more particularly to an implantable catheter having a curved elastic brace.

2. Description of the Related Art

10 [0002] There are a number of conditions in patients for which it is desirable to add or withdraw fluid. Some fluid management conditions involve the mammalian brain. Within the cranium, gray and white matter is suspended in cerebrospinal fluid and nourished by blood delivered through cerebral arteries. The gray matter has closely spaced cell bodies of neurons, such as in the cerebral cortex, and the underlying white matter contains densely packed axons
15 that transmit signals to other neurons. Human brain tissue has different densities and comprises approximately eighty percent of the intracranial content, with blood and cerebrospinal fluid each normally comprising approximately ten percent.

[0003] Cerebrospinal fluid is produced by choroid plexus in several connected chambers known as ventricles and typically is renewed four to five times per day. Cerebrospinal fluid in a
20 healthy human flows slowly and continuously through the ventricles, propelled by pulsations of the cerebral arteries. The fluid flows around the brain tissues and the spinal column, and then through small openings into the arachnoid membrane, which is the middle layer of the meninges surrounding the brain parenchyma and ventricles, where the fluid is finally reabsorbed into the bloodstream.

25 [0004] Under normal conditions, bodily mechanisms compensate for a change in fluid volume within the cranium through tissue resilience and by adjusting the total volume of blood and cerebrospinal fluid so that a small increase in fluid volume does not increase intracranial pressure. Similarly, a healthy brain compensates for an increase in intracranial pressure to minimize a corresponding increase in intracranial volume. This volume- and pressure-

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relationship can be explained in terms of cerebral compliance, which term is intended to include herein the terms elastance and intracranial compliance.

[0005] The brain is compliant as long as a person's auto-regulatory mechanism can compensate for any change in volume. As soon as the brain's auto-regulation or compensatory mechanisms fail, blood and cerebrospinal fluid cannot be displaced, and the brain can no longer adapt to any increase in fluid volume. A reduction in cerebral compliance eventually will lead to an undesired increase in intracranial pressure, also known as hydrocephalus. As more fluid volume is added, a threshold is reached beyond which small increases in volume lead to dramatic and unhealthy increases in intracranial pressure.

10 [0006] A typical device to treat fluid conditions such as hydrocephalus is a ventricular catheter disclosed by Watson et al. in U.S. Patent No. 5,738,666. In one embodiment, ventricular catheter 22 has a plurality of fluid management openings, referred to as fluid flow apertures 56, near a distal tip 58 having a slit 60. The "distal" tip is the end farthest from a surgeon during implantation of the catheter. A terminal end 40 of a rigid introducer cannula 34 is inserted through the slit 60 during final placement of the ventricular catheter. A Tuohy-Borst adaptor 32 is secured to the proximal end of the introducer cannula 34. During set-up, a fiber-optic shaft 66 of an endoscope is advanced through the adaptor 32 and the cannula 34 until a fiber-optic terminal end 28 emerges past ventricular catheter terminal end 58 and aligns with introducer terminal end 40. Fiber-optic shaft 66 is then interlocked relative to introducer cannula 34. The aligned tips of the fiber-optic shaft 66 and the introducer cannula are then retracted proximally within catheter 22 during advancement through tissue until a selected ventricle is reached.

25 [0007] Unfortunately, complications associated with the ingrowth of choroid plexus into implanted ventricular catheters, also known as ventricular shunts, are common. The most common cause of ventricular shunt malfunction during treatment of hydrocephalus is occlusion, sometimes referred to as proximal shunt occlusion, with the fluid management openings frequently blocked by choroid plexus and/or brain parenchyma. Accurate placement of the catheter depends on both proper insertion trajectory and proper catheter tip positioning vis-a-vis ventricular configuration. Surgeons often attempt to place the distal tip of the ventricular catheter in front of the foramen of Monro to avoid the choroid plexus. However, creating a direct path to the front region restricts the surgical approaches to the ventricle. Theories on how

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the approaches differ based on seizure risk, choroid plexus obstruction, size and shape of target ventricular chamber and incidence of infection remain controversial.

[0008] Pre-curved catheters have been utilized for a variety of applications, typically where larger outer diameters are tolerated. U.S. Patent No. 3,867,945 by Wendell Long
5 discloses a Foley urethral catheter with a stylet that is semi-rigid and sufficiently stiff with an optimal curvature to guide the catheter during insertion.

[0009] Reinforced retention structures having an elastic member are disclosed by Teague et al. in U.S. Patent No. 6,569,150. The retention structure provides an anchoring geometry to retain a catheter in position within the body of a patient, such as within a kidney and ureter.

10 [00010] It is therefore desirable to have a more versatile device and technique for positioning a catheter to manage bodily fluids, especially cerebrospinal fluid. A device is needed that minimizes obstruction and failure of a shunt system by facilitating the final catheter position within a ventricle of a brain, particularly when a more challenging occipital approach is utilized.

15 **SUMMARY OF THE INVENTION**

[00011] An object of the present invention is to enable a distal portion of a fluid management catheter to be positioned as desired within a patient.

[00012] Another object of the present invention is to minimize exposure of the distal
20 portion of the catheter to tissue, such as choroid plexus, which may obscure openings in the catheter.

[00013] Yet another object of the invention is to optimize the trajectory and final position of shunt catheters, particularly in children with small or slit ventricles.

[00014] A still further object is to reduce the need for repair and/or replacement of implanted catheters.

25 [00015] This invention features a catheter curvature brace that is attachable to a distal portion of a shaft of a catheter and has an elongated frame with a distal end and a proximal end. The frame is formed with at least one curve in a relaxed curved configuration. At least two coupling elements are connected to the frame, each coupling element configured to engage an outer surface of the catheter. At least the frame is formed of an elastic, biocompatible material
30 capable of being straightened by a force and then returning to the relaxed curved configuration after the force is removed, thereby bending the catheter to substantially conform to the relaxed

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curved configuration. The term "distal" refers to the end that is farthest from a surgeon or other user during implantation, while "proximal" refers to the end that is closest to the user.

[00016] In a preferred embodiment, the elastic, biocompatible material is a nitinol alloy. In some embodiments, at least one of the coupling elements is a ring and, in other embodiments, at least one of the coupling elements is a C-type member. In certain embodiments, at least one of the coupling elements is formed as a continuation of the frame.

[00017] In some embodiments, there are at least first and second catheter curvature braces, with the curvature of the second brace being different from that of the first brace.

[00018] This invention may be expressed as a fluid management catheter assembly suitable for implantation into the ventricle of a brain of a patient, including a catheter with an elongated shaft having a distal end and a proximal end, the shaft defining at least one lumen extending substantially therethrough, the shaft further defining a plurality of fluid management openings along a distal portion of the shaft, with the fluid management openings being in fluid communication with the lumen. The assembly further includes a catheter curvature brace attached to the distal portion of the shaft, the brace having an elongated frame with a distal end and a proximal end, the frame being formed with at least one curve in a relaxed curved configuration, and at least two coupling elements connected to the frame, each coupling element configured to engage an outer surface of the catheter. At least the frame is formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the relaxed curved configuration after the force is removed, thereby bending the catheter to substantially conform to the relaxed curved configuration.

[00019] This invention may be still further expressed as a fluid management kit having a catheter as described above together with at least first and second catheter curvature braces. At least one curve of the second catheter brace differs from at least one curve of the first catheter brace.

[00020] This invention may also be expressed as a method for managing fluid within a patient, including selecting a catheter with an elongated shaft having a distal end and a proximal end. The shaft defines at least one lumen extending substantially therethrough. The shaft further defines a plurality of fluid management openings along a distal portion of the shaft, the fluid management openings being in fluid communication with the lumen. The method further includes selecting a catheter curvature brace attachable to the distal portion of the shaft, the brace

having an elongated frame with a distal end and a proximal end, the frame being formed with at least one curve in a desired relaxed curved configuration, at least two coupling elements connected to the frame, each coupling element configured to engage an outer surface of the catheter, and at least the frame being formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the desired relaxed curved configuration after the force is removed. The catheter brace is attached to the distal portion of the catheter to form a catheter assembly, a stylet is placed within the catheter lumen to apply the force to straighten the catheter assembly, and the catheter assembly is inserted within the patient at a targeted location, such as a ventricle of the brain of the patient. The stylet is then removed to allow the distal portion of the catheter to substantially conform to the desired relaxed curved configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

[00021] In what follows, preferred embodiments of the invention are explained in more detail with reference to the drawings, in which:

FIG. 1 is a schematic side view of a first catheter curvature brace according to the present invention;

FIG. 2 is a schematic side view of a second catheter curvature brace according to the present invention having a different curvature than the brace of FIG. 1;

FIG. 3 is a schematic side view of yet another catheter curvature brace according to the present invention having a complex curvature;

FIG. 4 is an enlarged view of the distal end of the brace of FIG. 3;

FIGS. 5 and 6 are schematic side views of the brace of FIG. 1 attached to a ventricular catheter to form a catheter assembly, with the assembly further including a stylet in FIG. 6 which forces the assembly to a straightened condition; and

FIG. 7 is an upper, partial cross-sectional view of a patient's head showing the ventricular catheter assembly of FIG. 5 after implantation within a ventricle of the brain.

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DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[00022] This invention may be accomplished by a catheter curvature brace that is attachable to a distal portion of a shaft of a catheter and has an elongated frame with a distal end and a proximal end. The frame is formed with at least one curve in a relaxed curved configuration. At least two coupling elements are connected to the frame, each coupling element configured to engage an outer surface of the catheter. At least the frame is formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the relaxed curved configuration after the force is removed, thereby bending the catheter to substantially conform to the relaxed curved configuration.

10 [00023] FIG. 1 shows a first curvature brace 10 having a frame 12 and ring-shaped coupling elements 14 and 16. Frame 12 has a proximal end 22, a distal end 24, and is formed in a first curve at an angle, represented by arrow 18 relative to longitudinal axis 20 of proximal end 22, of approximately twenty degrees in this construction. Similarly, FIG. 2 shows a second curvature brace 30 having a frame 32 and ring-shaped coupling elements 34 and 36. Frame 32 has a proximal end 42, a distal end 44, and is formed in a second curve at an angle, represented by arrow 38 relative to longitudinal axis 40 of proximal end 42, of approximately thirty degrees in this construction.

15 [00024] A third curvature brace 50 is shown in FIG. 3 having a frame 52 formed in a relaxed complex curvature having a plurality of curves 54 and 56. In some constructions, frame 52 has multiple curves along a single plane and, in other constructions, has multi-planar curves. A first, C-shaped coupling element 58, having curved legs 59 and 61, is connected to frame 52 at proximal end 60, a second, ring-shaped coupling element 62 is connected to frame 52 at distal end 64, and a third, C-shaped coupling element 66, having curved legs 68 and 70, is connected to frame 52 at an intermediate position 67.

20 [00025] In preferred constructions, at least frames 12, 32 and 52 are formed of a super-elastic material such as a nitinol alloy or super-elastic polymers. Various suitable super-elastic materials are described in US Patent No. 6,569,150 by Teague et al., for example. Known techniques can be utilized to impart desired curvatures, such as heating the elastic material to a sufficiently high temperature and then bending the material into the desired shapes.

25 [00026] One or more of the coupling elements 14, 16, 34, 36, 58, 62 and 66 are formed of the same material as the corresponding frames 12, 32 and 52 in some constructions and are

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formed of different materials in other constructions. When the coupling elements are ring-shaped, such as illustrated for coupling elements 14, 16, 34, 36 and 62, it is preferable to form them as a continuation of material forming corresponding frames 12, 32 and 52, respectively. One ring-shaped configuration is illustrated in FIG. 4 for coupling element 62, wherein nitinol wire forming frame 52 and coupling element 62 terminates in an end 63 that is not physically connected to distal end 64 of frame 52. Coupling element 62 may also be said to have an open-ring shape. Otherwise, open- or closed-ring-shaped material can be attached by brazing or other suitable biocompatible attachment technique. Similarly, legs 59, 61, 68 and 70 are attached as individual legs in some constructions and as paired, continuous legs in other constructions.

10 [00027] Catheter curvature brace 10, FIG. 1, is shown mated with a ventricular catheter 82 in FIGS. 5 and 6 to form a catheter assembly 80. Catheter 82 has at least one lumen 84 in which a stylet 86 is insertable as illustrated in FIG. 6 to force catheter assembly 80 to match the orientation of stylet 86, which is straight in this construction. A plurality of fluid management openings 90 are formed in a distal portion 92 which terminates in a distal tip 94. Suitable ventricular catheters and stylets are commercially available from Codman & Shurtleff of Raynham, Massachusetts, for example.

15 [00028] Catheter assembly 80 returns to the relaxed curved configuration shown in FIGS. 1 and 5 after force is discontinued, such as by removing stylet 86. In other words, distal portion 92 returns substantially to the angle represented by arrow 18, shown in FIG. 5 relative to the longitudinal axis 96 of catheter 82 and axis 98 of the center of distal tip 94. Brace 10 is typically placed on the "outside" of a desired curve, with coupling elements positioned along catheter 82 to minimize blockage of openings 90.

20 [00029] In one assembly technique, a surgeon or other healthcare professional selects an appropriate fluid management catheter and selects a curvature brace according to the present invention having a desired relaxed curved configuration for a particular fluid management procedure for a patient. In addition to having a desired curvature, the brace is also selected to have a plurality of coupling elements which are appropriately sized for the outer diameter of the selected catheter. The professional then forces the distal tip of the catheter through the coupling elements by squeezing or stretching the catheter. In one technique according to the present invention, a ventricular catheter is introduced through the coupling elements by pushing the catheter through the coupling elements utilizing a rigid stylet. A sleeve, pliers or other tool can

be utilized to assist in the assembly process. A spreading device may be utilized to temporarily widen an open-ring-shaped coupling element such as shown in FIG. 4 or a C-shaped coupling element as illustrated in FIG. 3.

[00030] FIG. 7 illustrates catheter assembly 80 after placement through burr hole BH and through tissue of brain B of a patient P. Distal portion 92 is shown positioned within a ventricle V. Brace 10 bends and holds distal portion 92 in a desired curved configuration after a stylet, endoscope or other delivery device, utilized in a conventional manner to place catheter assembly 80, has been removed from lumen 84. Proximal end 99 of catheter 82 typically remains outside of the skull of patient P to be connected to a pump or other fluid management device. Preferably, an orientation mark 104, such as a groove, contrasting color dot or stripe, and/or darker material, indicates the rotational position of brace 10 relative to mark 104.

[00031] Dashed circle 100, FIG. 7, represents a more forward location of a burr hole needed for conventional catheter placement along substantially straight trajectory 102 to achieve the alignment axis 98 of distal tip 94, such as illustrated in FIG. 5. However, such a conventional placement of a conventional catheter itself would not achieve a curved configuration as accomplished by the present invention to ideally match the curvature of the ventricle V, FIG. 7, and maintain fluid management openings 90 away from the choroid plexus CP lining portions of the ventricle.

[00032] Thus, while there have been shown, described, and pointed out fundamental novel features of the invention as applied to preferred embodiments thereof, it will be understood that various omissions, substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, it is expressly intended that all combinations of those elements and/or steps that perform substantially the same function, in substantially the same way, to achieve the same results be within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is also to be understood that the drawings are not necessarily drawn to scale, but that they are merely conceptual in nature. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

[00033] Every issued patent, pending patent application, publication, journal article, book or any other reference cited herein is each incorporated by reference in their entirety.

Reivindicaciones:

1. Un primer soporte de curvatura de catéter, que comprende:
una estructura alargada que tiene un extremo distal y un extremo proximal, la
5 estructura se forma con al menos una primera curva en una primera configuración
curvada relajada;
al menos dos elementos de acoplamiento se conectan a la estructura, cada
uno de los elementos de acoplamiento están configurados para unirse a una
superficie externa de un catéter y
10 al menos la estructura se forma de un material biocompatible elástico, capaz
de enderezarse mediante la aplicación de fuerza y, después, vuelve a la primera
configuración curvada, relajada, después de eliminar la fuerza.
2. El soporte de catéter de acuerdo con la reivindicación 1, en donde el material
biocompatible, elástico, es una aleación de nitinol.
- 15 3. El soporte de catéter de acuerdo con la reivindicación 1, en donde al menos
uno de los elementos de acoplamiento se forma prácticamente como un anillo
circular.
4. El soporte de catéter de acuerdo con la reivindicación 1, en donde al menos
uno de los elementos de acoplamiento se forma como un miembro del tipo C.
- 20 5. El soporte de catéter de acuerdo con la reivindicación 1, en donde al menos
uno de los elementos de acoplamiento se forma como una continuación de la
estructura.
6. El soporte de catéter de acuerdo con la reivindicación 1, que incluye,
además, al menos un segundo soporte de curvatura de catéter, prácticamente, el
25 mismo que el primer soporte de catéter excepto que el segundo soporte de
catéter tiene al menos una segunda curva en una segunda configuración curvada
relajada; la segunda curva es diferente que la primera curva.

7. Una unidad de catéter para la administración de fluidos adecuado para la implantación en un ventrículo en un cerebro de un paciente; la unidad comprende:

un catéter con un vástago alargado que tiene un extremo distal y un extremo proximal, el vástago define al menos un lumen que se extiende, prácticamente, a través de este, además, el vástago que define una pluralidad de aberturas para la administración de fluidos a lo largo de una porción distal del vástago, las aberturas para la administración de fluidos están en comunicación continua con el lumen y

un soporte de curvatura de catéter unido a la porción distal del vástago; el soporte tiene una estructura alargada con extremo distal y un extremo proximal, la estructura se forma con al menos una curva en una configuración curvada relajada y al menos dos elementos de acoplamiento conectados a la estructura, cada elemento de acoplamiento está configurado para unirse a una superficie externa del catéter; y

al menos la estructura se forma de un material biocompatible, elástico, capaz de enderezarse mediante la aplicación de una fuerza y, después, vuelve a la configuración curvada, relajada, después de eliminar la fuerza; de este modo, se dobla el catéter para ajustarlo, prácticamente, a la configuración curvada relajada.

8. El soporte de catéter de acuerdo con la reivindicación 7, en donde el material biocompatible, elástico, es una aleación de nitinol.

9. El soporte de catéter de acuerdo con la reivindicación 7, en donde al menos uno de los elementos de acoplamiento se forma, prácticamente, como un anillo circular.

10. El soporte de catéter de acuerdo con la reivindicación 7, en donde al menos uno de los elementos de acoplamiento se forma como una continuación de la estructura.

11. Un kit para administrar fluidos; el kit comprende:

un catéter con un vástago alargado que tiene un extremo distal y un extremo proximal, el vástago define al menos un lumen que se extiende, prácticamente, a

través de este; el vástago define, además, una pluralidad de aberturas para administración de fluidos a lo largo de una porción distal del vástago; las aberturas para administración de fluido están en comunicación continua con el lumen y

al menos el primer y el segundo soporte de curvatura de catéter unidos a la
5 porción distal del vástago; cada soporte tiene una estructura alargada con un extremo distal y un extremo proximal; la estructura se forma con al menos una curva en una configuración curvada relajada; al menos dos elementos de acoplamiento conectados a la estructura; cada elemento de acoplamiento está configurado para unirse a una superficie externa del catéter; y al menos la estructura se forma de un
10 material biocompatible, elástico, capaz de enderezarse mediante la aplicación de una fuerza y, después, vuelve a la configuración curvada relajada después de eliminar la fuerza; de este modo, se dobla el catéter para ajustarse, prácticamente, a la configuración curvada relajada; y

en donde al menos una curva del primer soporte de catéter es diferente de al
15 menos una curva del segundo soporte.

12. El soporte de catéter de acuerdo con la reivindicación 11, en donde el material biocompatible, elástico, es una aleación de nitinol.

13. El soporte de catéter de acuerdo con la reivindicación 11, en donde al menos uno de los elementos de acoplamiento se forma, prácticamente, como un anillo
20 circular.

14. Un método para administrar fluidos dentro de un paciente; el método comprende:

seleccionar un catéter con un vástago alargado que tiene un extremo distal y un extremo proximal, el vástago define al menos un lumen que se extiende,
25 prácticamente, a través de este; el vástago define, además, una pluralidad de aberturas para la administración de fluidos a lo largo de una porción distal del vástago; las aberturas para la administración de fluidos están en comunicación continua con el lumen

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seleccionar un soporte de curvatura de catéter que se une a la porción distal del vástago; el soporte tiene una estructura alargada con un extremo distal y un extremo proximal; la estructura se forma al menos con una curva en una configuración curvada relajada; al menos dos elementos de acoplamiento
5 conectados a la estructura; cada elemento de acoplamiento está configurado para unirse a una superficie externa del catéter; y al menos la estructura se forma de un material biocompatible, elástico, capaz de enderezarse por medio de la aplicación de una fuerza y, después, vuelve a la configuración curvada relajada deseada después de eliminar la fuerza

10 unir el soporte de catéter a la porción distal de catéter para formar una unidad de catéter y doblar la porción distal de catéter para ajustarse, prácticamente, a la configuración curvada relajada deseada;

colocar un estileto dentro del lumen de catéter para aplicar la fuerza para enderezar la unidad de catéter;

15 insertar la unidad de catéter dentro del paciente para implantar la porción distal en una ubicación objetivo; y

desplazar el estileto para permitir que la porción distal de catéter se ajuste, prácticamente, a la configuración curvada relajada deseada.

15. El método de acuerdo con la reivindicación 14, en donde el material
20 biocompatible, elástico, es una aleación de nitinol.

16. El método de acuerdo con la reivindicación 14, en donde al menos uno de los elementos de acoplamiento se forma, prácticamente, como un anillo circular.

17. El método de acuerdo con la reivindicación 14, en donde al menos uno de los elementos de acoplamiento se forma como una continuación de la estructura.

25 18. El método de acuerdo con la reivindicación 14, en donde el catéter se selecciona para que resulte adecuado para la implantación dentro del cerebro del paciente.

19. El método de acuerdo con la reivindicación 18, en donde la inserción del catéter dentro del paciente incluye colocar la porción distal dentro de un ventrículo del cerebro del paciente como la ubicación objetivo.

20. El método de acuerdo con la reivindicación 19, en donde seleccionar el
5 soporte de catéter incluye determinar una curvatura preferida para la porción distal de catéter después de la implantación y, después, elegir el soporte de catéter entre un pluralidad de soportes de catéter que tiene configuraciones curvadas relajadas diferentes.

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Claims

What is claimed is:

1. A first catheter curvature brace, comprising:
an elongated frame having a distal end and a proximal end, the frame being formed with at least a first curve in a first relaxed curved configuration;
at least two coupling elements connected to the frame, each coupling element configured to engage an outer surface of a catheter; and
at least the frame being formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the first relaxed curved configuration after the force is removed.
2. The catheter brace of claim 1 wherein the elastic, biocompatible material is a nitinol alloy.
3. The catheter brace of claim 1 wherein at least one of the coupling elements is formed as a substantially circular ring.
4. The catheter brace of claim 1 wherein at least one of the coupling elements is formed as a C-type member.
5. The catheter brace of claim 1 wherein at least one of the coupling elements is formed as a continuation of the frame.
6. The catheter brace of claim 1 further including at least a second catheter curvature brace substantially the same as the first catheter brace except that the second catheter brace has at least a second curve in a second relaxed curved configuration, the second curve being different than the first curve.
7. A fluid management catheter assembly suitable for implantation into a ventricle in a brain of a patient, comprising:
a catheter with an elongated shaft having a distal end and a proximal end, the shaft defining at least one lumen extending substantially therethrough, the shaft further defining a plurality of fluid management openings along a distal portion of the shaft, the fluid management openings being in fluid communication with the lumen; and
a catheter curvature brace attached to the distal portion of the shaft, the brace having an elongated frame with a distal end and a proximal end, the frame being formed with at least one

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curve in a relaxed curved configuration, and at least two coupling elements connected to the frame, each coupling element configured to engage an outer surface of the catheter; and

at least the frame being formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the relaxed curved configuration after the force is removed, thereby bending the catheter to substantially conform to the relaxed curved configuration.

8. The catheter brace of claim 7 wherein the elastic, biocompatible material is a nitinol alloy.

9. The catheter brace of claim 7 wherein at least one of the coupling elements is formed as a substantially circular ring.

10. The catheter brace of claim 7 wherein at least one of the coupling elements is formed as a continuation of the frame.

11. A fluid management kit, comprising:

a catheter with an elongated shaft having a distal end and a proximal end, the shaft defining at least one lumen extending substantially therethrough, the shaft further defining a plurality of fluid management openings along a distal portion of the shaft, the fluid management openings being in fluid communication with the lumen; and

at least first and second catheter curvature braces attachable to the distal portion of the shaft, each brace having an elongated frame with a distal end and a proximal end, the frame being formed with at least one curve in a relaxed curved configuration, at least two coupling elements connected to the frame, each coupling element configured to engage an outer surface of the catheter, and at least the frame being formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the relaxed curved configuration after the force is removed, thereby bending the catheter to substantially conform to the relaxed curved configuration; and

wherein the at least one curve of the first catheter brace is different from the at least one curve of the second brace.

12. The catheter brace of claim 11 wherein the elastic, biocompatible material is a nitinol alloy.

13. The catheter brace of claim 11 wherein at least one of the coupling elements is formed as a substantially circular ring.

14. A method for managing fluid within a patient, comprising:

selecting a catheter with an elongated shaft having a distal end and a proximal end, the shaft defining at least one lumen extending substantially therethrough, the shaft further defining a plurality of fluid management openings along a distal portion of the shaft, the fluid management openings being in fluid communication with the lumen;

selecting a catheter curvature brace attachable to the distal portion of the shaft, the brace having an elongated frame with a distal end and a proximal end, the frame being formed with at least one curve in a desired relaxed curved configuration, at least two coupling elements connected to the frame, each coupling element configured to engage an outer surface of the catheter, and at least the frame being formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the desired relaxed curved configuration after the force is removed;

attaching the catheter brace to the distal portion of the catheter to form a catheter assembly and bend the distal portion of the catheter to substantially conform to the desired relaxed curved configuration;

placing a stylet within the catheter lumen to apply the force to straighten the catheter assembly;

inserting the catheter assembly within the patient to implant the distal portion in a targeted location; and

removing the stylet to allow the distal portion of the catheter to substantially conform to the desired relaxed curved configuration.

15. The method of claim 14 wherein the elastic, biocompatible material is a nitinol alloy.

16. The method of claim 14 wherein at least one of the coupling elements is formed as a substantially circular ring.

17. The method of claim 14 wherein at least one of the coupling elements is formed as a continuation of the frame.

18. The method of claim 14 wherein the catheter is selected to be suitable for implantation within the brain of the patient.

19. The method of claim 18 wherein inserting the catheter within the patient includes positioning the distal portion within a ventricle of the brain of the patient as the targeted location.

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20. The method of claim 19 wherein selecting the catheter brace includes determining a preferred curvature for the distal portion of the catheter after implantation and then choosing the catheter brace from among a plurality of catheter braces having different relaxed curved configurations.

Abstract

A catheter curvature brace, catheter assembly and method for managing fluid in a patient, the brace being attachable to a distal portion of a shaft of a catheter and having an elongated frame with a distal end and a proximal end. The frame is formed with at least one curve in a relaxed curved configuration. At least two coupling elements are connected to the frame, each coupling element configured to engage an outer surface of the catheter. At least the frame is formed of an elastic, biocompatible material capable of being straightened by a force and then returning to the relaxed curved configuration after the force is removed, thereby bending the catheter to substantially conform to the relaxed curved configuration.



FIG. 1

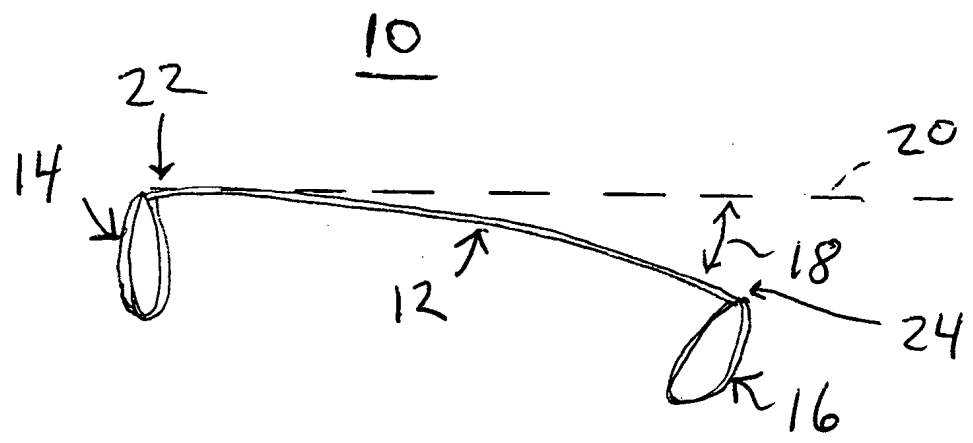


FIG. 2

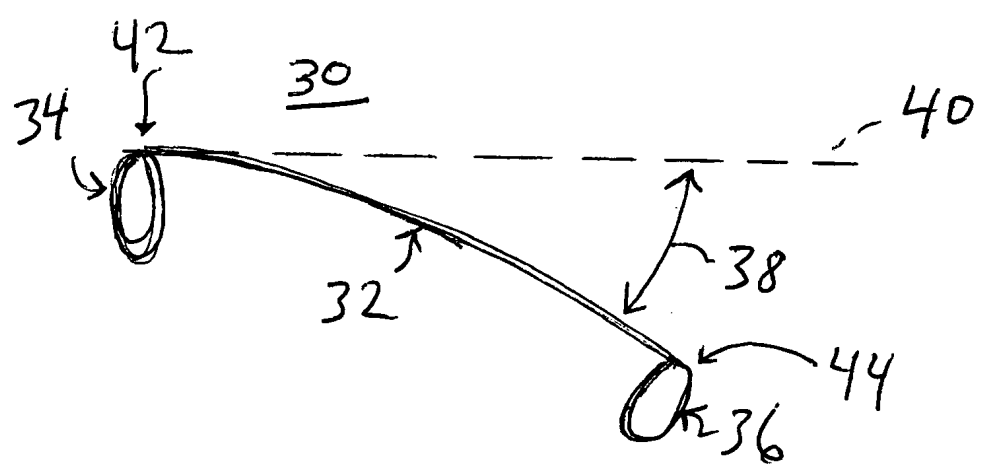
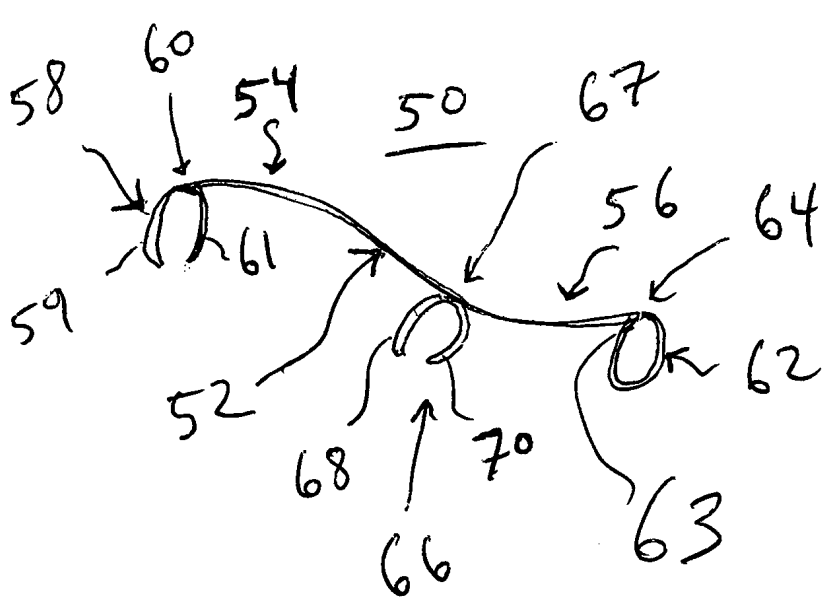
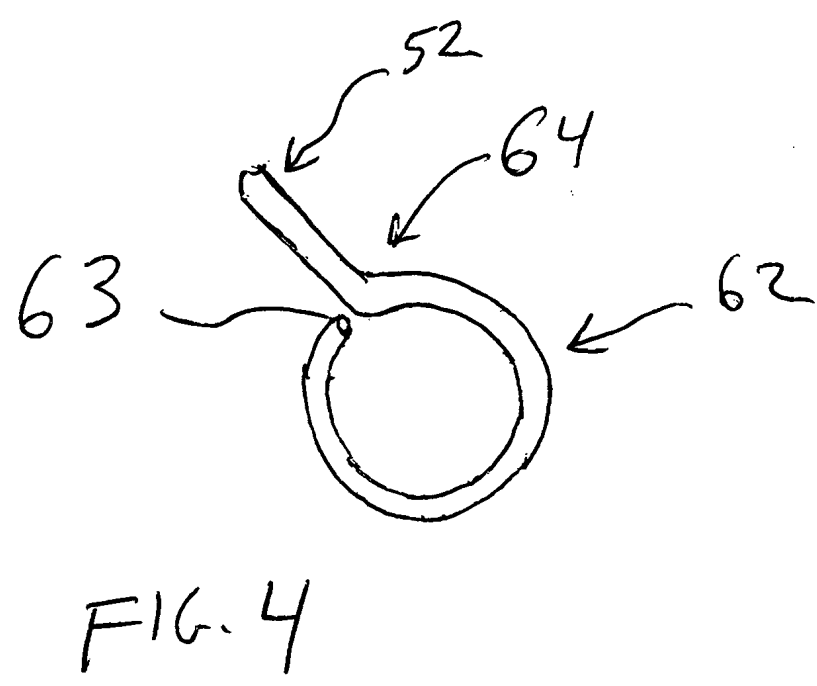
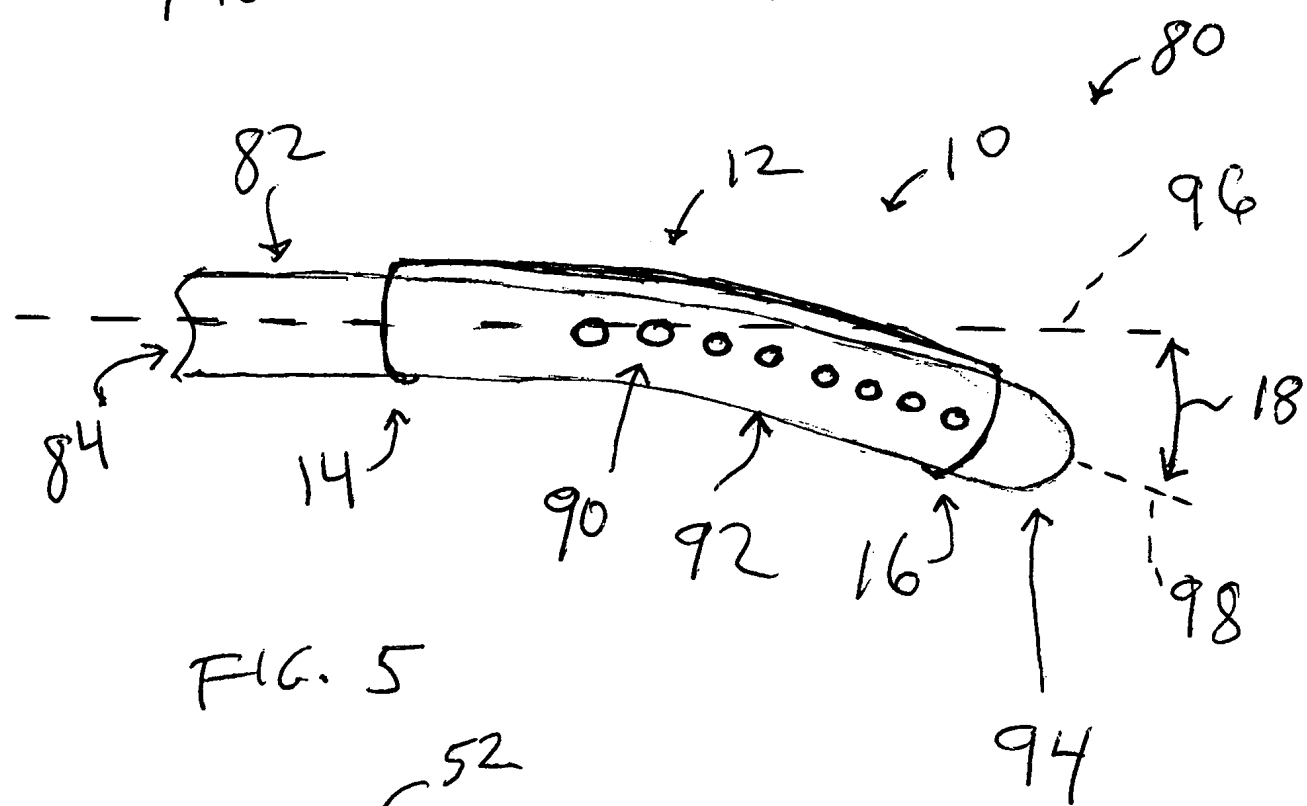
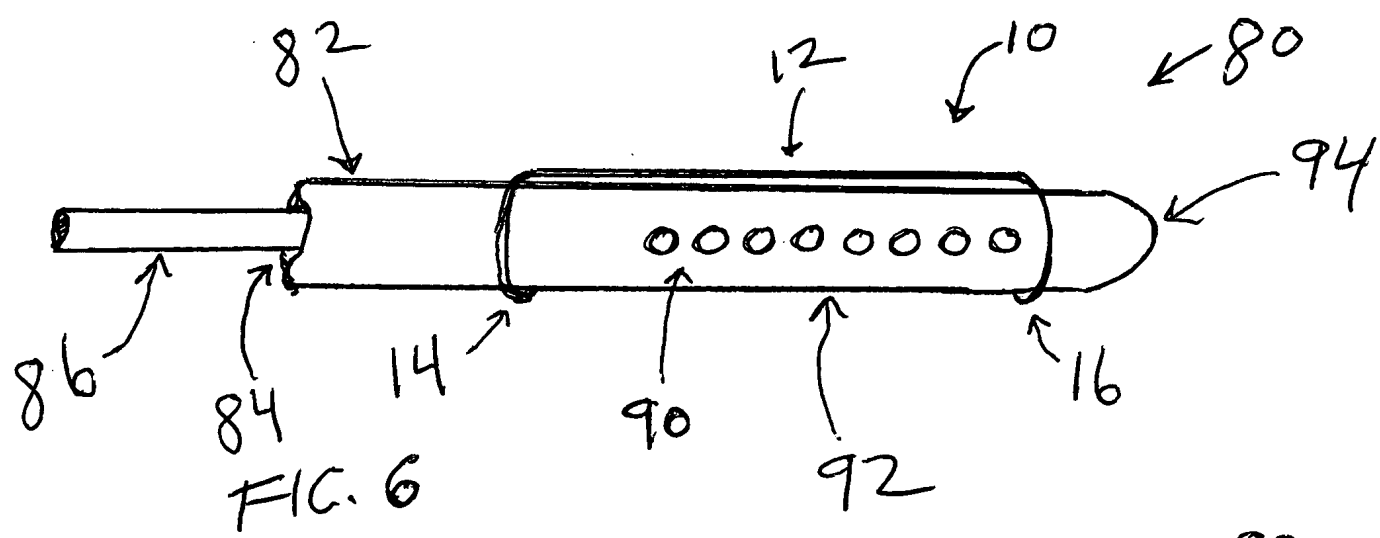


FIG. 3



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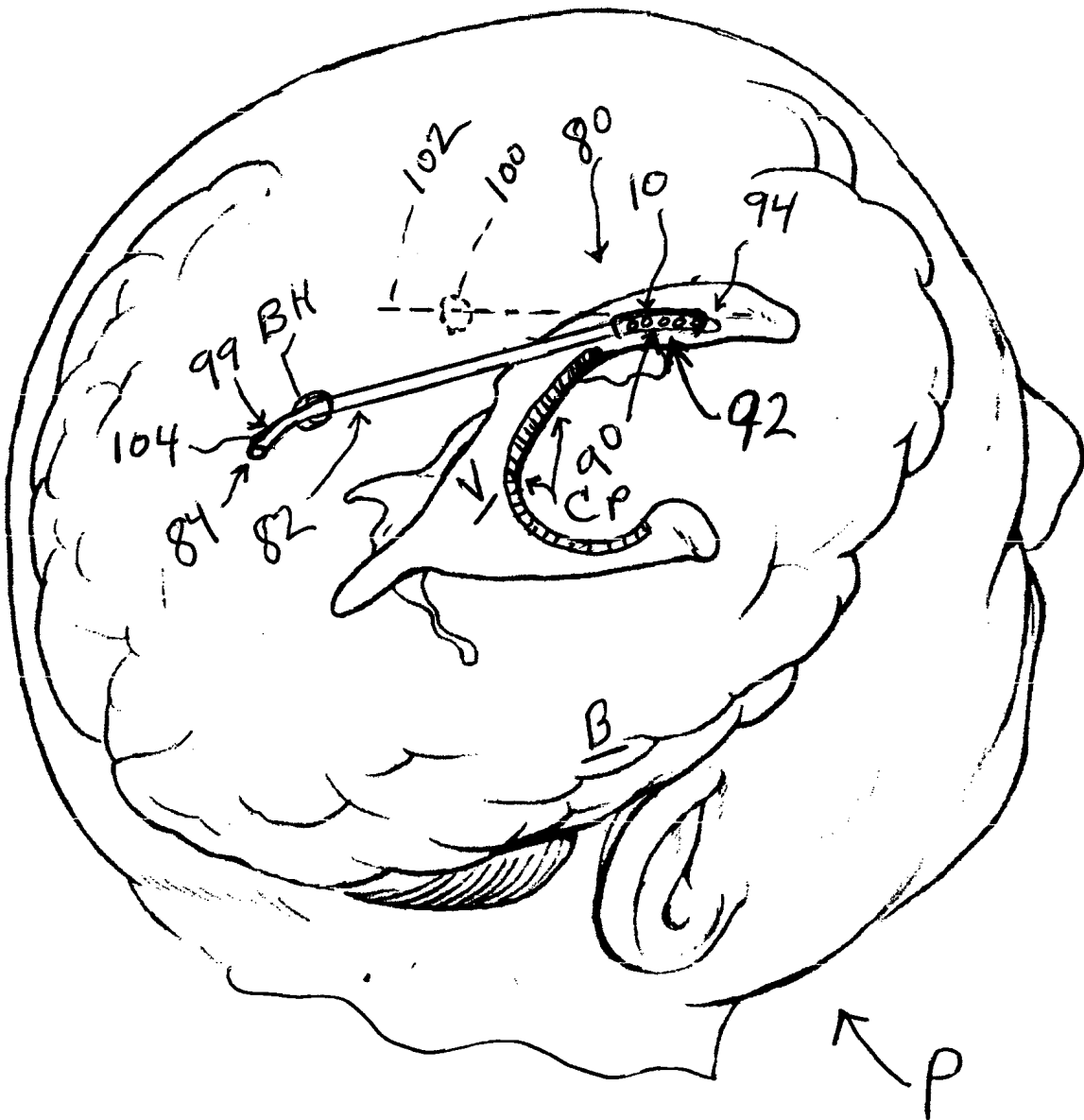


FIG. 7

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	COD5293USNP
		Application Number	
Title of Invention	CATHETER CURVATURE BRACES AND METHODS OF USING SAME		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

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Address 1		c/o CODMAN & SHURTLEFF, INC.			
Address 2		325 PARAMOUNT DRIVE			
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Title of the Invention	CATHETER CURVATURE BRACES AND METHODS OF USING SAME		
Attorney Docket Number	COD5293USNP	Small Entity Status Claimed ☐	
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	3	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	COD5293USNP
		Application Number	
Title of Invention	CATHETER CURVATURE BRACES AND METHODS OF USING SAME		

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Prior Application Status		Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	COD5293USNP
		Application Number	
Title of Invention	CATHETER CURVATURE BRACES AND METHODS OF USING SAME		

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Phone Number		Fax Number	
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Signature	/Eugene L. Szczecina, Jr./			Date (YYYY-MM-DD)	2012-05-23
First Name	Eugene L.	Last Name	Szczecina, Jr.	Registration Number	35029

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