Industria y Comercio

SUPERINTENDENCIA

301

Delegatura de Propiedad Industrial

División de Nuevas Creaciones

PCT

SOLICITUD

PATENTE DE INVENCION

21 **EXPEDIENTE No.** 05-102634

54 **TITULO** MONTAJE SEGURO DE AGUJA Y CATETER

51 **CLASIFICACION INTERNACIONAL**

71 **SOLICITANTE** MEDEX, INC.

DOMICILIO Carlsbad, Estado de California, Estados Unidos de América.

74 **APODERADO** EMILIO FERRERO

C.C. 438.019 de Usaquén.

22 **BOGOTA, D.C.,**

(FORMA P 10)

Industria y Comercio
SUPERINTENDENCIA

PETITORIO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Radicación 05120254 07/10/2005 Folios 66
Fecha (AMD) 2005-10-07 17:28:58
Tramite 001 PCT-PATENT 178 FASE NACI 411 PATENTE PC
Dependencia: 0000 DIVISION DE NUEVAS SOLICITUDES

FORMULARIO UNICO DE SOLICITUD DE PATENTE
PCT
ENTRADA EN FASE NACIONAL

SOLICITUD DE

1. ☒ Patente de Invención ☐ Patente de Modelo de Utilidad
   ☒ Capítulo I ☐ Capítulo II

2 **SOLICITANTE (71)**	Nombre **MEDEX, INC** sociedad constituida y existente bajo las leyes del Estado de Ohio, Estados Unidos de América Dirección 2231 Rutherford Road, Carlsbad, California 92008 Estados Unidos de América Domicilio Carlsbad California Estados Unidos de América	**IDENTIFICACIÓN** C C ☐ NIT ☐ C E ☐ Otro ☐ Cual ____ Numero ____
3 **REPRESENTANTE O APODERADO**	Nombre EMILIO FERRERO Dirección Carrera 4ª No 72-35 Teléfono 347 36 11 Fax 211 86 50 E-mail clientes@camyp.com. Domicilio Bogotá Colombia	**IDENTIFICACIÓN** C C ☒ NIT ☐ C E ☐ Otro ☐ Cual ____ Número 438 019 T P 31 929
4 **INVENTOR (ES) (72)**	**Joseph P McGURK** 5806 West Fountain Circle, Mason Ohio 45040 Estados Unidos de América	

5. **PCT (86)**
   Solicitud Internacional No PCT/US2004/006017 Fecha 27 de febrero de 2004
   Publicación Internacional No WO 2004/093961 A1 Fecha 4 de noviembre de 2004

6. **Título (54)**
   MONTAJE SEGURO DE AGUJA Y CATETER

7. **Clasificación Internacional (51)** A61M 25/00

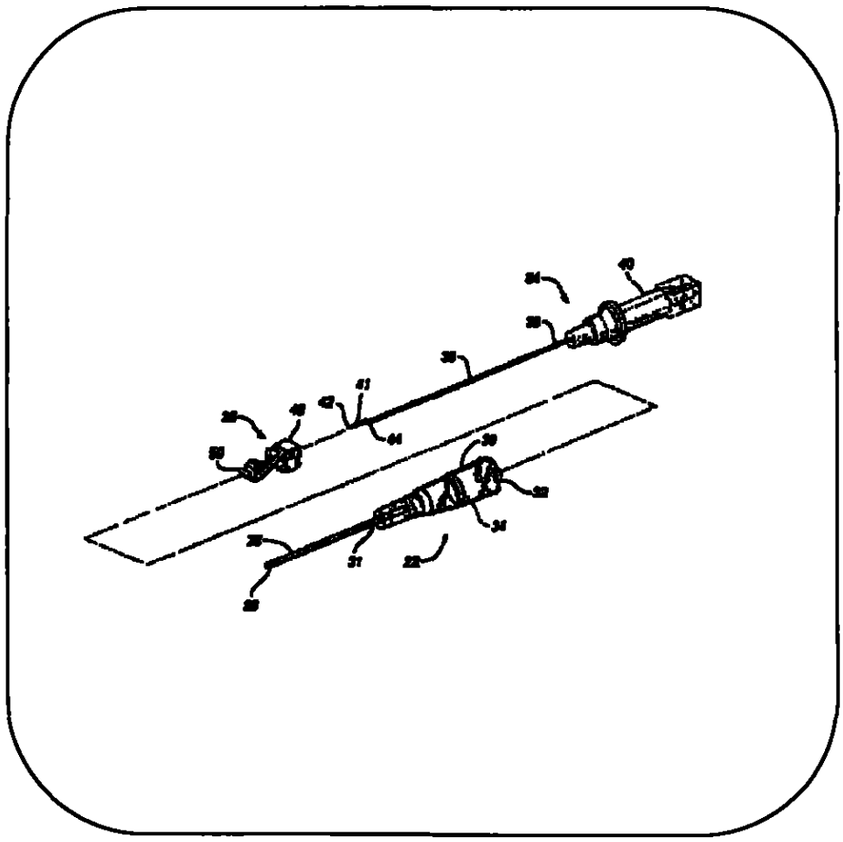
8 **Prioridad** SI☒ NO☐	(33) País de Origen	(32) Fecha	(31) Numero de Solicitud
	US	8 de abril de 2003	60/461,172

9. **Comprobante de pago No** 05-75,986 **Fecha** OCTUBRE 3 DE 2005

10 Anexos

- [x] Comprobante de pago de la tasa de presentación de la solicitud por $ 443 000 oo
- [ ] Comprobante de pago por reivindicación de prioridad
- [ ] Documento que acredita la existencia y representación legal cuando el solicitante sea persona jurídica
- [ ] Poderes, si fuere el caso
- [ ] Documento de cesión del inventor al solicitante o a su causante
- [ ] Declaraciones
- [x] Copia de la solicitud internacional (Resumen, descripción, reivindicaciones, dibujos)
- [x] Traducción de la solicitud internacional al castellano (Resumen, descripción, reivindicaciones, dibujos)
- [ ] Copia del examen preliminar efectuado por la IPEA
- [ ] Traducción del examen preliminar 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
- [x] 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
- [x] Otros VER HOJA DE DOCUMENTOS ANEXOS

11 FIGURA CARACTERÍSTICA



12

Solicito la concesión de la patente,

NOMBRE EMILIO FERRERO

FIRMA _____

C C 438 019 de Usaquén T P 31 929

JDF

DOCUMENTOS ANEXOS

1 ☒ Publicación Internacional WO 2004/093961 **A1**

Descripción

Páginas 10 en el idioma original

Páginas 14 en español

Reivindicaciones Número (s) 13

Figuras Número (s) 8

2 ☒ **Forma PCT/RO/101** PCT Request

3 ☐ **Forma PCT/RO/106** Invitation to Correct Defects

4 ☒ **Forma PCT/ISA/210** Informe de Busqueda Internacional

5 ☒ **Forma PCT/ISA/220** Notificación De La Transmisión Del Informe De Búsqueda Internacional Y De La Opinión Escrita De La Administración Encargada De La Búsqueda Internacional, O De La Declaración

6 ☒ **Forma PCT/ISA/237** Opinión Escrita De La Administración Encargada De La Búsqueda Internacional

7 ☐ **Forma PCT/IB/304.** Notification Concerning Submission Or Transmittal Of Priority Document

8 ☐ **Forma PCT/IB/306** Notification Of The Recoding Of A Change

Descripción De Modificación

———

9 ☐ **Forma PCT/IB/308** Notice Informing The Applicant Of The Communication Of The International Application To The Designated Offices

10 ☐ **Forma PCT/IB/332** Information Concerning Elected Offices Notified Of Their Election

11 ☐ **FORMA PCT/IB/345** Communication in cases for which no other form is applicable

———

12 ☐ **Forma PCT/IPEA/401** PCT Demand

13 ☐ **Forma PCT/IPEA/402** Notification Of Receipt Of Demand By Competent International Preliminary Examining Authority

14 ☐ **Forma PCT/IPEA/408** Written Opinion

15 ☐ **Forma PCT/IPEA/416** Notification Of Transmittal Of The International Preliminary Examination Report

16 ☐ **Forma PCT/IPEA/409** Informe Del Examen Preliminar Internacional

17 ☐ Traducción Al Español Del Informe Del Examen Preliminar Internacional

18 ☐ Traducción Al Español De Los Anexos Presentados Junto Con El Informe Del Examen Preliminar Internacional

19 ☒ Extracto de publicación

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 November 2004 (04.11 2004)

PCT

(10) International Publication Number
WO 2004/093961 A1

(51) International Patent Classification[7] A61M 25/00, 25/06 5/162, 5/00

(21) International Application Number: PCT/US2004/006017

(22) International Filing Date 27 February 2004 (27.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data
60/461 172 8 April 2003 (08 04.2003) US

(71) Applicant *(for all designated States except US)*: MEDEX, INC. [US/US] 2231 Rutherford Road Carlsbad CA 92008 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)* McGURK, Joseph, P [US/US], 5806 West Fountain Circle Mason, OH 45040 (US).

(74) Agents GROSSMAN, Kurt, L. et al Wood, Herron & Evans L.L.P., 2700 Carew Tower Cincinnati OH 45202 (US).

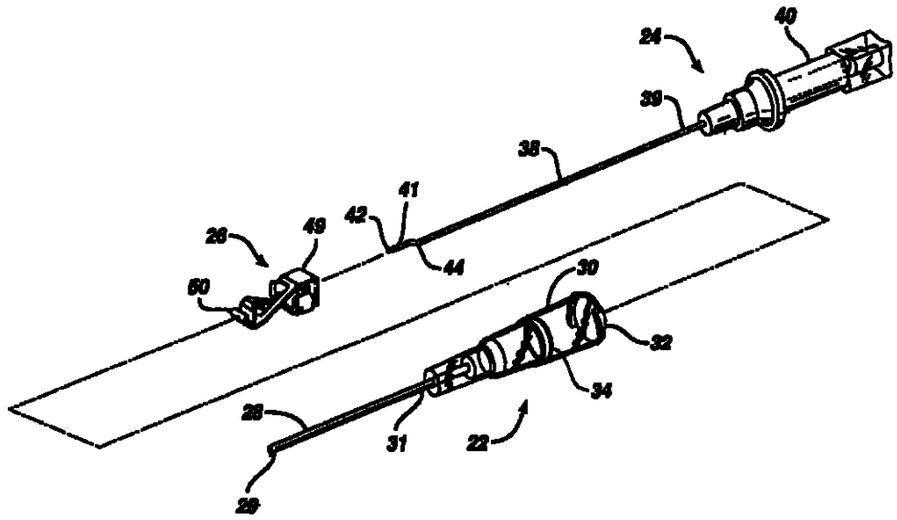
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)* AE, AG, AL, AM AT AU, AZ, BA, BB BG BR, BW BY BZ, CA CH CN CO CR, CU, CZ, DE, DK, DM, DZ, EC EE, EG ES FI GB GD, GE, GH GM HR, HU ID IL, IN IS JP KE, KG KP KR KZ, LC, LK, LR, LS, LT LU LV MA MD MG MK, MN, MW MX MZ, NA, NI, NO NZ, OM PG PH PL, PT RO, RU, SC, SD SE, SG SK, SL, SY TJ TM TN TR, TT TZ, UA, UG US, UZ, VC, VN YU ZA ZM ZW

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)* ARIPO (BW GH GM KE, LS, MW MZ, SD SL, SZ, TZ, UG ZM, ZW) Eurasian (AM AZ, BY KG KZ, MD RU TJ TM), European (AT, BE, BG CH, CY CZ, DE, DK, EE, ES FI FR GB GR, HU, IE, IT LU MC, NL, PT RO SE, SI SK, TR), OAPI (BF BJ CF CG CI, CM GA GN GQ, GW ML, MR, NE, SN TD TG)

Published.
— *with international search report*

[Continued on next page]

(54) Title SAFETY NEEDLE AND CATHETER ASSEMBLY



(57) Abstract A catheter and introducer needle assembly having an introducer needle (38) with proximal and distal ends (39 41) attached to a needle hub (40) and a bent area (44) therebetween The device further includes a tubular catheter (28) having proximal and distal ends (31 29) in which the introducer needle (38) can be coaxially received within the catheter (28) The device has a hollow catheter hub (30) having a distal end attached to the proximal end of the catheter and is in fluid communication therewith. The assembly includes a needle tip protector (26) having a proximal end (49) and a distal end (50) disposed within the catheter hub (30) The distal end of the protector covers the needle tip when the needle is removed from the catheter The protector has a proximal opening (72) at its proximal end wherein the bent area (44) is angled away from the proximal opening such that when the needle is removed from the catheter the protector remains attached to the needle

WO 2004/093961 A1

SAFETY NEEDLE AND CATHETER ASSEMBLY

Field of the Invention

The present invention relates, in general, to intravenous (IV) catheters and, more particularly, to a safety IV catheter with a needle tip protector that will automatically cover the needle tip upon needle withdrawal

Background of the Invention

An intravenous (IV) catheter is an instrument that is used to introduce certain fluids such as saline solution directly into the bloodstream of a patient Typically, a needle or other stylet is first introduced through the cannula portion of the catheter and into the skin of the patient at the desired location such as the back of the patient's hand or a vessel on the inside of the arm Once insertion is complete, the needle is removed from the cannula portion of the catheter After removing the needle, a fluid handling device such as a syringe is attached to the luer fitting located at the proximal end of the catheter hub Fluid then flows directly from the fluid handling device through the catheter into the bloodstream of the patient.

When the needle is removed from the cannula, the health care worker must place the exposed needle tip at a nearby location while simultaneously addressing the task required to accomplish the needle removal It is at this juncture that the exposed needle tip creates a danger of an accidental needle stick occurring which leaves the health care worker vulnerable to the transmission of various, dangerous blood-borne pathogens such as human immune virus (HIV) and hepatitis

The risk of a contaminated needle stick is not just isolated to the health care worker inserting the intravenous catheter Careless disposal of used needles can put other health care workers at risk as well Even others outside the health care profession, for example those involved in the clean-up and final disposal of medical waste, are at risk of an accidental needle stick from a carelessly discarded needle

The danger to health care workers and others outside the health care profession from accidental needle sticks has yielded the development of catheters with safety mechanisms in which the occurrence of such accidental needle sticks is prevented An example of a catheter having a safety mechanism is disclosed in US Patent No Re 34,416 issued to Lemieux A safety catheter is described which includes an element that covers the needle tip upon removal of the needle from the catheter The safety element includes a split flange at its proximal end which is expanded by the needle as the needle is inserted into an undersized hole at the center of this flange. The safety element is thus held secure within the catheter hub by inserting the needle through the undersized hole which forces the outside perimeter of the split flange against the inside wall of the catheter hub One of the drawbacks to this design is the amount of friction force exerted against the needle by the split flange. A tight fit of the flange against the catheter wall causes great friction against the needle making it difficult to be withdrawn from the catheter by the clinician. A lose fit leaves the flange prone to releasing prematurely from the catheter as the needle is withdrawn, creating the potential that the needle tip will be left exposed

Another example of a catheter having a safety mechanism is disclosed in US Patent No 6,117,108 issued to Woehr et al A safety IV catheter is described including a resilient needle guard which protects the needle tip upon removal of the needle from the catheter hub The needle guard includes an arm that includes an opening through which a needle passes causing axial movement of the arm. This axial movement forces the arm into a groove or behind a rib located on the inside of the catheter hub, capturing the needle guard in the catheter hub A potential issue with this design develops when the needle guard is not properly seated into the catheter hub If the distal end of the needle guard arm is not in alignment with the groove in the catheter hub, excessive forces are placed on the needle causing a high drag force as the clinician removes the needle And, since the needle guard arm is not properly seated in the groove, it may prematurely release from the catheter hub upon the removal of the needle leaving the needle tip exposed

The prior art safety catheters all exhibit one or more drawbacks that have thus far limited their usefulness and full acceptance by health-care workers What is

needed therefore is a safety IV catheter that functions reliably, is easy and inexpensive to manufacture, and easy to use

Summary of the Invention

In accordance with the present invention there is provided a catheter introducer assembly The catheter introducer assembly comprises a needle assembly having a needle attached to a needle hub and a distal end extending therefrom The needle includes a bent area disposed between its proximal and distal ends The catheter introducer assembly further includes a catheter assembly having a tubular catheter with a proximal end attached to a catheter hub The needle is coaxially received within the catheter The catheter introducer assembly further includes a needle tip protector disposed within the catheter hub The needle tip protector is slidably disposed onto the needle, whereby when the needle is proximally removed from the catheter the protector remains attached to the needle.

Brief Description of the Drawings

The novel features of the invention are set forth with particularity in the appended claims The invention itself, however, both as to organization and methods of operation, together with further objects and advantages thereof, may best be understood by reference to the following description, taken in conjunction with the accompanying drawings in which

Figure 1 is a perspective view of the catheter and needle assembly of the present invention,

Figure 2 is an exploded perspective view of the catheter assembly and needle assembly including the needle tip protector of the present invention,

Figure 3 is a perspective view of the needle tip protector of the present invention,

Figure 4 is an elevation view of Figure 3 taken along line 4 – 4 illustrating the hole positions in the rear flanges of the needle tip protector as manufactured,

Figure 5 is a section view of the catheter assembly and needle assembly taken along line 5 – 5 of Figure 1,

Figure 6 is an enlarged partial section view of Figure 5 illustrating the relative position of the needle tip protector tab and catheter hub rib,

Figure 7 is a section view of the catheter hub with needle tip protector installed taken along line 7 – 7 of Figure 5,

Figure 8 is a perspective view of the needle tip protector shown as installed in the catheter hub with the needle inserted therethrough,

Figure 9 is a perspective view of the needle tip protector shown as removed from the catheter hub and illustrating the needle tip covered by the protector;

Figure 10 is a perspective view of an alternate embodiment of the needle tip protector of the present invention

Detailed Description of the Invention

As used herein, the term "proximal" refers to a location on the catheter and needle assembly with needle tip protector closest to the clinician using the device and thus furthest from the patient on which the device is used Conversely, the term "distal" refers to a location farthest from the clinician and closest to the patient

As illustrated in Figures 1 and 2, IV catheter assembly 20 comprises catheter assembly 22 and needle assembly 24 Needle assembly 24 further includes needle tip protector 26 Catheter assembly 22 includes catheter 28 which is a tubular structure having a proximal end 31 and distal end 29 Proximal end 31 of catheter 28 is fixedly attached to catheter hub 30 Catheters are well known in the medical art and

one of many suitable materials, most of which are flexible thermoplastics, may be selected for use in catheter 28 Such materials may include, for example, polyurethane or fluorinated ethylene propylene Catheter hub 30 is a generally tubular structure having an internal cavity in fluid communication with the internal lumen of catheter 28 Catheter hub 30 may be made from a suitable, rigid medical grade thermoplastic such as, for example, polypropylene or polycarbonate For illustration purposes catheter hub 30 is shown translucent, though in actual use it may be translucent or opaque. At the proximal end of catheter hub 30 is integrally attached Luer fitting 32, commonly known in the medical art. Luer fitting 32 provides for secure, leakproof attachment of tubing, syringes, or any of many other medical devices used to infuse or withdraw fluids through the catheter assembly As is more clearly illustrated in Figures 5 and 6, rib 34 is a raised annular ring integral to and extending from internal sidewall 36 of catheter hub 30 Rib 34 is located approximately mid way between the proximal end and distal end of sidewall 36 Rib 34 plays an important role in securing needle tip protector 26 in catheter hub 30, as will be described in more detail later

Referring again to Figures 1 and 2, needle assembly 24 comprises needle 38, which is a tubular structure with a proximal end 39 and distal end 41, needle hub 40, and needle tip protector 26 Needle tip protector 26 is assembled slidably on needle 38 Needle 38 is preferably made of stainless steel Proximal end 39 of needle 38 is fixedly attached to needle hub 40 A bevel 42 is located at the most distal end of needle 38 creating a sharp piercing tip Needle bend 44 is located at the distal end of needle 38 proximal to bevel 42 and is curve in needle 38 Needle bend 44 can be created by bending method such as "rotary draw bending." Rotary draw bending is a process well known in the metal bending art and involves using a clamp die and a bend die, which are molded to match the nominal diameter of needle 38, to rotate needle 38 against a pressure die A mandrel is inserted into needle 38 during the procedure to minimize the stretching that occurs along the outer radius of needle 38, while a wiper die reduces wrinkling along the inner radius of needle 38 Bend 44 is formed at an angle away from second flange hole 72 in needle tip protector 26 and is important in preventing the complete removal of needle tip protector 26 from needle

38, as will be described in more detail later In the preferred embodiment the angle of bend 44 is 45 to 90 degrees away from second flange hole 72

Needle hub 40 is generally a tubular structure having an internal cavity in fluid communication with the lumen in needle 38 It is preferably made of a translucent or transparent generally rigid thermoplastic material such as, for example, polycarbonate At the most proximal end of the internal cavity in needle hub 40 is fixedly attached porous plug 46 A flashback chamber 48 is created in the cavity distal to porous plug 46 Porous plug 46 contains a plurality of microscopic openings which are large enough to permit the passage of air and other gasses but small enough to prevent the passage of blood Flashback chamber 48 fills with blood upon successful entry of the needle tip into the targeted vein, providing the clinician visual conformation of the correct placement of the needle

Referring now to Figures 3 and 4, needle tip protector 26 has a proximal end 49 and distal end 50 and is preferably a unitary structure formed from a single piece of thin, resilient material, preferably stainless steel First flange 66 and second flange 68 are generally square and are integrally connected at right angles to first outer wall 74 and second outer wall 76, respectively First outer wall 74 is connected at a right angle to first tab flange 78 First tab flange 78 and second tab flange 80 are each formed at angles slightly greater than 90 degrees to second outer wall 76 so that the resulting dimension c is slightly larger than inside diameter d (see Figures 5 - 7) across rib 34 in catheter hub 30 In the preferred embodiment angles a and b are each approximately 94 25 degrees In the preferred embodiment dimension c is approximately 005 - 009 inches larger than dimension d First flange hole 70 is located in the center of first flange 66 and is over-sized to slidably receive needle 38 Second flange hole 72 and skirt 82 are located in the center of second flange 68 Skirt 82 is integral to second flange hole 72 and is formed by extruding material from second flange hole 72 in a direction distal to second flange 68 This permits for a very close but slidably fit over the nominal diameter of needle 38 Skirt 82 also functions to help maintain alignment of needle 38 to the center axis of needle tip protector 26 As would be understood by one skilled in the art, flange hole 72 would be appropriately sized to the particular needle "gauge" size to which it is designed to

receive. First tab 86 and second tab 88 are connected at right angles to first tab flange 78 and second tab flange 80, respectively, and protrude outward away from the center axis of needle tip protector 26 First tab edge 90, located on the outer portion of first tab 86, and second tab edge 92, located on the outer portion of second tab 88, are each arcuate to approximately match the curve of sidewall 36 in catheter hub 30

Referring again to Figure 3, first beam 96 extends distally from first outer wall 74 and is angled toward and extends past the center axis of needle tip protector 26 At the distal end of first beam 96 is integrally formed curved first lip 98 which extends across and through the center axis of needle tip protector 26 Second beam 100 extends distally from second outer wall 76 and is angled toward and extends past the center axis of needle tip protector 26 At the distal end of second beam 100 is stop flange 102 which extends across and normal to the center axis of needle tip protector 26 At the end of stop flange 102 opposite its connection to second beam 100 is integrally formed curved second lip 104

Referring now to Figures 5-9, needle tip protector 26 is assembled to needle 38 as follows,

The proximal end of needle 38 is fixedly attached to the distal end of needle hub 40, which contains porous plug 46 fixedly attached to its proximal end,

The distal end of needle 38 is inserted through first flange hole 70 and then through second flange hole 72 in needle tip protector 26, moving from proximal to distal,

First beam 96 and second beam 100 are flexed, as a result of their resilient properties, normal to the center axis of needle tip protector 26 so that needle 38 will pass between first lip 98 and second lip 104 (see Figure 8),

Needle bend 44 is added to the distal end of needle 38 just proximal to bevel 42 Bend 44 is angled away from second flange hole 72 locally (see Figure 9) thus

preventing the complete removal of needle tip protector 26 from the distal end of needle 38

Now needle assembly 24, including needle tip protector 26, is assembled into catheter assembly 22 as follows,

The distal end of needle 38 is positioned into the proximal end of catheter hub 30 and needle assembly 24 is moved distally causing needle 38 to enter catheter 28,

As needle assembly 24 continues to move distally, needle tip protector 26 enters the opening in the proximal end of catheter hub 30,

Continued distal movement of needle assembly 24 causes the distal edge of needle hub 40 to push first tab 86 and second tab 88 on needle tip protector 26 into contact with rib 34 located on hub sidewall 36,

Continued distal movement forces first tab 86 and second tab 88, due to the resilient properties of needle tip protector 26, past rib 34 and in contact with sidewall 36, just distal to rib 34

Needle tip protector 26 is thus held distal to rib 34 inside the cavity in catheter hub 30 by the flexural forces of first tab 86 and second tab 88 since dimension c on needle tip protector 26 is larger than dimension d across rib 34 inside catheter hub 30 (see Figure 6)

As is best illustrated in Figure 7, the movement of first tab 86 and second tab 88 as needle tip protector 26 is finally seated distal to rib 34 causes flexure in second outer wall 76 and first tab flange 78 resulting in the approximate alignment of first flange hole 70 and second flange hole 72

Now, in actual clinical use, the IV catheter assembly 20 of the present invention functions as follows,

The distal end of needle 38, which extends just past the distal end of catheter 28 is inserted into the patient's vein,

The clinician observes blood in the flash chamber in needle hub 40,

The clinician grasps needle hub 40, and catheter assembly 22 alone is moved distally into the vein,

The clinician applies slight pressure to the insertion site to hold catheter assembly 22 secure,

The clinician grasps the needle hub and begins withdrawal of needle assembly 24 from catheter assembly 22 During this process, needle tip protector 26 remains secure inside catheter hub 30 until bend 44 on the distal end of needle 38 comes into contact with second flange hole 72 Just before bend 44 encounters second flange hole 72, the biasing forces of first beam 96 and second beam 100 cause stop flange 102 and first lip 98 to move normal to and across the center axis of needle 38, blocking any further distal movement of needle 38 relative to needle tip protector 26 After stop flange 102 and first lip 98 move normal to and across the center axis of needle 38, first beam 96 and second beam 100 prevent axial movement of needle 38 preventing needle 38 from being twisted enabling bend 44 to be manipulated through second flange hole 72,

Since bend 44 is angled away from second flange hole 72 and first beam 96 and second beam 100 prevent axial movement of needle 38 securing bend 44 from being manipulated through second flange hole 72, continued proximal movement of needle 38 carries needle tip protector 26 proximal as well, forcing first tab 86 and second tab 88 on needle tip protector 26 against rib 34 First tab 86 and second tab 88 are forced to flex normal to and toward the center axis of needle tip protector 26, permitting continued movement proximal, past rib 34,

Needle assembly 24 is now removed entirely from catheter assembly 22, with the needle tip covered by needle tip protector 26 of the present invention.

Figure 10 shows an alternate embodiment of the present invention In this embodiment, needle 138, similar to needle 38, includes sleeve 199 Sleeve 199 can be slidably or fixedly attached on needle 138 proximal to bend 144 such that sleeve 199 is biased against second flange hole 172 when needle 138 is removed from catheter assembly 22 Sleeve 199 helps prevent needle tip protector 126 from being completely removed from needle 138 by ensuring that bend 144 can not be manipulated through second flange hole 172

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention Accordingly, it is intended that the invention be limited only by the spirit and scope of the appended claims In addition, it should be understood that every structure described above has a function and such structure can be referred to as a means for performing that function.

WHAT IS CLAIMED IS.

1 A catheter introducer assembly, comprising.

a) a needle assembly comprising a needle having a diameter, a proximal end, attached to a needle hub, a distal end extending therefrom, and a longitudinal axis therebetween, said needle further including a bent area disposed between said proximal and distal ends,

b) a catheter assembly comprising a tubular catheter having proximal end attached to a catheter hub, and distal end, said introducer needle being coaxially received within said catheter;

c) a needle tip protector disposed within said catheter hub, said needle tip protector is slidably disposed onto said needle, whereby when said needle is proximally removed from said catheter said protector remains attached to said needle

2 The catheter introducer assembly of claim 1 wherein said bent area on said needle is angled 45 – 90 degrees away from its original direction

3 The catheter introducer assembly of claim 1 wherein said needle diameter is constant between its distal and proximal ends

4 The catheter introducer assembly of claim 1 wherein said needle further comprises of a sleeve

5 The catheter introducer assembly of claim 5 wherein said sleeve is attached proximal to said bent area to help secure said needle in said protector when said needle is removed from said catheter

6 A catheter introducer assembly, comprising

a) a needle assembly comprising a hollow needle having an outer diameter, a proximal end, attached to a needle hub, a distal end extending therefrom, and a longitudinal axis therebetween, said needle further including a bent area disposed between said proximal and distal ends such that a longitudinal axis of said distal end of said needle is off set from a longitudinal axis of said proximal end of said needle ,

b) a catheter assembly comprising a tubular catheter having proximal end attached to a catheter hub, and distal end, said introducer needle being coaxially received within said catheter;

c) a needle tip protector disposed within said catheter hub, said needle tip protector is slidably disposed about said needle such that when said needle is proximally removed from said catheter said bent area prevents said needle tip protector from sliding off said needle so that said needle tip protector remains attached to said needle

7 The catheter introducer assembly of claim 6 wherein said bent area on said needle is angled 45 – 90 degrees away from its original direction

8 The catheter introducer assembly of claim 6 wherein said needle further comprises of a sleeve

9 The catheter introducer assembly of claim 8 wherein said sleeve is attached proximal to said bent area to help secure said needle in said protector when said needle is removed from said catheter

10 A catheter introducer assembly, comprising

a) a needle assembly comprising a hollow needle having a proximal end, attached to a needle hub, a distal end extending therefrom, and a longitudinal axis therebetween and a constant outer diameter between said distal end proximal end, said needle further including a bent area disposed between said

proximal and distal ends such that a longitudinal axis of said distal end of said needle is off set from a longitudinal axis of said proximal end of said needle,

b) a catheter assembly comprising a tubular catheter having proximal end attached to a catheter hub, and distal end, said introducer needle being coaxially received within said catheter;

c) a needle tip protector disposed within said catheter hub, said needle tip protector is slidably disposed about said needle such that when said needle is proximally removed from said catheter said bent area prevents said needle tip protector from sliding off said needle so that said needle tip protector remains attached to said needle.

11 The catheter introducer assembly of claim 10 wherein said bent area on said needle is angled 45 – 90 degrees away from its original direction

12 The catheter introducer assembly of claim 10 wherein said needle further comprises of a sleeve

13 The catheter introducer assembly of claim 12 wherein said sleeve is attached proximal to said bent area to help secure said needle in said protector when said needle is removed from said catheter

ABSTRACT

A catheter and introducer needle assembly having an introducer needle (38) with proximal and distal ends (39, 41) attached to a needle hub (40) and a bent area (44) therebetween. The device further includes a tubular catheter (28) having proximal and distal ends (31, 29) in which the introducer needle (38) can be coaxially received within the catheter (28) The device has a hollow catheter hub (30) having a distal end attached to the proximal end of the catheter and is in fluid communication therewith The assembly includes a needle tip protector (26) having a proximal end (49) and a distal end (50) disposed within the catheter hub (30) The distal end of the protector covers the needle tip when the needle is removed from the catheter The protector has a proximal opening (72) at its proximal end wherein the bent area (44) is angled away from the proximal opening such that when the needle is removed from the catheter the protector remains attached to the needle

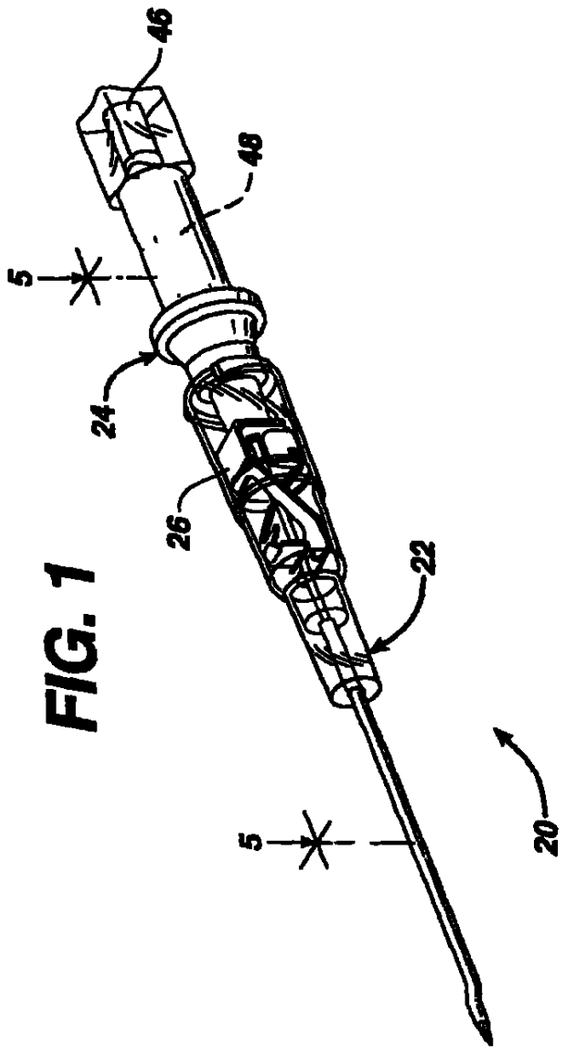


FIG. 1

FIG. 2

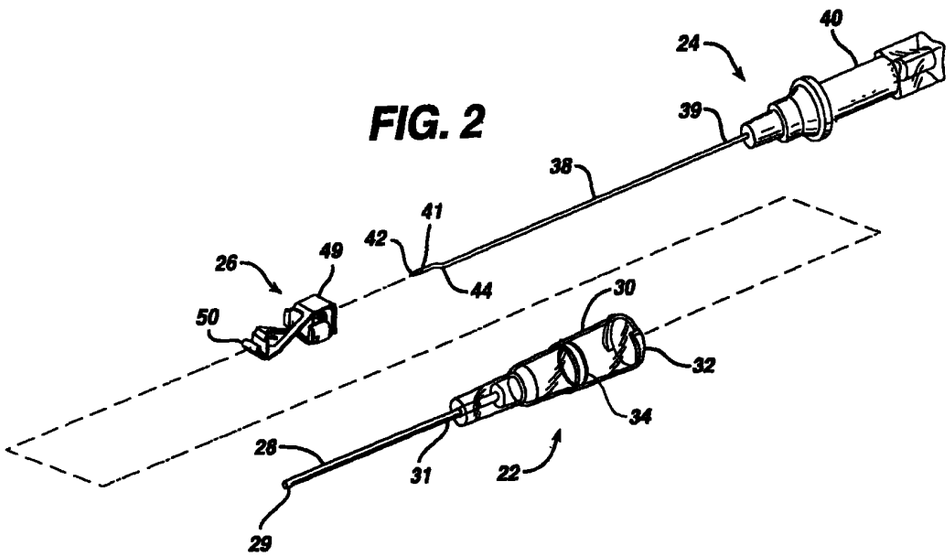


FIG. 3

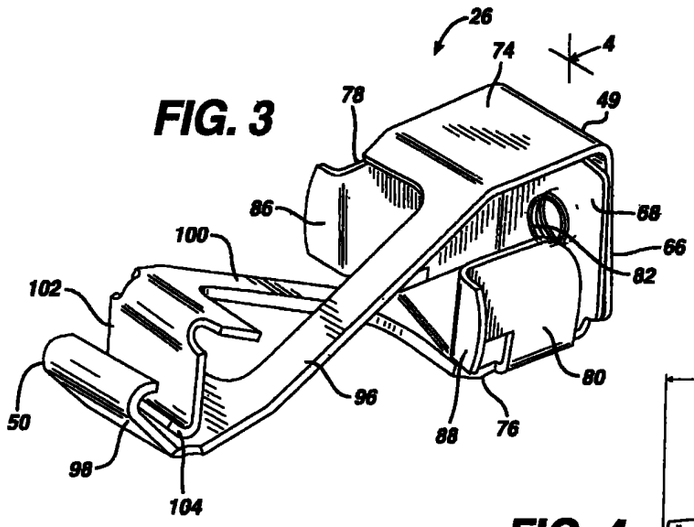

26
74
4
78
49
4
86
68
100
66
82
102
80
96
50
88
76
98
104

FIG. 4

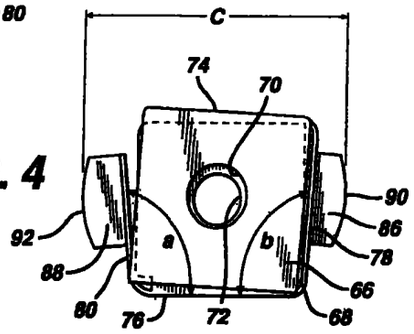

C
74
70
90
92
86
a
b
78
88
66
80
76
72
68

FIG. 5

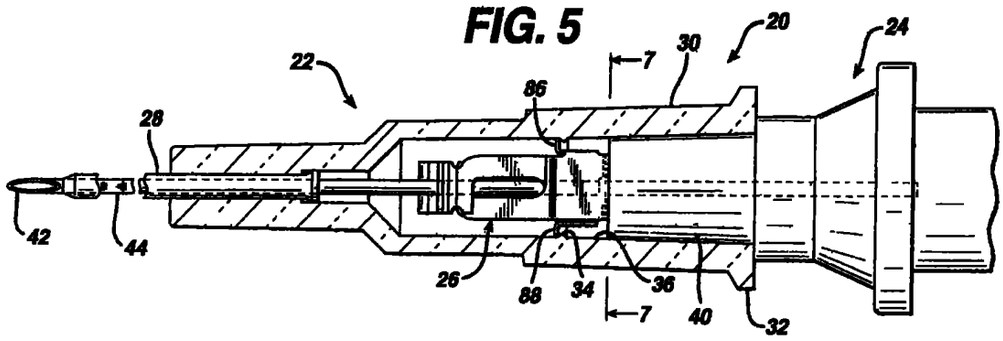


FIG. 6

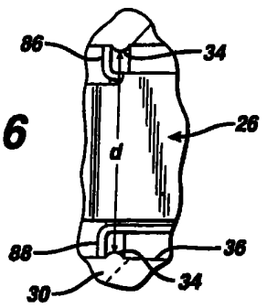


FIG. 7

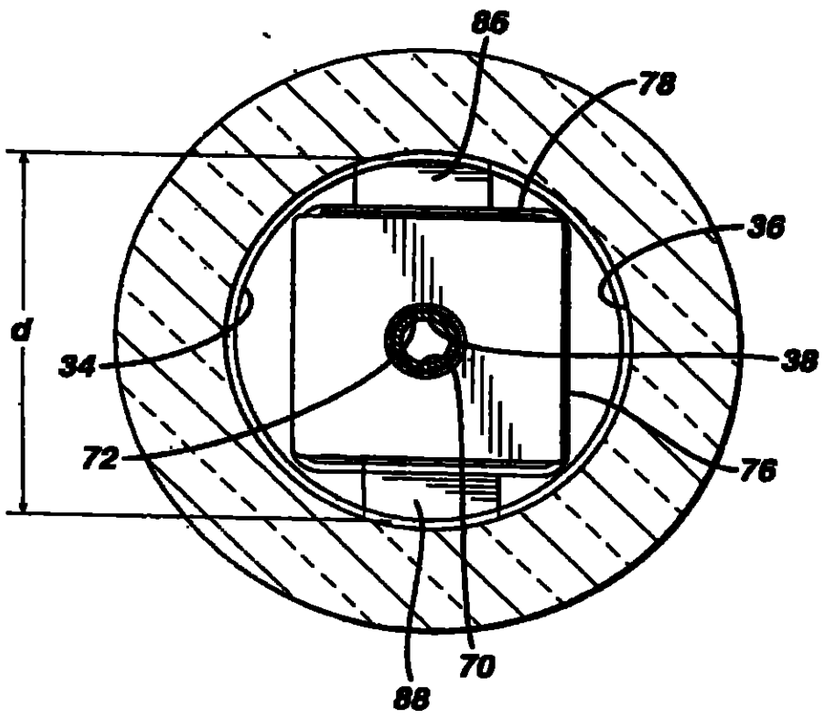


FIG. 8

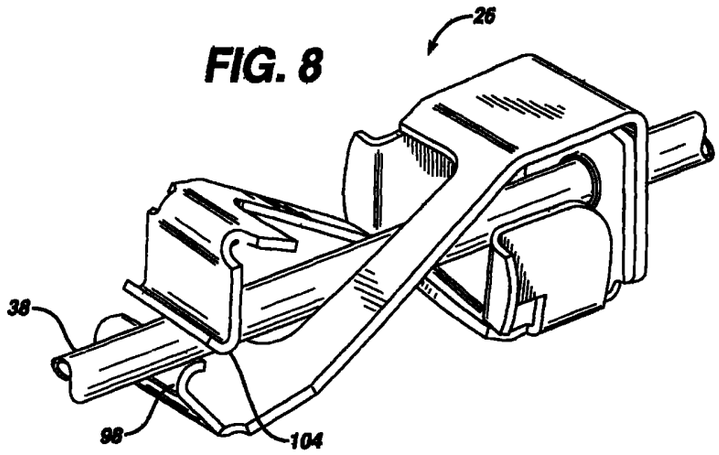


FIG. 9

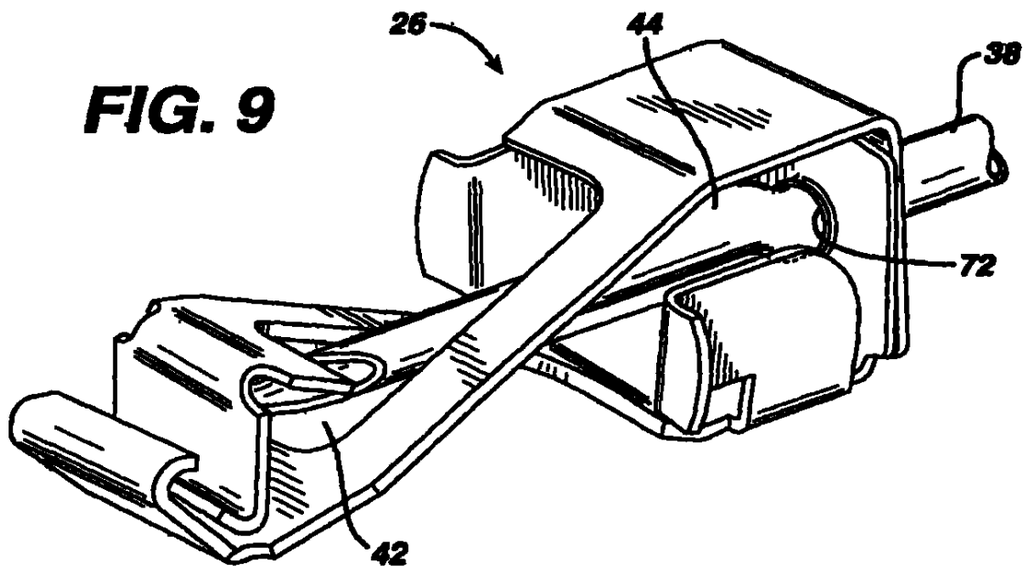
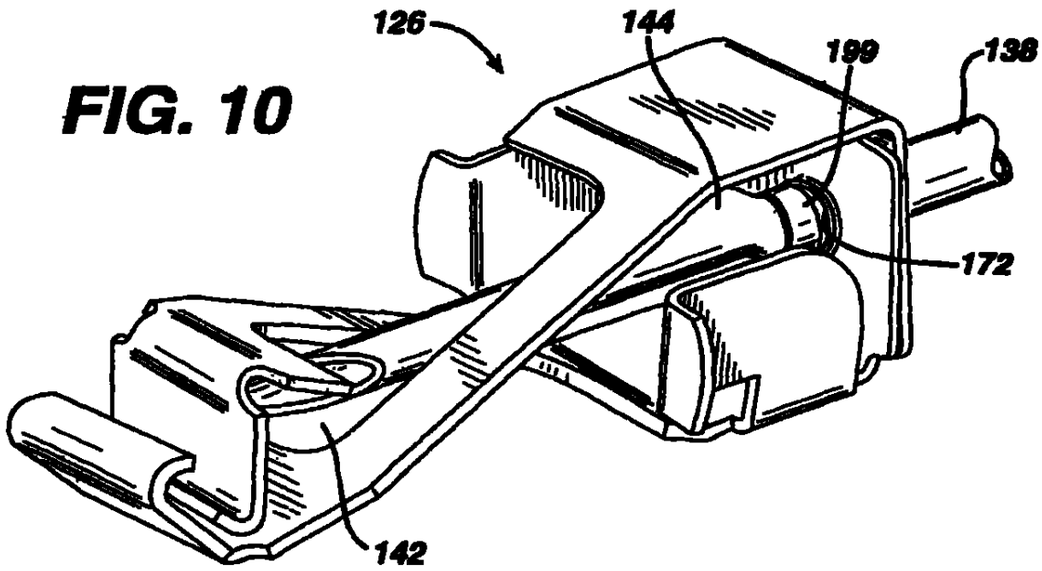


FIG. 10



MONTAJE SEGURO DE AGUJA Y CATÉTER

Campo de la Invención

La presente invención se relaciona en general, con catéteres intravenosos (IV) y, más particularmente, con un catéter IV seguro con un protector de punta de aguja que automáticamente cubrirá la punta de la aguja luego de retiro de la aguja

Antecedentes de la Invención

Un catéter intravenoso (IV) es un instrumento que se utiliza para introducir ciertos fluidos tales como solución salina directamente a la corriente sanguínea de un paciente Típicamente, una aguja u otro estilete es primero introducido a través de la porción de cánula del catéter y hacia la piel del paciente en el sitio deseado tal como la parte posterior de la mano del paciente o una vasija en el interior del brazo Una vez se completa la inserción, la aguja es removida de la porción de cánula del catéter Después de remover la aguja, un dispositivo de manejo de fluido como una jeringa es unido al ajuste luer localizado en el extremo próximo del eje del catéter El fluido entonces fluye directamente desde el dispositivo del manejo del fluido a través del catéter hacia la corriente sanguínea del paciente

Cuando la aguja es removida de la cánula, el trabajador de cuidado de la salud debe ubicar la punta de la aguja expuesta en un sitio cercano mientras simultáneamente maneja la tarea requerida para lograr la remoción de la aguja Es en esta unión que la punta de la aguja expuesta crea un peligro de un pinchazo accidental de la aguja cuya ocurrencia deja al trabajador de cuidado de la salud

vulnerable a la transmisión de varios patógenos peligrosos que llevan la sangre tal como el virus de la inmunodeficiencia humana (VIH) y el de la hepatitis

El riesgo de pincharse con una aguja contaminada no es solo aislado para el trabajador de cuidados de la salud que inserta el catéter intravenoso El desechado cuidadoso de las agujas utilizadas puede poner a otros trabajadores de cuidado de la salud en riesgo también Aún otros por fuera de la profesión de cuidado de la salud, por ejemplo aquellos involucrados en la limpieza y desecho final de desperdicios médicos, están en riesgo de un pinchazo accidental con una aguja proveniente de una aguja descartada de manera descuidada

El peligro para los trabajadores de cuidado de la salud y otros por fuera de la profesión de cuidado de la salud de pinchazos accidentales con aguja ha producido el desarrollo de catéteres con mecanismos de seguridad en los cuales se previene la ocurrencia de tales pinchazos accidentales con aguja Un ejemplo de un catéter que tiene un mecanismo de seguridad se describe en la Patente US No Re 34,416 de Lemieux Se describe un catéter de seguridad el cual incluye un elemento que cubre una punta de aguja luego de remoción de la aguja del catéter El elemento de seguridad incluye un reborde dividido en su extremo próximo que se expande por la aguja en la medida en que la aguja se inserta en un hueco de tamaño inferior en el centro de este reborde El elemento de seguridad se mantiene así seguro dentro del eje del catéter al insertar la aguja a través del hueco de tamaño inferior que forza el perímetro exterior del reborde dividido contra la pared interior del eje del catéter Uno de los inconvenientes en este diseño es la cantidad de fuerza de fricción ejercida contra la aguja por e reborde dividido Un ajuste fuerte del reborde contra la pared del catéter originará gran fricción contra la aguja haciéndole difícil ser retirada del catéter por el médico Un ajuste ligero deja

el reborde propenso a liberarse prematuramente del catéter en la medida en que la aguja es retirada, creando el potencial de que la punta de la aguja será dejada expuesta

Otro ejemplo de un catéter que tiene un mecanismo de seguridad se describe en la Patente US No 6,117,108 hecha por Woehr et al Un catéter de seguridad IV se describe el cual incluye una guarda de aguja elástica que protege la punta de la aguja luego de la remoción de la aguja del eje del catéter La guarda de la aguja incluye un brazo que incluye una abertura a través de la cual la aguja pasa originando el movimiento axial del brazo Este movimiento axial forza el brazo hacia la ranura o detrás de una costilla localizada al interior del eje del catéter, capturando la guarda de aguja en el eje del catéter El tema potencial con este diseño se desarrolla cuando la guarda de aguja no está adecuadamente sentada en el eje del catéter Si el extremo distante del brazo de guarda de la aguja no está alineado con la ranura en el eje del catéter, es expuesta a una fuerza excesiva sobre la aguja originando una fuerza de arrastre alta en la medida en que el médico remueve la aguja Y, en razón a que el brazo de guarda de aguja no está adecuadamente sentado en la ranura, éste puede prematuramente liberarse del eje del catéter luego de la remoción de la aguja dejando la punta de la aguja expuesta

Los catéteres de seguridad de la técnica anterior exhiben todos uno o más inconvenientes que han de esta manera limitado su utilidad y completa aceptación por los trabajadores de cuidado de la salud Por lo tanto lo que se requiere es un catéter IV de seguridad que funcione confiablemente sea fácil y poco costoso de elaborar, y fácil de utilizar

Resumen de la Invención

De acuerdo con la presente invención se suministra un montaje introductor de catéter El montaje introductor de catéter comprende un montaje de aguja que tiene una aguja unida a un eje de aguja y un extremo distante que se extiende de éste La aguja incluye un área inclinada dispuesta entre sus extremos próximos y distantes El montaje introductor del catéter incluye además un montaje de catéter que tiene un catéter tubular con un extremo próximo unido al eje del catéter La aguja es coaxialmente recibida dentro del catéter El montaje introductor de catéter incluye además un protector de punta de aguja dispuesto dentro del eje del catéter El protector de la punta de la aguja está deslizablemente dispuesto sobre la aguja, por lo que cuando la aguja está próxima a ser removida del catéter el protector permanece unido a la aguja

Breve Descripción de los Dibujos

Las características novedosas de la invención se establecen con particularidad en las reivindicaciones finales La invención en si misma, sin embargo, tanto en su organización como métodos de operación, junto con sus objetos y ventajas adicionales de ésta, pueden ser mejor entendidos con referencia a la siguiente descripción, tomada en conjunto con los dibujos que la acompañan en los cuales

La figura 1 es una vista en perspectiva del montaje del catéter y aguja de la presente invención,

La figura 2 es una vista en perspectiva en explosión del montaje de catéter y el montaje de aguja que incluye el protector de punta de aguja de la presente invención,

La figura 3 es una vista en perspectiva del protector de punta de aguja de la presente invención,

La figura 4 es una vista en elevación de la figura 3 tomada a lo largo de la línea 4-4 que ilustra las posiciones del hueco en los rebordes posteriores del protector de punta de aguja según se fabricó,

La figura 5 es una vista en sección del montaje de catéter y el montaje de aguja tomado a lo largo de la línea 5-5 de la figura 1,

La figura 6 es una vista en sección parcial agrandada de la figura 5 que ilustra la posición relativa de la lengüeta protector de la punta de aguja y de la costilla del eje del catéter;

La figura 7 es una vista de sección del eje del catéter con el protector de punta de aguja instalado tomado a lo largo de la línea 7-7 de la figura 5,

La figura 8 es una vista en perspectiva del protector de punta de aguja mostrado segun se instaló en el eje del catéter con la aguja insertada a su través,

La figura 9 es una vista en perspectiva de un protector de punta de aguja mostrado removido del eje del catéter y que ilustra la punta de aguja cubierta por el protector,

La figura 10 es una vista en perspectiva de una modalidad alternativa del protector de punta de aguja de la presente invención

Descripción Detallada de la Invención

Como se utiliza aquí, el término "próximo" se refiere a un sitio sobre el montaje de catéter y aguja con el protector de punta de aguja más cercano al médico utilizando el dispositivo en sí más lejano del paciente sobre el cual el dispositivo es utilizado Por el contrario, el término "distante" se refiere a un sitio más alejado del médico y más cercano al paciente

Como se ilustra en las figuras 1 y 2, el ensamblaje de catéter IV 20 comprende un montaje de catéter 22 y un montaje de aguja 24 El montaje de aguja 24 incluye además un protector de punta de aguja 26 El montaje de catéter 22 incluye un catéter 28 que es una estructura tubular que tiene un extremo próximo 31 y un extremo distante 29 El extremo próximo 31 del catéter 28 se fija unido al eje del catéter 30 Los catéter son bien conocidos en la técnica médica y uno de los muchos materiales solubles, la mayoría de las cuales son termoplásticos flexibles, se puede seleccionar para uso en el catéter 28 Tales materiales pueden incluir, por ejemplo, poliuretano o etileno propileno fluorinado El eje del catéter 30 es una estructura generalmente tubular que tiene una cavidad interna en comunicación fluida con el lumen interno del catéter 28 El eje del catéter 30 puede ser hecho de un termoplástico rígido grado médico adecuado tal como, por ejemplo, polipropileno o policarbonato Con propósitos de ilustración el eje del catéter 30 se muestra traslúcido, de tal forma que en su uso presente este puede ser traslucido u opaco En el extremo próximo del eje del catéter 30 está

integralmente unido un acople Luer 32, comunmente conocido en la técnica médica El acople Luer 32 suministra una unión segura, a prueba de chorreaduras de tuberías, jeringas, y cualquiera de muchos otros dispositivos médicos utilizados para infundir o retirar líquidos a través del montaje de catéter Como se ilustra más claramente en las figuras 5 y 6, la costilla 34 es un anillo anular levantado integral con y que se extiende desde la pared lateral interna 36 del eje del catéter 30 La costilla 34 está localizada aproximadamente a la mitad del camino dentro del extremo próximo y el extremo distante en la pared lateral 36 La costilla 34 juega un papel importante en asegurar el protector de punta de aguja 26 en el eje de catéter 30, como se describirá con más detalle más tarde

En relación de nuevo a las figuras 1 y 2, el montaje de aguja 24 comprende la aguja 38, que es una estructura tubular con un extremo próximo 39 y un extremo distante 41, el eje de aguja 40, y el protector de punta de aguja 26 El protector de punta de aguja 26 es ensamblado deslizablemente sobre la aguja 38 La aguja 38 es hecha preferiblemente de acero inoxidable El extremo próximo 39 de la aguja 38 es adhendo fijamente al eje de la aguja 40 Un bisel 42 está localizado en el extremo más distante de la aguja 38 creando una punta perforante aguda Un doblez de hoja 44 está localizado en el extremo distante de la aguja 38 próxima al bisel 42 y es curvo en la aguja 38 El doblez de aguja 44 se puede crear mediante el método de doblado tal como "doblez de arrastre rotatorio" El doblez de arrastre rotatorio es un proceso bien conocido en la técnica de doblez de metal que involucra el uso de un troquel de abrazadera y un troquel de doblez, que son moldeados para casar con el diámetro nominal de la aguja 38, para rotar la aguja 38 contra el troquel de presión Se inserta un mandril durante la aguja 38 durante el procedimiento para minimizar el tensionamiento que ocurre a lo largo del radio exterior de la aguja 38, aunque un troquel limpiador reduce el

arrugamiento a lo largo del radio interior de la aguja 38 El doblez 44 se forma en un ángulo alejado del segundo hueco de reborde 72 en el protector de punta de aguja 26 y es importante para prevenir la remoción completa del protector de punta de aguija 26 de la aguja 38, como se describirá con más detalle más tarde En la modalidad preferida el ángulo de doblez 44 es 45 a 90 grados alejado del segundo hueco de reborde 72

El eje de aguja 40 es generalmente una estructura tubular que tiene una cavidad interna en comunicación fluida con el lumen en la aguja 38 Esta es o preferiblemente hecha de un material termoplástico traslucido o transparente generalmente rígido tal como, por ejemplo, policarbonato En el extremo más próximo de la cavidad interna en el eje de la aguja 40 está unido fijamente un tarugo poroso 46 Una cámara de retorno 48 es creada en la cavidad distante del tarugo poroso 46 El tarugo poroso 46 contiene una pluralidad de aberturas microscópicas que son suficientemente grandes para permitir el paso de aire y otros gases pero suficientemente pequeña para evitar el paso de sangre La cámara de retorno 48 se llena con sangre luego de la entrada exitosa de la punta de la aguja dentro de la vena objetivo, suministrándole al médico conformación visual de la ubicación correcta de la aguja

Con relación ahora a las figuras 3 y 4, el protector de punta de aguja 20 tiene un extremo próximo 49 y un extremo distante 50 y es preferiblemente una estructura unitaria formada de una pieza simple de acero de material delgado, elástico, preferiblemente acero inoxidable El primer reborde 66 y el segundo reborde 68 son generalmente cuadrados y están integralmente conectados en ángulos rectos con la primer pared exterior 74 y la segunda pared exterior 76, respectivamente La primer pared exterior 74 está conectada con un ángulo recto

con el primer reborde de lengüeta 78 El primer reborde de lengüeta 78 y el segundo reborde de lengüeta 80 están cada uno formados con ángulos ligeramente mayores de 90 grados y la segunda pared exterior 76 de tal forma que la dimensión resultante c es ligeramente mayor que el diámetro interior d (ver figuras 5-7) a través de la costilla 34 en el eje del catéter 30 En los ángulos de la modalidad preferida a y b son cada uno aproximadamente 94 25 grados En las dimensiones de la modalidad preferida se es aproximadamente 005- 009 pulgadas mayor que la dimensión d El primer hueco de reborde 70 está localizado en el centro del primer reborde 66 está sobre dimensionado para recibir deslizablemente la aguja 38 El segundo hueco de reborde 72 y la falda 82 están localizados en el centro del segundo reborde 68 La falda 82 es integral al segundo hueco de reborde 72 y está formada por material extruido del segundo hueco de reborde 72 en una dirección distante al segundo reborde 68 Esto permite un ajuste muy cerrado pero deslizable sobre el diámetro nominal de la aguja 38 La falda 82 también funciona para ayudar a mantener el alineamiento de la aguja 38 con el eje central del protector de la punta de aguja 26 Como se entenderá por un experto en la técnica, el hueco del reborde 72 sería aproximadamente hecho con un tamaño del "calibre" de la aguja particular con el cual este se diseño para recibir La primer lengüeta 86 y la segunda lengüeta 88 están conectadas en ángulos rectos con el primer reborde de lengüeta 78 y el segundo reborde de lengüeta 80, respectivamente, y sobresalen hacia fuera del eje central del protector de punta de aguja 26 El primer borde de lengüeta 90, localizados en la porción exterior de la primer lengüeta 86, y el segundo reborde de lengüeta 92, localizados en la porción exterior de la segunda lengüeta 88, son cada uno arqueados para coincidir aproximadamente con la curva de la pared lateral 36 en el eje del catéter 30

En relación de nuevo a la figura 3, el primer haz 96 se extiende distantemente de la primer pared exterior 74 y es angulado hacia y se extiende pasando el eje central del protector de punta de aguja 26 El extremo distante del primer haz 96 está integralmente formado el primer labio curvado 98 que se extiende a través del eje central del protector de punta de aguja 26 El segundo haz 100 se extiende distantemente de la segunda pared de exterior 76 y es angulado hacia y se extiende pasando el eje central del protector de punta de aguja 26 En el extremo distante del segundo haz 100 está el reborde de borde 102 que se extiende a través y normal al eje central del protector de punta de aguja 26 En el extremo del reborde de tope 102 puesto a su conexión al segundo haz 100 está integralmente formado el segundo labio curvado 104

En relación ahora a las figuras 5-9, el protector de punta de aguja 26 es ensamblado a la aguja 38 como sigue,

El extremo próximo de la aguja 38 como sigue

El extremo próximo de la aguja 38 está unido fijamente al extremo distante del eje de la aguja 40, que contiene un tarugo poroso 46 fijamente unido a su extremo próximo,

El extremo distante de la aguja 38 se inserta a través del primer hueco de reborde 70 y luego a través del segundo hueco de reborde 72 en el protector de punta de aguja 26, moviéndose desde el punto próximo al distante,

El primer haz 96 y el segundo haz 100 son fijos, como resultado de sus propiedades elásticas, normales al eje central del protector de punta de aguja 26

de tal forma que la aguja 38 pasará entre el primer labio 98 y el segundo labio 104 (ver figura 8)

El doblez de la aguja 44 se agrega al extremo distante de la aguja 38 justo próximo al bisel 42 El doblez 44 es angulado alejado del segundo hueco del reborde 72 localmente (ver figura 9) evitando así la remoción completa del protector de punta de aguja 26 del extremo distante de la aguja 38

Ahora el montaje de la aguja 24, incluyendo el protector de punta de aguja 26, se ensambla dentro del montaje de catéter 22 como sigue,

El extremo distante de la aguja 38 está ubicado en su extremo próximo del eje del catéter 30 del montaje se aguja 24 se mueve distantemente haciendo que la aguja 38 entre al catéter 28,

En la medida que el montaje de aguja 24 continua moviéndose distantemente, el protector de punta de aguja 26 entra a la abertura del extremo próximo del eje del catéter 30

El movimiento distante continuado del montaje de aguja 24 origina que el borde distante del eje de aguja 40 empuje primero la lengüeta 86 y la segunda lengüeta 88 sobre el protector de punta de aguja 26 en contacto con la costilla 34 localizada sobre la pared lateral del eje 36,

El movimiento distante continuado puede ser la primer lengüeta 86 y la segunda lengüeta 88, debido a las propiedades elásticas del protector de punta de

aguja 26, al pasar la costilla 34 y en contacto con la pared lateral 36, justo distante a la costilla 34

El protector de punta de aguja 26 es así mantenido distante en la costilla 34 dentro de la cavidad en el eje del catéter 30 por fuerzas de flexión de la primer lengüeta 86 y la segunda lengüeta 88 en razón a que la dimensión c sobre el protector de punta de aguja 26 es mayor que la dimensión d a través de la costilla 34 dentro del eje del catéter 30 (Ver figura 6)

Como se ilustra mejor en la figura 7, en el movimiento de la primer lengüeta 86 y la segunda lengüeta 88 en la medida en que el protector de punta de aguja 26 es finalmente sentado distante a la costilla 34 origina flexión en la segunda pared exterior 76 y el primer reborde de lengüeta 78 dando como resultado el alineamiento aproximado del primer hueco de reborde 70 y el segundo hueco de reborde 72

Ahora, en el uso clínico presente, el montaje de catéter IV 20 de la presente invención funciona como sigue,

El extremo distante de la aguja 38, que se extiende justo pasando el extremo distante del catéter 28 se inserta dentro de la vena del paciente,

Los médicos observan la sangre en la cámara de retorno en el eje de la aguja 40,

El médico agarra el eje de aguja 40, y el montaje de catéter 22 solo, es movido distantemente hacia la vena,

El médico aplica presión ligera al sitio de inserción para mantener el montaje de catéter 22 seguro,

El médico agarra el eje de aguja para iniciar el retiro de montaje de aguja 24 del montaje de catéter 22 Durante este proceso, el protector de punta de aguja 26 permanece seguro dentro del eje del catéter 30 hasta que el doblez 44 sobre el eje distante de la aguja 38 entra en contacto con el segundo hueco de reborde 72 Justo antes de que el doblez 44 encuentre el segundo hueco de reborde 72, las fuerzas de empuje del primer haz 96 y el segundo haz 100 originan que el reborde de tope 102 y el primer labio 98 se muevan normales y a través del eje central de la aguja 38, bloqueando cualquier movimiento distante de la aguja 38 con relación al protector de punta de aguja 26 Después bloqueando cualquier movimiento distante adicional de la aguja 38 con relación al protector de punta de aguja 26 Después de que el reborde de tope 102 y el primer labio 98 se mueven normales y a través del eje central de la aguja 38, el primer haz 96 y el segundo haz 100 evitan el movimiento axial de la aguja 38 evitando que la aguja 38 sea girada posibilitándole al doblez 44 ser manipulado a través del segundo hueco de reborde 72,

En razón a que el doblez 44 es angulado alejado del segundo hueco de reborde 72 y el primer haz 96 y el segundo haz 100 evitan el movimiento axial de la aguja 38 asegurando que el doblez 44 sea manipulado a través del segundo hueco de reborde 72, el movimiento próximo continuado de la aguja 38 lleva el protector de punta de aguja 26 próximo también, rozando la primer lengüeta 86 y la segunda lengüeta 88 sobre el protector de punta de aguja 26 contra la costilla 34 La primer lengüeta 86 y la segunda lengüeta 88 son forzadas para flexionarse

normales y hacia el eje central del protector de punta de aguja 26, permitiendo con movimiento continuado próximo, pase la costilla 34,

El montaje de aguja 24 es ahora removido completamente del montaje de catéter 22, con la punta de aguja cubierta por el protector de punta de aguja 26 de la presente invención

La figura 10 muestra una modalidad alternativa de la presente invención En esta modalidad, la aguja 138, similar a la aguja 38, incluye el mango 199 El mango 199 puede ser deslizablemente fijamente unido sobre la aguja 138 próxima al doblez 144 de tal forma que el mango 199 es empujado contra el segundo hueco de reborde 172 cuando la aguja 138 es removida del montaje de catéter 22 El mango 199 ayuda a evitar que el protector de punta de aguja 126 sea completamente removido de la aguja 138 al asegurar que el doblez 144 no pueda ser manipulado a través del segundo hueco de reborde 172

Aunque las modalidades preferidas de la presente invención han sido mostradas y descritas aquí, será obvio para aquellos expertos en la técnica que tales modalidades sean suministradas por vía solamente de ejemplo Numerosas variaciones, cambios y sustituciones ocurrirán ahora a aquellos expertos en la técnica sin apartarse de la invención De acuerdo con esto, se pretende que la invención sea limitada solamente al espíritu y alcance de las reivindicaciones finales Además, se debe entender que cada estructura descrita anteriormente tiene una función y tal estructura puede ser referida como a medios para desarrollar tal función

REIVINDICACIONES

1 Un montaje introductor de catéter, que comprende

a) un montaje de aguja que comprende una aguja que tiene un diámetro, un extremo próximo, unido a un eje de aguja, un extremo distante que se extiende desde este, un eje longitudinal entre ellos, dicha aguja incluyendo además un área de doblez dispuesta entre dichos extremos próximo y distante,

b) un montaje de catéter que comprende un catéter tubular que tiene un extremo próximo unido a un eje de catéter, y un extremo distante, dicha aguja introductora siendo coaxialmente recibida dentro de dicho catéter;

c) El protector de punta de aguja dispuesto dentro de dicho eje de catéter, dicho protector de punta de aguja está deslizablemente dispuesto sobre dicha aguja, por medio del cual cuando dicha aguja es próximamente removida de dicho catéter dicho protector permanece unido a dicha aguja

2 El montaje introductor de catéter de la reivindicación 1 donde dicha área de doblez sobre dicha aguja es angulada 45-90 grados distante de su dirección original

3 El montaje introductor de catéter de la reivindicación 1 en donde el diámetro de la aguja es constante entre sus extremos distante y próximo

42

4 El montaje introductor de catéter de la reivindicación 1 en donde dicha aguja comprende además un mango

5 El montaje introductor de catéter de la reivindicación 5 en donde dicho mango está unido próximo a dicha área de doblez para ayudar a asegurar dicha aguja en dicho protector cuando dicha aguja es removida de dicho catéter

6 Un montaje introductor de catéter, que comprende

a) Un montaje de aguja que comprende una aguja hueca que tiene un diámetro exterior, un extremo próximo, unido a un eje de aguja, un extremo distante que se extiende desde este, y un eje longitudinal entre ellos, dicha aguja incluye además un área de doblez dispuesta entre dichos extremos próximos distantes de tal forma que el eje longitudinal de dicho extremo distante de dicha aguja está descentrado el eje longitudinal de dicho extremo próximo de dicha aguja,

b) Un montaje de catéter que comprende un catéter tubular que tiene un extremo próximo unido al eje del catéter, y un extremo distante, dicha aguja introductora siendo coaxialmente recibida dentro de dicho catéter;

c) un protector de punta de aguja dispuesto dentro de dicho eje de catéter, dicho protector de punta de aguja está deslizablemente dispuesto alrededor de dicha aguja de tal forma que cuando dicha aguja es próximamente removida de dicho catéter dicha área de doblez evita

que dicho protector de punta de aguja sea deslizado por fuera de dicha aguja de tal forma que dicho protector de punta de aguja permanezca unido a dicha aguja

7 El montaje introductor de catéter de la reivindicación 6 en donde dicha área de doblez sobre dicha aguja es angulada 45-90 grados distante de su dirección original

8 El montaje introductor de catéter de la reivindicación 6 en donde dicha aguja comprende además un mango

9 El montaje introductor de catéter por la reivindicación 8 en donde dicho mango está unido próximo a dicha área de doblez para ayudar a asegurar dicha aguja en dicho protector cuando dicha aguja se remueve de dicho catéter

10 Un montaje introductor de catéter, que comprende

a) un montaje de aguja que comprende una aguja hueca que tiene un extremo próximo, unido a un eje de aguja, un extremo distante que se extiende desde este, y un eje longitudinal entre ellos y un diámetro exterior constante entre dicho extremo próximo, dicha aguja incluye además un área de doblez dispuesta entre dicho extremo próximo distante de tal forma que el eje longitudinal de dicho extremo distante de dicha aguja está descentrado del eje longitudinal de dicho extremo p+próximo de dicha aguja,

b) un montaje de catéter que comprende un catéter tubular que tiene un extremo próximo unido a un eje de catéter, y un extremo distante, dicha aguja introductora siendo coaxialmente recibida dentro de dicho catéter,

c) un protector de punta de aguja dispuesto dentro de dicho eje de catéter, dicho protector de punta de aguja está deslizablemente dispuesto alrededor de dicha aguja de tal forma que cuando dicha aguja es próximamente removida de dicho catéter dicha área doblada evita que dicho protector de punta de aguja se deslice por fuera de dicha aguja de tal forma que dicho protector de punta de aguja permanece unido a dicha aguja

11 El montaje introductor de catéter de la reivindicación 10 en donde dicha área de doblez sobre dicha aguja es angulado 45-90 grados alejado de su dirección original

12 El montaje introductor del catéter de la reivindicación 10 en donde dicha aguja comprende además un mango

13 Un montaje introductor de catéter de la reivindicación 12 en donde dicho mango está unido próximo a dicha área de doblez para ayudar en forma segura dicha aguja en dicho protector cuando dicha aguja es removida en dicho catéter

45

RESUMEN

Un montaje de catéter y de aguja introductora que tiene una aguja introductora (38) con extremos próximos y distantes (39,41) unida a un eje de aguja (40) y un área de doblez (44) entre ellas El dispositivo incluye además un catéter tubular (28) que tiene extremos próximos y distantes (31, 29) en el cual la aguja introductora (38) puede ser coaxialmente recibida dentro del catéter (28) El dispositivo tiene un eje de catéter hueco (30) que tiene un extremo distante unido al extremo próximo del catéter y está en comunicación fluida con este El montaje incluye un protector de punta de aguja (26) que tiene un extremo próximo (49) y un extremo distante (50) dispuesto dentro del eje del catéter (30) El extremo distante del protector cubre la punta de la aguja cuando la aguja es removida del catéter El protector tiene una abertura próxima (72) en su extremo próximo en donde el área de doblez (44) es angulada alejada de la abertura próxima de tal forma que cuando la aguja es removida del catéter el protector permanece unido a la aguja

PATENT COOPERATION TREATY

40

From the INTERNATIONAL SEARCHING AUTHORITY

2004 JUL 19 AM 10 27

PCT

To

WOOD, HERRON & EVANS, L L P
Attn Grossman, Kurt L
2700 Carew Tower
Cincinnati, Ohio 45202
UNITED STATES OF AMERICA

FOREIGN DEPT LAW
DATE 7/19/04

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

(PCT Rule 44.1)

Applicant's or agent's file reference MDXVA-21WO	Date of mailing (day/month/year) 16/07/2004 FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2004/006017	International filing date (day/month/year) 27/02/2004
Applicant MEDEX, INC	

1 [x] 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 2 months from the date of transmittal of the International Search Report; however for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20 Switzerland Fascimile No (41-22) 740.14.35

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 thereon 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 90*bis*.1 and 90*bis*.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 International Searching Authority	Authorized officer
European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel (+31-70) 340-2040 Tx 31 651 epo nl Fax. (+31-70) 340-3016	Vera Eberhardt

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, 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

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 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 (Administrative Instructions, 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.

BNSDOCID: <XB____ISA220NOENP4_I_>

47
48

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. References 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 under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

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, where 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 Volume II of the PCT Applicant's Guide.

ENSDOCID: <WO_____ISA220NOENP4_I_>

49

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as where applicable item 5 below
MDXVA-21WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2004/006017	27/02/2004	08/04/2003
Applicant		
MEDEX, 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 4 sheets.

[X] 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 unless otherwise indicated under this item

[ ] The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23 1(b))

b [ ] 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 II)

3. [ ] Unity of invention is lacking (see Box III)

4 With regard to the title,

[X] 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,

[X] 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 regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 2

[ ] as suggested by the applicant.

[ ] as selected by this Authority because the applicant failed to suggest a figure

[X] 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/US2004/006017

A CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00 A61M25/06 A61M5/162 A61M5/00

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)
IPC 7 A61M

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 practical, search terms used)
EPO-Internal

C DOCUMENTS CONSIDERED TO BE RELEVANT

Category°	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/08742 A (BRAUN MELSUNGEN AG) 25 February 1999 (1999-02-25)	1,3
A	page 8, line 11 -page 22, line 19, figures	6,10
A	WO 94/23778 A (LEIJD NICKLAS) 27 October 1994 (1994-10-27) page 4, line 14 -page 6, line 15, figures	1,6,10
A	US 5 120 321 A (EISNER JOSEPH ET AL) 9 June 1992 (1992-06-09) the whole document	1,6,10
A	US 2002/177818 A1 (VAILLANCOURT VINCENT L) 28 November 2002 (2002-11-28) paragraph '0047', figures 15,17	1,6,10

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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 document but 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	Date of mailing of the international search report
7 July 2004	16/07/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx 31 651 epo nl, Fax: (+31-70) 340-3016	Vänttinen, H

2

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/006017

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication where appropriate of the relevant passages	Relevant to claim No
A	EP 1 112 754 A (ETHICON INC) 4 July 2001 (2001-07-04) abstract, figures 1-3	1,6,10
A	EP 0 747 086 A (JOHNSON & JOHNSON MEDICAL) 11 December 1996 (1996-12-11) the whole document	1,6,10
A	US 6 402 734 B1 (WEISS JEFFREY N) 11 June 2002 (2002-06-11) the whole document	2,7,11
A	US 4 013 080 A (FRONING EDWARD C) 22 March 1977 (1977-03-22) the whole document	2,7,11

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/006017

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9908742	A	25-02-1999	US	6117108 A	12-09-2000
			AU	730988 B2	22-03-2001
			AU	9532398 A	08-03-1999
			BR	9812128 A	18-07-2000
			CN	1267226 T	20-09-2000
			WO	9908742 A1	25-02-1999
			EP	1421969 A1	26-05-2004
			EP	1003588 A1	31-05-2000
			JP	3486169 B2	13-01-2004
			JP	2001514943 T	18-09-2001
			JP	3486188 B2	13-01-2004
			JP	2003265615 A	24-09-2003
			US	6287278 B1	11-09-2001
			US	2003195471 A1	16-10-2003
			US	6616630 B1	09-09-2003
			ZA	9807377 A	17-02-1999
WO 9423778	A	27-10-1994	SE	503972 C2	07-10-1996
			AU	6547794 A	08-11-1994
			EP	0774985 A1	28-05-1997
			SE	9301291 A	21-10-1994
			WO	9423778 A1	27-10-1994
			US	5624401 A	29-04-1997
US 5120321	A	09-06-1992	NONE		
US 2002177818	A1	28-11-2002	NONE		
EP 1112754	A	04-07-2001	US	6210373 B1	03-04-2001
			AU	771613 B2	01-04-2004
			AU	7257600 A	05-07-2001
			BR	0006320 A	31-07-2001
			CA	2329502 A1	30-06-2001
			EP	1112754 A1	04-07-2001
			JP	2001218844 A	14-08-2001
			SG	98014 A1	20-08-2003
			TW	522027 B	01-03-2003
			ZA	200100035 A	02-07-2002
EP 0747086	A	11-12-1996	US	5569202 A	29-10-1996
			BR	9602637 A	22-04-1998
			DE	69607410 D1	04-05-2000
			DE	69607410 T2	07-09-2000
			EP	0747086 A2	11-12-1996
			JP	9108347 A	28-04-1997
			TW	390205 Y	11-05-2000
			ZA	9604768 A	08-12-1997
US 6402734	B1	11-06-2002	US	2003057347 A1	27-03-2003
US 4013080	A	22-03-1977	US	3941127 A	02-03-1976
			US	3964480 A	22-06-1976

PATENT COOPERATION TREATY

53

From the
INTERNATIONAL SEARCHING AUTHORITY

To

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis* 1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/006017	27 02 2004	08 04 2003

International Patent Classification (IPC) or both national classification and IPC
A61M25/00 A61M25/06 A61M5/162, A61M5/00

Applicant
MEDEX, 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 43*bis* 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 usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") However, 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 1*bis*(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 three 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

European Patent Office
D-80298 Munich
Tel +49 89 2399 0 Tx 523656 epmu d
Fax +49 89 2399 4465

Authorized Officer

Väntinen, H

Telephone No +49 89 2399-7442

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No
PCT/US2004/006017

Box No. I Basis of the 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, unless otherwise indicated under this item

☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b))

2 With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention 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

☐ in written format

☐ in computer readable form

c time of filing/furnishing

☐ contained in the international application as filed

☐ filed together with the international application in computer readable form

☐ furnished subsequently to this Authority for the purposes of search

3 ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table 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

4 Additional comments

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No PCT/US2004/006017

Box No. II Priority

1 ☒ The following document has not been furnished

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66 7(a))

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66 7(b))

Consequently it has not been possible to consider the validity of the priority claim This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date

2 ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64 1) Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date

3 Additional observations, if necessary

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)	Yes	Claims	1 13
	No	Claims	
Inventive step (IS)	Yes	Claims	4-13
	No	Claims	1-3
Industrial applicability (IA)	Yes	Claims	1 13
	No	Claims	

2 Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

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

see separate sheet

Box No VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description are made

see separate sheet

1 Concerning Item V

1 1 WO-A-99/08742 (D1) discloses a catheter introducer assembly comprising a needle assembly (12, 16), a catheter assembly (24, 26) and a needle tip protector (40) within the catheter hub (26) When the needle is removed from the catheter, the needle tip protector (40) remains attached to the needle at its distal end by means of a slot (60) or a bulge (61) Thus, the subject-matter of claim 1 differs from the disclosure of D1 by that the needle has a bent area Just having a bent area does not appear to solve a specific technical problem and needle with a bent area are well known in the field of medicine Consequently, having a bent needle is considered to come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance Thus, the subject-matter of claims 1 and 2 does not meet the requirement of Article 33(3) PCT Also the subject-matter of claim 3 does not meet the requirement of Article 33(3) PCT, because it is known from D1

1 2 The subject-matters of claims 6 and 10 are considered to differ from the disclosure of D1 by that (i) the needle has a bent area and that (ii) the bent area of the needle prevents the needle tip protector from sliding off said needle None of the cited documents discloses a needle having a bent area in combination with a needle tip protector cooperating with the bent area as defined in claims 6 and 10 Thus, the skilled person is not considered to arrive at the subject-matters of said claims in an obvious manner Consequently, the subject-matters of claims 6 and 10 as well as their dependent claims 7-9 and 11-13 appear to meet the requirements of Article 33(2) and (3) PCT

1 4 Furthermore, the technical features of claims 4 and 5 do not appear to be derivable in an obvious manner from any of the cited documents Thus, said claims appear to meet the requirements of Article 33(2) and (3) PCT

1 3 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-13 is self-evident

2 Concerning Item VII

The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT Furthermore, the independent claims are not in the two-part form as required by Rule 6 3(b) PCT In addition, the claims do not include reference signs in parentheses as required by Rule 6 2(b) PCT

3 Concerning Item VIII

For the entrance into the European Phase, the applicant is reminded about Article 84 and Rule 29(2) EPC which do not allow a plurality of independent claims in the same category

WO 2004/093961
PCT/US2004/006017

PATENT COOPERATION TREA[T]

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL APPLICATION AS PUBLISHED OR REPUBLISHED

To

GROSSMAN, Kurt, L.
Wood Herron & Evans L.L.P
2700 Carew Tower
Cincinnati, OH 45202
ETATS-UNIS D'AMERIQUE

LAL
11-9-04

Date of mailing *(day/month/year)*	
04 November 2004 (04 11 2004)	
Applicant's or agent's file reference	IMPORTANT NOTICE
MDXVA-21WO	

International application No	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/006017	27 February 2004 (27 02 2004)	08 April 2003 (08 04 2003)

Applicant

MEDEX INC et al

The International Bureau transmits herewith the following documents.

☑ copy of the international application as published by the International Bureau on 04 November 2004 (04.11 2004) under No WO 2004/093961

☐ copy of international application as republished by the International Bureau on under No WO
For an explanation as to the reason for this republication of the international application, reference is made to INID codes (15), (48) or (88) (*as the case may be*) on the front page of the attached document.

The International Bureau of WIPO	Authorized officer
34 chemin des Colombettes 1211 Geneva 20, Switzerland	Simin Baharlou
Facsimile No +41 22 740 14 35	Facsimile No.+41 22 338 71 30

Form PCT/IB/311 (January 2004)

R 19

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)* MDXVA-21WO

Box No. I TITLE OF INVENTION
SAFETY NEEDLE AND CATHETER ASSEMBLY

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.)*

MEDEX, INC
2231 Rutherford Road
Carlsbad, California 92008
United States of America

Telephone No
760-602-4400

Facsimile No
760-603-8778

Teleprinter 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 ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(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. 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.)*

McGURK, Joseph P
5806 West Fountain Circle
Mason Ohio 45040
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 ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ 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.)*

GROSSMAN Kurt L
WOOD HERRON & EVANS, L L P
2700 Carew Tower
Cincinnati, Ohio 45202
United States of America

Telephone No
513-241-2324

Facsimile No
513-241-6234

Teleprinter No

Agent's registration No with the Office

☐ **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.

60

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 two persons are to be indicated as applicants and/or inventors 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 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 patent grant and the date of grant of the parent patent or other patent grant or the date of filing of 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 49 bis 1(d))*

Continuation of Box IV

John D Poffenberger Bruce Tittel David J Josephic, Donald F Frei David S Stallard J Robert Chambers Gregory J Lunn Kurt L Grossman Clement H Luken Jr Thomas J Burger Gregory F Ahrens Wayne L. Jacobs Kurt A. Summe Kevin G Rooney Keith R Haupt, Theodore R. Remaklus Thomas W Humphrey Scott A. Stinebruner David H Brinkman Thomas W Flynn Joseph R Jordan C Richard Eby David E. Pritchard J Dwight Poffenberger Jr Beverly A. Lyman Ph D Kristi L. Davidson P Andrew Blatt, Ph D David E Jefferies William R. Allen Ph D Douglas A. Scholer David W Dorton John P Davis

All are members of the firm of Wood Herron & Evans L.L.P 2700 Carew Tower Cincinnati Ohio 45202, United States of America

61

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

☐ 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

(The check-boxes above may be used to exclude (irrevocably) the designations concerned in order to avoid the ceasing of the effect, under the national law of an earlier national application from which priority is claimed. See the Notes to Box No. V as to the consequences of such national law provisions in these and certain other States)

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	regional application * regional Office	international application receiving Office
Item (1) 08 APRIL 2003 (08 04.2003)	60/461 172	US		
Item (2)				
Item (3)				

☐ Further priority claims are indicated in the Supplemental Box

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as.

☐ all items ☒ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

** Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii))*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(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)*

ISA/ EP

Request to use results of earlier search, reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*

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) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*		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	

62

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application contains

(a) in paper form, the following number of sheets

request (including declaration sheets)	4
description (excluding sequence listing and/or tables related thereto)	10
claims	3
abstract	1
drawings	8
Sub-total number of sheets	26
sequence listing	
tables related thereto	
(for both, actual number of sheets if filed in paper form, whether or not also filed in computer readable form see (c)	
Total number of sheets	26

(b) ☐ **only in computer readable form (Section 801(a)(i))**
- (i) ☐ sequence listing
- (ii) ☐ tables related thereto

(c) ☐ **also in computer readable form (Section 801(a)(ii))**
- (i) ☐ sequence listing
- (ii) ☐ tables related thereto

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)

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

1 ☒ fee calculation sheet
2. ☐ original separate power of attorney
3 ☐ original general power of attorney
4 ☐ copy of general power of attorney; reference number if any
5 ☐ statement explaining lack of signature
6 ☐ priority document(s) identified in Box No. VI as item(s)
7 ☐ translation of international application into *(language)*
8 ☐ separate indications concerning deposited microorganism or other biological material
9 ☐ sequence listing in computer readable form *(indicate type and number of carriers)*
- (i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)
- (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 13*ter*
- (iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing mentioned in left column

10 ☐ tables in computer readable form related to sequence listing *(indicate type and number of carriers)*
- (i) ☐ copy submitted for the purposes of international search under Section 802(b-*quater*) only (and not as part of the international application)
- (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*)
- (iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column

11 ☒ other *(specify)* Trans. Ltr , Postcard, Check in amt. of $3173

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).

KURT L. GROSSMAN

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

63

This sheet is not part of and does not count as a sheet of the international application

PCT

FEE CALCULATION SHEET

Annex to the Request

For receiving Office use only

International Application No.

Date stamp of the receiving Office

Applicant's or agent's file reference: MDXVA-21WO

Applicant: MEDEX, INC

CALCULATION OF PRESCRIBED FEES

1 TRANSMITTAL FEE — 300.00 [T]

2 SEARCH FEE — 1,818.00 [S]

International search to be carried out by EP

(If two or more International Searching Authorities are competent to carry out the international search, indicate the name of the Authority which is chosen to carry out the international search.)

3 INTERNATIONAL FILING FEE

Where item (b) and/or (c) of Box No IX apply enter Sub-total number of sheets / Where item (b) and (c) of Box No. IX do not apply, enter Total number of sheets: 28

[i1] first 30 sheets — 1,035.00 [i1]

[i2] 0 (number of sheets in excess of 30) x 11.00 (fee per sheet) = 0.00 [i2]

[i3] additional component (only if sequence listing and/or tables related thereto are filed in computer readable form under Section 801(a)(i), or both in that form and on paper, under Section 801(a)(ii))

400 x _____ (fee per sheet) = _____ [i3]

Add amounts entered at i1, i2 and i3 and enter total at I — 1,035.00 [I]

(Applicants from certain States are entitled to a reduction of 75% of the international filing fee. Where the applicant is (or all applicants are) so entitled

4 FEE FOR PRIORITY DOCUMENT *(if applicable)* — 20.00 [P]

5 TOTAL FEES PAYABLE — 3,173.00 TOTAL

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

MODE OF PAYMENT

- [x] authorization to charge deposit account (see below)
- [ ] postal money order
- [ ] cash
- [ ] coupons
- [x] cheque
- [ ] bank draft
- [ ] revenue stamps
- [ ] other *(specify)*

AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT

(This mode of payment may not be available at all receiving Offices)

- [ ] Authorization to charge the total fees indicated above.
- [x] *(This check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit)* Authorization to charge any deficiency or credit any overpayment in the total fees indicated above
- [ ] Authorization to charge the fee for priority document

Receiving Office: US

Deposit Account No: 23-3000

Date: 27 FEBRUARY 2004

Name: JOHN L GROSSMAN

Signature: [signature]

Industria y Comercio

FORMATO DE DIGITALIZACION
RELACI N DE ANEXOS

Royal Technologies S.A

64

Item		Expediente No 05102634	No de Folio
		No de unidades	√
1	CD		
2	DVD		
3	REVISTA		
4	LIBRO		
5	PERIODICO		
6	DISQUETES		
7	SOBRE DE MANILA		
8	SOBRE BLANCO TAMAÑO CARTA		
9	SOBRE BLANCO TAMAÑO OFICIO X	1	
10	OTROS.		

Observaciones Un sobre que contiene Arte Final

05

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT 800176089-2

SUPERINTENDENCIA I CUNEMLIU Folios 56
Radicacion 05180634
Fecha (AMD): 2005-10-07 17:28:38
Tramite : 611 PCT-PATENT 376 PRIM. NACI 411 PRESENTAL
Dependencia :020 DIVISION DE NUEVAS CREACIONES

RECIBO OFICIAL DE CAJA 05 - 75,986
FECHA OCTUBRE 3 DE 2005

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No PAGO	FECHA PGO	Vr PAGO
CAVELIER ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	31556028	03/10/2005	58,956,360 00

***** C O N C E P T O *****

CANT	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	1 TRAMITES DE SOL DE PATENTE DE IN	443 000 00
		TOTAL $	443,000 00

SON CUATROCIENTOS CUARENTA Y TRES MIL PESOS

RESPONSABLE _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No _____

Cdo 14343-841-001-9

SUPERINTENDENCIA Y DESARROLLO

Folio: 56

Fecha (AAAA) 2003-10-07 17:28:58

Tramite 411 PC1-PRIMT 378 FASE NACI 411 PRESENTAC

Dependencia 4000 DIVISION DE NUEVAS CONFECCIONES

REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

		USUARIO	RADICADOR
PATENTE DE INVENCIÓN	MODELO DE UTILIDAD	( )	( )
- Indicación de que se solicita la concesión de una patente		( )	( )
- Datos de identificación del solicitante o de la persona que se presenta la solicitud.		( )	( )
- Descripcion 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 identificacion del solicitante o de la persona que presenta		( )	( )
- la solicitud			
- Representacion grafica o fotografica 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 solicita el registro de un Esquema de trazado		( )	( )
- Datos de identificación del solcitante o de la persona que presenta La solicitud		( )	( )
Representacion gráfica del esquema de trazado		( )	( )
Comprobante de pago de las tasas establecidas		( )	( )
COMPLETA ( )	INCOMPLETA	( )	( )

Firma Responsable:

Fecha

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCI

58
59

Bogotá,
2020

Doctor(a)
FERRERO EMILIO

REFERENCIA	Radicación No	5 102634
	Solicitud internacional	US2004/006017
	Fecha inicio fase nacional	08/11/2005
	Trámite	11
	Evento	378
	Actuación	439
	Oficio No	10421

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 La traducción de los capitulos descriptivo y reivindicatorio, deberán estar acompañadas de los respectivos dibujos

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 (Art 26-k) Decisión 486

3 La solicitud no contiene el poder debidamente otorgado, con el lleno de los requisitos exigidos por los artículos 63 y subsiguientes del Código de Procedimiento Civil Adicionalmente, deberá presentar el documento que acredita la existencia y representación legal de la sociedad solicitante, cuando ésta fuere persona jurídica

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 Unica No 10 de 2001

ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista de fecha 04 NOV 2005
adpa11