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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 August 2016 (04.08.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/123616 A1

(51) International Patent Classification:
A61M 25/01 (2006.01) *A61M 25/00* (2006.01)
A61M 5/32 (2006.01)

(21) International Application Number:
PCT/US2016/015965

(22) International Filing Date:
1 February 2016 (01.02.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/109,673	30 January 2015 (30.01.2015)	US
62/109,742	30 January 2015 (30.01.2015)	US
62/109,735	30 January 2015 (30.01.2015)	US
62/109,766	30 January 2015 (30.01.2015)	US
62/109,750	30 January 2015 (30.01.2015)	US
62/109,710	30 January 2015 (30.01.2015)	US
62/109,755	30 January 2015 (30.01.2015)	US
62/109,715	30 January 2015 (30.01.2015)	US
62/109,722	30 January 2015 (30.01.2015)	US
62/109,759	30 January 2015 (30.01.2015)	US
62/109,745	30 January 2015 (30.01.2015)	US

(71) Applicant: **SMITHS MEDICAL ASD, INC.** [US/US]; 160 Weymouth Street, Rockland, MA 02370 (US).

(72) Inventors: **GORAL, David**; c/o Smiths Medical ASD, Inc., 160 Weymouth Street, Rockland, MA 02370 (US). **ROEHL, Christopher**; c/o Smiths Medical ASD, Inc., 160 Weymouth Street, Rockland, MA 02370 (US). **CHHEDA, Harsh**; c/o Smiths Medical ASD, Inc., 160 Weymouth Street, Rockland, MA 02370 (US).

(74) Agents: **PATTERSON, James H.** et al.; Patterson Thuente Pedersen, P.A., 4800 IDS Center, 80 South Eighth Street, Minneapolis, MN 55402-2100 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: INTRAVENOUS CATHETER ASSEMBLY DESIGN

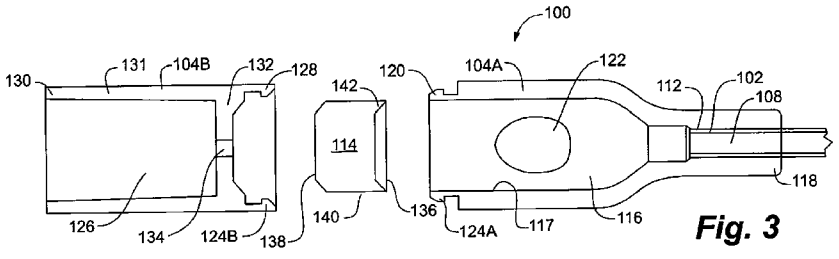


Fig. 3

(57) Abstract: An intravenous catheter assembly. The intravenous catheter assembly including a catheter and a catheter hub having a catheter hub body, a septum, and a septum retainer, the catheter hub body having an internal wall defining a transition step, wherein the septum is positioned such that a first end of the septum abuts up against the transition step, the septum retainer at least partially insertable within the catheter hub body and configured to secure the septum in position.

WO 2016/123616 A1

INTRAVENOUS CATHETER ASSEMBLY DESIGN

RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Application Nos. 62/109,673; 62/109,710; 62/109,715; 62/109,722; 62/109,735; 62/109,742; 62/109,745; 62/109,750; 62/109,755; 62/109,759; 62/109,766, all of which were filed January 30, 2015 and are hereby incorporated herein by reference in their entirety.

TECHNICAL FIELD

The present disclosure relates generally to intravenous catheters, and more particularly to an intravenous catheter assembly that minimizes the risk of blood exposure to a clinician.

BACKGROUND

Intravenous (IV) therapy is a versatile technique used for the administration of medical fluids to and withdrawal of bodily fluids from patients. IV therapy has been used for various purposes such as the maintenance of fluid and electrolyte balance, the transfusion of blood, the administration of nutritional supplements, chemotherapy, and the administration of drugs and medications. Fluids may be administered intravenously by injection through a hypodermic needle, or intermittently or continuously by infusion using a needle or catheter. The most common intravenous access method utilized by clinicians is the peripheral IV catheter.

A peripheral IV catheter is made of soft, flexible plastic or silicone, generally between fourteen to twenty-four gauge in size. In the conventional venipuncture procedure, a catheter is inserted into a vein in the patient's hand, foot, or the inner aspect of the arm or any vein in the body that will accept an IV catheter. In order to properly place the IV catheter into a patient's vein, a sharp introducer needle is used to puncture the skin, tissue, and vein wall to provide a path for placement of the catheter into the vein.

Referring to Figs. 1 and 2, a conventional IV catheter assembly 20 configured for insertion of an “over-the needle” catheter 22 is depicted. Catheter 22 generally has a first end 26 for insertion into a biological site, a second end 28 and a flexible wall defining a lumen extending therebetween. Frequently, the second end 28 of the catheter 22 is operably coupled to a catheter hub 34. The catheter 22 is operably coupleable to the needle assembly 20, in part by positioning the catheter 22 coaxially over a needle 24 of the safety needle assembly 20. The catheter 22 thus rides with the needle 24 through the skin, tissue, and vein wall and into the patient's vein. Once the catheter 22 has entered the patient’s vein, the catheter 22 can be

advanced further into the vein as desired and the needle 24 can be withdrawn from the catheter 22. The catheter 22 can then be secured into place on the patient and connected to an IV fluid supply line.

Various catheter insertion devices have been developed to provide a needle 24 for catheterization. In some cases, a conventional hollow hypodermic needle 24, such as that depicted in Figs. 1 and 2, is used to facilitate catheterization. One such example of this type catheter insertion device is marketed by Smiths Medical ASD, Inc. of St. Paul, MN, under the JELCO trademark, as described in U.S. Patent Nos. 7,291,130 and 8,257,322 (depicting an IV catheter insertion device marketed by Smiths Medical ASD, Inc. under the INTUITIV Safety IV Catheters trademark), both of which are incorporated by reference herein. In other cases, the catheter insertion device provides a safety needle assembly that functions to house the sharpened tip of the needle to reduce the likelihood of an inadvertent needle stick. Examples of this type of catheter insertion device are described in U.S. Patent No. 5,000,740 (depicting an IV catheter insertion device marketed by Smiths Medical ASD, Inc. under the PROTECTIV trademark), U.S. Patent No. 7,736,342 (depicting an IV catheter insertion device marketed by Smiths Medical ASD, Inc. under the VIAVALVE trademark), both of which are incorporated by reference herein.

SUMMARY OF THE DISCLOSURE

One embodiment of the present disclosure provides an intravenous catheter assembly including a catheter and a catheter hub. The catheter has a first end for insertion into a biological site, a second end and a flexible wall defining a lumen extending therebetween. The catheter hub has a first catheter hub portion, a second catheter hub portion, and a septum. The first catheter hub portion has a first end operably coupled to the second end of the catheter, a second end, and an internal wall defining a first internal fluid passageway therebetween. The internal wall of the first catheter hub portion further defines a side port in fluid communication with the internal fluid passageway. The second catheter hub portion has a first end operably coupled to the second end the first catheter hub portion, a second end, and an internal wall defining a second internal fluid passageway therebetween. The second catheter hub portion further has a baffle positioned within the internal fluid passageway between the first end and the second end of the second catheter hub portion. The septum is housed within the first internal fluid passageway of the first catheter hub portion and is retained in position by the baffle of the second catheter hub portion.

In some versions, the first catheter hub portion and the second catheter hub portion are operably coupled together via a circumferential tongue and groove assembly. In some versions,

the side port is configured to be connected to one or more lengths of hollow tubing so that the inside of the hollow tubing is in fluid communication with the internal fluid passageway. In some versions, the intravenous catheter assembly further includes hollow tubing connected to the side port, where the tubing includes a tube connector configured to be connected to an IV fluid supply line. In some versions, the septum is self-sealing, such that an insertion needle can pass therethrough and when withdrawn any void left by the withdrawn needle will seal to maintain fluid impermeability of the septum. In some versions, the septum has a first end positioned proximate to the side port that includes a peripheral chamfered lip configured to aid in enabling a fluid tight seal with the internal wall of the first catheter hub portion. In some versions, the catheter hub includes one or more wings extending radially outward from the catheter hub. In some versions, the wings are integrally molded onto the catheter hub. In some versions, the wings are coupled to the catheter hub via a collar that at least partially surrounds the catheter hub.

Another embodiment of the present disclosure provides an intravenous catheter assembly including a catheter and a catheter hub. The catheter has a first end for insertion into a biological site, a second end and a flexible wall defining a lumen extending therebetween. The catheter hub has a catheter hub body and a septum. The catheter hub body has a first end operably coupled to the second end of the catheter, a second end, and an internal wall defining an internal fluid passageway therebetween. The internal wall of the catheter hub body further defines a side port in fluid communication with the internal fluid passageway. The septum is fixedly coupled within the internal fluid passageway of the catheter hub body between the second end and the side port. The septum has a first end positioned proximate to the side port that includes a peripheral chamfered lip configured to aid in enabling a fluid tight seal with the internal wall of the first catheter hub portion.

In some versions, the side port is configured to be connected to one or more lengths of hollow tubing so that the inside of the hollow tubing is in fluid communication with the internal fluid passageway. In some versions, the intravenous catheter assembly further includes hollow tubing connected to the side port, wherein the tubing includes a tube connector configured to be connected to an IV fluid supply line. In some versions, the septum is self-sealing, such that an insertion needle can pass therethrough and when withdrawn any void left by the withdrawn needle will seal to maintain fluid impermeability of the septum. In some versions, the catheter hub includes one or more wings extending radially outward from the catheter hub. In some versions, the wings are integrally molded onto the catheter hub. In some versions, the wings are coupled to the catheter hub via a collar that at least partially surrounds the catheter hub.

Another embodiment of the present disclosure provides an intravenous catheter assembly including a catheter and a catheter hub. The catheter has a first end for insertion into a biological site, a second end and a flexible wall defining a lumen extending therebetween. The catheter hub has a catheter hub body, a septum, and a septum retainer. The catheter hub body has a first end operably coupled to the second end of the catheter hub body, a second end, and an internal wall defining an internal fluid passageway therebetween. The internal wall of the catheter hub body further defines a side port in fluid communication with the internal fluid passageway. The septum is positioned within the internal fluid passageway between the second end of the catheter hub body and the side port, wherein the septum has a first end positioned proximate to the side port. The septum retainer is configured to secure the septum in position within the internal fluid passageway. The septum retainer has a first end, a second end, and a wall defining an internal conduit therebetween. The septum retainer wall further defines one or more apertures in fluid communication with the internal fluid passageway of the catheter hub body, wherein the first end of the septum retainer is fixedly coupled to the first end of the catheter hub body, such that the lumen of the catheter is in fluid communication with the internal conduit of the septum retainer. The second end of the septum retainer includes a flared portion embedded within the septum.

In some versions, the side port is configured to be connected to one or more lengths of hollow tubing so that the inside of the hollow tubing is in fluid communication with the internal fluid passageway. In some versions, the intravenous catheter assembly further includes hollow tubing connected to the side port, wherein the tubing includes a tube connector configured to be connected to an IV fluid supply line. In some versions, the septum is self-sealing, such that an insertion needle can pass therethrough and when withdrawn any void left by the withdrawn needle will seal to maintain fluid impermeability of the septum. In some versions, the septum has a first end positioned proximate to the side port that includes a peripheral chamfered lip configured to aid in enabling a fluid tight seal with the internal wall of the first catheter hub portion. In some versions, the catheter hub includes one or more wings extending radially outward from the catheter hub. In some versions, the wings are integrally molded onto the catheter hub. In some versions, the wings are coupled to the catheter hub via a collar that at least partially surrounds the catheter hub.

Another embodiment of the present disclosure provides an intravenous catheter assembly having a two-way septum valve for controlling the flow of fluid in a closed system environment to and from a patient's blood vessel. The intravenous catheter assembly includes a catheter and a catheter hub. The catheter has a first end for insertion into a biological site, a second end and a flexible wall defining a lumen extending therebetween. The catheter hub has a catheter hub

body, a septum, and a septum retainer. The catheter hub includes a catheter hub body, a two-way septum valve and a septum retainer. The catheter hub body has a first end operably coupled to the second end of the catheter, a second end, and an internal wall defining a first internal fluid passageway therebetween. The internal wall of the catheter hub body further defines a transition step within the first internal fluid passageway between a smaller diameter portion of the first internal fluid passageway proximal to the first end and a larger diameter portion of the first internal fluid passageway proximal to the second end. The two-way septum valve has a first end and a second end, wherein the two-way septum valve is positioned within the first internal fluid passageway such that the first end of the septum abuts up against the transition step. The septum retainer is at least partially insertable within the first internal fluid passageway of the catheter hub body and is configured to secure the two-way septum valve in position within the first internal fluid passageway. The septum retainer has an outer wall shaped and sized to interlock with the internal wall of the catheter hub body, and an internal wall defining a second internal fluid passageway.

In some versions, when the catheter is inserted into a patient's blood vessel the first internal fluid passageway is in uninterrupted fluid communication with the patient's blood vessel having a venous blood pressure. In some versions, the two-way septum valve is shiftable between a first open position, a closed position and a second open position. In the first open position a first differential pressure between the venous blood pressure and pressure of fluid contained in the second internal fluid passageway enables a fluid flow towards the patient's blood vessel. The first differential pressure is met when the pressure of fluid contained in the second internal fluid passageway exceeds the venous blood pressure. In the closed position fluid flow through the fluid passageway of the two-way septum valve is inhibited. In the second open position a second differential pressure between the venous blood pressure and pressure of fluid contained in the second internal fluid passageway enables a fluid flow away from the patient's blood vessel. The second differential pressure is met when the venous blood pressure exceeds the pressure of fluid contained in the second internal fluid passageway by at least 8.5 inches of water. In some versions, the two-way septum valve is biased to the closed position.

In some versions, the second differential pressure is met when the venous blood pressure exceeds the pressure of fluid contained in the second internal fluid passageway by at least 22 inches of water. In some versions, the second differential pressure is met when the venous blood pressure exceeds the pressure of fluid contained in the second internal fluid passageway by at least 40 inches of water. In some versions, a valve opening of the two-way septum valve is in the form of at least one slit. In some versions, the valve opening of the two-way septum valve is in

the form of two crossed slits. In some versions, the two-way septum valve is substantially dome shaped. In some versions, the peak of the dome extends towards the first portion of the internal fluid passageway of the catheter hub. In some versions, the two-way septum valve includes a circumferential flange operably coupled to the catheter hub. In some versions, the circumferential flange is coupled to a central portion of the two-way septum valve by one or more circumferential living hinges. In some versions, the one or more circumferential living hinges pivot when the two-way septum valve shifts to the second open position. In some versions, the two-way septum valve includes two circumferential living hinges.

The summary above is not intended to describe each illustrated embodiment or every implementation of the present disclosure. The figures and the detailed description that follow more particularly exemplify these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure can be more completely understood in consideration of the following detailed description of various embodiments of the disclosure, in connection with the accompanying drawings, in which:

Fig. 1 is a perspective view depicting a conventional IV needle assembly with a catheter positioned over a needle.

Fig. 2 is a perspective view depicting the conventional IV needle assembly of Fig. 1 with the catheter removed from the needle.

Fig. 3 is a fragmentary exploded sectional view depicting a first embodiment of an intravenous catheter assembly in accordance with an embodiment of the disclosure.

Fig. 4 is a fragmentary sectional view depicting the intravenous catheter assembly of Fig. 3 in an assembled state.

Fig. 5 is an exploded perspective view depicting a catheter hub in accordance with an embodiment of the disclosure.

Fig. 6 is a fragmentary cross sectional view depicting an intravenous catheter assembly operably coupled to a catheter insertion device in accordance with a second embodiment of the disclosure.

Fig. 7 is a fragmentary cross sectional view depicting the intravenous catheter assembly of Fig. 6.

Fig. 8 is a perspective view depicting the intravenous catheter assembly of Fig. 7, including views of internal parts.

Fig. 9A is a fragmentary cross sectional view depicting an intravenous catheter assembly with a two-way septum valve operably coupled to a catheter insertion device in accordance with an embodiment of the disclosure.

Fig. 9B is a fragmentary cross sectional view depicting the intravenous catheter assembly of Fig. 9A, with the two-way septum valve in a first open position.

Fig. 9C is a fragmentary cross sectional view depicting the intravenous catheter assembly of Fig. 9A, with the two-way septum valve in a closed position.

Fig. 9D is a fragmentary cross sectional view depicting the intravenous catheter assembly of Fig. 9A, with the two-way septum valve in a second open position.

Fig. 10 is a cross sectional view depicting a two-way septum valve in place in an overmolded ring in accordance with an embodiment of the disclosure.

Fig. 11 is a perspective view depicting a two-way septum valve in accordance with an embodiment of the disclosure.

Fig. 12 is a perspective view depicting an intravenous catheter assembly including tubing, a clamp and a tube connector in accordance with an embodiment of the disclosure.

Fig. 13A is a fragmentary side view depicting a tube connector coupled with tubing in accordance with an embodiment of the disclosure.

Fig. 13B is a cross sectional view depicting the tube connector of Fig. 143 in a closed configuration.

Fig. 13C is a fragmentary cross sectional view depicting the tube connector of Fig. 13A in an open configuration, in conjunction with an IV fluid supply line.

Fig. 14A is an exploded side view depicting a first catheter insertion device for use with an intravenous catheter assembly (not shown) in accordance with an embodiment of the disclosure.

Fig. 14B is an exploded top view depicting the first catheter insertion device of Fig. 14A.

Fig. 15 is a perspective view depicting a first catheter insertion device operably coupled to an intravenous catheter assembly in accordance with an embodiment of the disclosure.

Fig. 16A is a perspective view depicting a first catheter insertion device and an intravenous catheter assembly in accordance with an embodiment of the disclosure, wherein the first catheter insertion device and intravenous catheter assembly are separated from one another.

Fig. 16B is a perspective view depicting the first catheter insertion device and the intravenous catheter of Fig. 16A, wherein the first catheter insertion device and intravenous catheter assembly are operably coupled to one another.

Fig. 17A is a top perspective view depicting a second catheter insertion device and an intravenous catheter assembly in accordance with an embodiment of the disclosure, wherein the second catheter insertion device is in a first position.

Fig. 17B is a top perspective view depicting the second catheter insertion device and the intravenous catheter assembly of Fig. 17A, wherein the second catheter insertion device is in a second position and separated from the intravenous catheter.

Fig. 18A is a bottom perspective view depicting a second catheter insertion device and an intravenous catheter assembly in accordance with an embodiment of the disclosure, wherein the second catheter insertion device is in a first position.

Fig. 18B is a bottom perspective view depicting the second catheter insertion device and the intravenous catheter of Fig. 18A, wherein the second catheter insertion device is in a second position.

Fig. 19 is a perspective view depicting a third catheter insertion device operably coupled to an intravenous catheter assembly in accordance with an embodiment of the disclosure.

Fig. 20A is a perspective view depicting a catheter insertion device and an intravenous catheter assembly in accordance with an embodiment of the disclosure, wherein the catheter insertion device is in a first position.

Fig. 20B is a perspective view depicting the catheter insertion device and the intravenous catheter assembly of Fig. 20A, wherein a cap of the third catheter insertion device has been removed.

Fig. 20C is a perspective view depicting the catheter insertion device and the intravenous catheter assembly of Fig. 20A, wherein the third catheter insertion device is in a second position, with the needle housing separated from the catheter hub 304.

While embodiments of the disclosure are amenable to various modifications and alternative forms, specifics thereof shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the appended claims.

DETAILED DESCRIPTION

Referring to Figs. 1 and 2, a conventional IV catheter assembly 20 is depicted. Details of the conventional IV catheter assembly 20 are described in the Background section above.

First Embodiment

Referring to Figs. 3-5, an intravenous catheter assembly 100 according to a first embodiment of the disclosure is depicted. Intravenous catheter assembly 100 generally includes a catheter 102 and a catheter hub 104. Catheter hub 104 can be comprised of a first catheter hub portion 104A, a second catheter hub portion 104B, and a valve and/or septum 114.

First catheter hub portion 104A can have a first end 118, a second end 120, and an internal wall 117 defining a first internal fluid passageway 116 therebetween. In one version, the internal wall 117 further defines a side port 122. In other versions, the intravenous catheter assembly 100 does not include a side port. In one version, the first end 118 is operably coupled to the second end 112 of the catheter 102. For example, a portion 112 of catheter 102 can extend into and overlap with first catheter hub portion 104A so that the catheter lumen 108 is in fluid communication with the first internal fluid passageway 116.

In one version, the side port 122 is in fluid communication with first internal fluid passageway 116. In one version, the side port 122 extends away from the first internal fluid passageway 116 at an oblique angle to the catheter lumen 108. Side port 122 can provide a connection point to one or more lengths of a tubing 544 (as depicted for example in Fig. 12), so that the inside of the tubing 544 is in fluid communication with the internal fluid passageway 116.

The second catheter hub portion 104B can have a first end 128 operably coupled to the second end 120 the first catheter hub portion 104A, a second end 130, and an internal wall 131 defining a second internal fluid passageway 126 therebetween. In one version, the second end 120 of first catheter hub portion 104A and the first end 128 of the second catheter hub portion 104B can each define a respective first and second portion of a coupling 124A/B, such that second portion 124B is configured to selectively couple with first portion 124A. For example, in one version, each portion of the coupling 124 is configured with a circumferential tongue, a circumferential groove, or both a tongue and a groove to lock one portion of the coupling with the other portion. In other versions, respective portions of coupling can be friction fit, screwed, ultrasonically welded, adhered, or otherwise pieced together to complete coupling 124. In this manner, first catheter hub portion 104A can be locked together with second catheter hub portion 104B during assembly.

In one version, the second catheter hub portion 104B further has a baffle 132 positioned within the second internal fluid passageway 126 between the first end 128 and the second end 130 of the second catheter hub portion 104B. In one version, the baffle 132 can include an aperture 134 sized to enable a needle to pass there through.

Septum 114 can have a first end 136, a second end 138 and an outer perimeter 140. In one version, the septum 114 is constructed of a flexible, fluid impermeable material. For example, in one version, septum 114 is constructed of silicon. In one version, the septum 114 is self-sealing, so that when a needle is withdrawn through septum 114, any void left by the withdrawn needle will close and the septum 114 will maintain its fluid impermeability.

In one version, the septum 114 is positioned partially within the first internal fluid passageway 116 of first catheter hub portion 104A, at least partially within the second end 120. Septum 114 can be constrained about its perimeter by internal wall 117 of first catheter hub portion 104A. That is, septum 114 is sized to be received within the first internal fluid passageway 116 to create a fluid tight seal with internal wall 117 to guard against fluid within the lumen 108 or first internal fluid passageway 116 from escaping through the second end 120 of first catheter hub portion 104A. In one version, septum 114 is adhered to the internal wall 117 of first internal fluid passageway 116, so as to constrain septum 114 axially and facilitate a radial fluid tight seal with internal wall 117. Septum 114 is constrained on its second end 138 by baffle 132. Accordingly, in one version, the septum 114 is positioned within the first internal fluid passageway 116 and constrained by the coupling of first catheter hub portion 104A to second catheter hub portion 104B. In another version, a feature such as a groove, step or baffle in the first catheter hub portion 104A can constrain septum 114.

In one version, the first end 136 of septum 114 includes a peripheral chamfered lip 142. Peripheral chamfered lip 142 is configured to aid in enabling a fluid tight seal with internal wall 117. In particular, the flexibility of septum 114 and the structure of peripheral chamfered lip 142 enable this portion of the septum 114 to deform under the internal fluid pressure of first internal fluid passageway 116 to further aid in the creation of a fluid tight seal with internal wall 117. In one version, the second end 138 of septum is also chamfered to aid in construction by reducing the possibility that excess septum material will get caught in the coupling 124 when first catheter hub portion 104A is mated with second catheter hub portion 104B. In other versions, peripheral chamfered lip 142 can be filleted, or there can be no lip at all.

Second Embodiment

Referring to Figs. 6-8, an intravenous catheter assembly 200 according to a second embodiment of the disclosure is depicted. Intravenous catheter assembly 200 generally includes a catheter 202 and a catheter hub 204. Catheter hub 204 can be comprised of a catheter hub body 205, a valve and/or septum 214, and a valve and/or septum retainer 215.

Catheter hub body 205 can have a first end 218, a second end 220, and an internal wall 217 defining a first internal fluid passageway 216 therebetween. In one version, the internal wall 217 further defines a side port 222. In other versions, the intravenous catheter assembly 200 does not include a side port. In one version, the first end 218 is operably coupled to the second end 212 of the catheter 202. For example, a portion of catheter 202 can extend into and overlap with catheter hub body 205 so that the catheter lumen 208 is in fluid communication with the internal fluid passageway 216.

In one version, the side port 222 is in fluid communication with first internal fluid passageway 216. In one version, the side port 222 extends away from the first internal fluid passageway 216 at an oblique angle to the catheter lumen 208. Side port 222 can provide a connection point to one or more lengths of a tubing 544 (as depicted for example in Fig. 12), so that the inside of the tubing 544 is in fluid communication with the internal fluid passageway 216.

Septum 214 can have a first end 236, a second end 238 and an outer perimeter 240. In one version, the septum 214 is constructed of a flexible, fluid impermeable material. For example, in one version, septum 214 is constructed of silicone, polyisopren, or the like. In one version, the septum 214 is self-sealing, so that when a needle 160 is withdrawn through septum 214, any void left by the withdrawn needle will close and the septum 214 will maintain its fluid impermeability.

In one version, the first end 236 of septum 214 includes a peripheral chamfered lip 242. Peripheral chamfered lip 242 is configured to aid in enabling a fluid tight seal with internal wall 217. In particular, the flexibility of septum 214 and the structure of peripheral chamfered lip 242 enable this portion of the septum 214 to deform under the internal fluid pressure of first internal fluid passageway 216 to further aid in the creation of a fluid tight seal with internal wall 217. In other versions, peripheral chamfered lip 242 can be filleted, or there can be no lip at all.

In one version, the septum 214 is positioned partially within the internal fluid passageway 216 proximal to side port 222. Septum 214 can be constrained about its outer perimeter 240 by internal wall 217 of catheter hub body 205. In particular, in one version, the septum 214 is sized to be within the first internal fluid passageway 216 to create a fluid tight seal with internal wall 217 to inhibit fluid within the lumen 208 or first internal fluid passageway 216 from escaping through the second end 220 of catheter hub 204. Septum 214 can be axially constrained by septum retainer 215. As shown, an outer diameter of the outer perimeter 240 of the septum may be out of contact with the internal wall 217 or in contact but at a lower pressure

level than portions of the septum 214 proximal to the second end 238. This may reduce the axial pressure on the needle in order to reduce needle withdrawal forces.

Septum retainer 215 can be configured to secure the septum 214 in position within the internal fluid passageway 216. In one version, the septum retainer 215 has a first end 219, a second end 221, and a wall 224 defining an internal conduit 227 therebetween. Internal conduit 227 can be in fluid communication with catheter lumen 108. In one version, the wall 224 can further define one or more apertures 223 in fluid communication with the internal fluid passageway 216 of the catheter hub body 205, thereby enabling fluid to flow pass through lumen 208, through one or more apertures 223, and into internal fluid passageway 216.

In one version, the first end 219 of the septum retainer 215 is operably coupled to the first end 218 of the catheter hub body 205, such that the lumen 208 of the catheter 202 is in fluid communication with the internal conduit 227 of the septum retainer 215. In one version, the internal conduit 227 can be tapered so that the diameter of the portion of internal conduit 227 proximate to the connection to catheter 202 is approximately equal to the diameter of the lumen 208. In one version, the first end 219 of septum retainer 215 is press fit into catheter hub 204. In other versions, septum retainer 215 is fixedly coupled to catheter hub 204 by adhesive, ultrasonic welding, or another method.

In one version, the second end 221 of the septum retainer 215 can include a flared portion 225 embedded within the septum 214, so that septum 214 is fixedly coupled to catheter hub body 205 by septum retainer 215.

Septums and Valves

As depicted in Figs. 3-8, the septum 114, 214 can include a peripheral chamfered lip configured to aid in enabling a fluid tight seal with internal wall. It is to be appreciated, however, that the septum 114, 214 can have other configurations.

Referring to Figs. 9A-11, in some versions, catheter hub 104 and 204 (or other types of catheter hubs) can include a two-way septum valve 387.

In some versions, a two-way septum valve 387 can have a first end 388 and a second end 389, wherein the two-way septum valve 387 is positioned within the first internal fluid passageway 316 such that the first end 388 of the two-way septum valve 387 abuts up against the transition step 307. In some versions, septum retainer 315 is at least partially insertable within the first internal fluid passageway 316 of the catheter hub body 305 and is configured to secure the two-way septum valve 387 in position within the first internal fluid passageway 316. For example, the septum retainer 315 can have an outer wall 324 shaped and sized to interlock with

the internal wall 317 of the catheter hub body 305. The septum retainer 315 can also have an internal wall 323 defining a second internal fluid passageway 326.

The two-way septum valve 387 can be positioned between the first internal fluid passageway 316 and the second internal fluid passageway 326, and can be configured to control the flow of fluid between the two internal fluid passageways. When the catheter 302 is inserted into a patient's blood vessel the first internal fluid passageway 316 is in uninterrupted fluid communication with the patient's blood vessel, wherein the patient's blood vessel has a venous blood pressure.

In one version, the two-way septum valve 387 is biased to a closed position, in which the flow of fluid between the first internal fluid passageway 316 and the second internal fluid passageway 326 is inhibited, but is configured to enable a needle 160 of a catheter insertion device to pass therethrough (as depicted in Fig. 9A). The two-way septum valve 387 can additionally be configured to shift between various open and closed positions based on the differential pressure between the first internal fluid passageway 316 and the second internal fluid passageway 326. For example, in one version, the two-way septum valve 387 is shiftable between a first open position (as depicted in Fig. 9B), a closed position (as depicted in Fig. 9C) and a second open position (as depicted in Fig. 9D).

In the first open position, a first differential pressure between the venous blood pressure and pressure of fluid contained in the second internal fluid passageway 326 enables a fluid flow towards the patient's blood vessel. For example, the first differential pressure is met when the pressure of fluid contained in the second internal fluid passageway 326 exceeds the venous blood pressure. In the closed position, fluid flow through the fluid passageway of the two-way septum valve is inhibited. In the second open position, a second differential pressure between the venous blood pressure and pressure of fluid contained in the second internal fluid passageway 326 enables a fluid flow away from the patient's blood vessel. For example, the second differential pressure is met when the venous blood pressure exceeds the pressure of fluid contained in the second internal fluid passageway by at least 8.5 inches of water. In some versions, the second differential pressure is met when the venous blood pressure exceeds the pressure of fluid contained in the second internal fluid passageway 326 by at least 22 inches of water or at least 40 inches of water.

Referring to Fig. 10, a cross-sectional view of an example embodiment of two-way septum valve 387 is depicted. Two-way septum valve 387 can be fixed to an overmolded plastic ring 390. Overmolded plastic ring 390 generally includes a cylindrical portion 391 and a valve engaging portion 392. When the two-way septum valve 387 is supported in the overmolded

plastic ring 390, the overall diameter of the two-way septum valve 387 is reduced, thus more readily permitting accommodation within catheter hub 104 and 204.

Referring to Fig. 11, the shape of two-way septum valve 387 is depicted as being generally circular; this, however, should not be considered limiting, as other shapes can be used according to the disclosure. In one version, the two-way septum valve 387 is a unitary structure, having a central portion 393, a circumferential flange 394, a flexible membrane 395 having one or more valve openings 396, and one or more circumferential living hinges 397. In one version, there are two circumferential living hinges 379A and 379B. First living hinge 379A is located between circumferential flange 394 and support. Second living hinge 379B is located on the central portion 393 between support and flexible membrane 395.

As discussed herein, two-way septum valve 387 has a differential pressure response in that the pressure required to open two-way septum valve 387 in a first direction (enabling fluid flow towards the patient's blood vessel) is substantially less than the pressure required to open two-way septum valve 387 in the second direction (enabling fluid flow from the patient's blood vessel). Accordingly, two-way septum valve 387 inhibits leakage of fluid under normal blood pressure while permitting IV fluid to flow, as well as enabling the aspiration of blood through two-way septum valve 387 either by application of a reduced or negative pressure of fluid contained in the second internal fluid passageway 326, or the or by insertion of a needle through valve opening 396.

In one version, the central portion 393 is substantially dome shaped having a dome peak 399. In one version, the one or more valve openings 396 are in the form of at least one of an aperture, a single slit, a tri-slit, and a cross slit. In one version, the dome shaped central portion 393 has an opening pressure in the first direction of about 15 mm of mercury which is equivalent to 0.3 pounds per square inch, and an aspiration pressure in the second direction of approximately 300 mm mercury or about 6 pounds per square inch. In one version, the two-way septum valve 387 has an infusion flow rate at 40 inches of water pressure in the first direction of approximately 4,500 ml/hour (75ml/min).

Universal Wings

Referring to Fig. 12, in some versions, catheter hub 104, 204 and 304 can include one or more wings 484 that extend radially from catheter hub 304. In one version, the one or more wings 484 generally extend outwardly from the central axis of the catheter 302 and catheter hub 304, so as to provide an adequate gripping surface for a user or clinician, as well as an extended

surface for aid in securing catheter hub 304 in place on the patient. In one version, the one or more wings 484 are integrally molded onto a portion of catheter hub 304.

Universal Tubing, Clamp and Tube Connector

Referring to Figs. 12-13C, in some versions, intravenous catheter assembly 100, 200 and 300 include at least one of a hollow tubing extension 544, a tubing clamp 546 and a tube connector 548. In one version, the hollow tubing 544 can be substantially transparent or translucent to enable the observation of fluid within the hollow tubing 544. In one version, the tube clamp 546 is constructed of a resilient material that can be deformed to selectively occlude hollow tubing 544 to restrict the passage of fluid.

Tube connector 548 is configured to connect hollow tubing 544 to an IV fluid supply line 558. In one version, the tube connector 548 is a luer lock. In another version, tube connector 548 is a needle-free connector, for example the connector described in U.S. Pat. No. 7,713,248 (depicting a needle-free connector marketed by ICU Medical, Inc. under the Clave® trademark), which is hereby incorporated by reference. In one version, the tube connector 548 is comprised of a conical internal conduit 550 with one or more fluid path windows 552, a flexible compression seal 554 capable of selectively covering the conduit 550, and a housing 556 substantially surrounding conduit 550 and compression seal 554. Tube connector 548 can guard against contamination of the fluid path. As depicted in Fig. 13B, when compression seal 554 is in its uncompressed state it extends over the fluid path window 552 of conduit 550, thereby creating a fluid seal to restrict fluid from escaping from tubing 544. Conversely, as depicted in Fig. 13C, when a portion of an IV fluid supply line 558, such as a portion of a luer connector, is inserted into housing 556, compression seal 545 is shifted to a compressed state, thereby exposing the fluid path windows 552 to the fluid path of the IV fluid supply line 558. In one version, the tube connector 548 further includes a venting adapter (not shown) to vent trapped gas from tubing 544. Venting adapter can be comprised of a material that enables air to vent as blood or fluid fills the tubing 544, but inhibits the fluid from passing through the tube connector 548.

Connection to Various Catheter Insertion Devices

Referring to Figs. 14A-20C in some versions, the second end 130 of second catheter hub portion 104B, or the second end 220 and 320 of catheter hub bodies 205 and 305 can be configured to receive a portion of a catheter insertion device 600, 700 and 800. In some versions, second end 130, 220 is tapered to create a friction fit with needle insertion device 600, 700 and

800, thereby selectively coupling catheter hub 104, 204 and 304 to needle insertion device 600, 700 and 800.

First Catheter Insertion Device

Referring to Figs. 14A-16B, in some versions, catheter insertion device 600 generally includes needle 660 and needle hub 662. Needle 660 can be a thin walled hollow tube, defining a lumen 663 along its central axis, with a first end 664 and a second end 666. First end 664 can be defined by a sharpened tip 668 to reduce the insertion force required to penetrate the skin of a patient. Second end 666 can be fixedly coupled to needle hub 662.

In one version, needle hub 662 has a first end 670 and a second end 672. First end 674 of needle hub 662 can be configured with a tapered blunt tip sized to create a friction fit with a portion of catheter hub 304. In one version, the needle hub 662 includes a flash chamber 674.

Flash chamber 674 can be configured as a cavity in fluid communication with the lumen 663 of hypodermic needle 660 opposite sharpened tip 668. Flash chamber 670 functions in cooperation with other elements of the catheter insertion device 600 so that blood from the user visibly flows into the flash chamber 674 to positively indicate when the needle 660 has pierced a vein. In one version, the flash chamber 674 can be constructed of a transparent or translucent material to enable a clinician to visually see when fluid enters the flash chamber 674. The rear 676 of flash chamber 674 can be plugged with a microporous flash plug 678. Flash plug 678 can be comprised of a material that enables air to vent from the flash chamber 674 as fluid fills the chamber, but inhibit the fluid from passing from the flash chamber 674. In other versions, plug 678 can be non-microporous.

In some versions, flash chamber 674 can further include a diagnostic sampling port configured to enable selective access to fluid contained within flash chamber 674. Various needle assemblies having diagnostic sampling ports are disclosed in a concurrently filed application entitled "Needle Assembly with Diagnostic Analysis Provisions," Attorney Docket No. 4176.178US02, which is incorporated by reference herein.

In one version, needle hub 662 can include at least one wing 680 that extends outwardly from the needle hub 662. In one version, the wing 680 is generally longitudinally aligned with the central axis of the needle 660. Wing 680 can be configured with sufficient surface area to enable a user or clinician to easily grasp and maneuver the catheter insertion device 600, while providing the user or clinician an unobstructed view of the flash chamber 674 during catheterization. In one version, the wider grip portion 682 of wing 680 can be provided for this purpose. In one version, for better control of the catheter assembly, wing 680 can extend forward

of the first end 670 of needle hub 662 to overlap with the needle 660. In one version, the wing 680 and the rest of needle hub 662 are integrally formed of a plastic material. In another version, wing 680 is formed as an extension of flash plug 678.

Second Catheter Insertion Device

Referring to Figs. 12 and 17A-18B, in some versions, catheter insertion device 700 generally includes needle housing 718 and needle hub 720 coupled to needle 760. Needle housing 718 has a first end 724 and a second end 726. First end 724 of needle housing 718 can be configured with a tapered blunt tip sized to create a friction fit with a portion of catheter hub 104, 204 and 304. In some versions, first end 724 can be at least partially inserted into a socket defined in catheter hub 104, 204 and 304. First end 724 can further define an aperture 728 through which needle 760 can pass.

Needle hub 720, which in some versions can be fixedly coupled to the needle 760, can be slideably coupled to the needle housing 718. For example, in one version, the needle hub 720 can have a "C" shaped cross section 730 conformed to fit around the outer surface of the needle housing 718 in a manner that inhibits the needle hub 720 from readily separating from the needle housing 718, yet enables the needle hub 720 to slide along the longitudinal axis of the needle housing 718 with minimal resistance. In a further version, the needle hub 720 can be configured to slide along a groove 734 defined in the needle housing 718 to restrict the needle hub 720 from rotating about the longitudinal axis of the needle housing 718. In one version, the needle hub 720 can include a protuberance 736 (as depicted in Figs. 18A-B) configured to fit within the groove 734 of the needle housing 718, thereby enabling linear movement of the needle hub 720 substantially parallel to the longitudinal axis of the needle housing 718, but restricting the rotational movement of the needle hub 720 relative to the needle housing 718.

In one version, the needle hub 720 is slideable between a first position (as depicted in Figs. 17A and 18A) and a second position (as depicted in Figs. 17B and 18B). In the first position, a portion of the needle 760 extends through needle housing aperture 728, the catheter hub 304 and catheter lumen 308, such that the sharpened tip 768 of the needle 760 protrudes slightly beyond first end 310 of catheter 302. In the second position, the needle 760 is withdrawn from the catheter lumen 308 and the catheter hub 304 and the sharpened tip 768 is sheathed by needle housing 718 in a manner intended to reduce or eliminate the likelihood of an inadvertent needle stick. In some versions, catheter insertion device 700 can include a catheter hub coupling and release mechanism configured to couple to catheter hub 104, 204, or 304 in the first position, and release from catheter hub 104, 204, 304 in the second position. Various catheter hub

coupling and release mechanism are disclosed in a concurrently filed application entitled "Releaseable Catheter Hub Retainer," Attorney Docket No. 4176.180US02, which is incorporated by reference herein.

In one version, the needle 760 can be locked in position relative to the needle housing 718. Several different types of locking mechanisms can be used for this purpose. For example, in one version, the groove 734 of the needle housing 718 can have a bottleneck 738 defined in it, where the bottleneck 738 portion of groove 734 generally has a narrower width than the rest of groove 734. Protuberance 736 of needle hub 720 can be triangular or wedge-like in shape (as depicted in Figs. 18A-B) where the apex of the wedge faces the bottleneck 738 when in the first position. When an external force is applied to the needle hub 720 in an effort to slide it into the second position, the apex of the wedge of the protuberance 736 comes into contact with the bottleneck 738. Bottleneck 738, which can have a width narrower than that of the protuberance 736 will initially resist movement of the protuberance 736 through the bottleneck 738. However, with sufficient force the wedge-shape protuberance 736 will cause the bottleneck 738 to temporarily deform, thereby enabling the protuberance 736 to pass through the bottleneck 738. Thereafter the protuberance 736 will be unable to pass back through the bottleneck 738 in the opposite direction, and the needle 760 will be locked in position relative to the needle housing 718.

In one version, the movable element 720 further includes a flash chamber 774. Flash chamber 774 can be configured as a cavity in fluid communication with the lumen of hypodermic needle 760 opposite sharpened tip 768. In one version, the flash chamber 774 can be constructed of a transparent or translucent material to enable a clinician to visually see when fluid enters flash chamber 774. The rear 726 of flash chamber 774 can be plugged with a microporous flash plug 778. Flash plug 778 can be comprised of a material that enables air to vent from the flash chamber 774 as fluid fills the chamber, but inhibits the fluid from passing from the flash chamber 774.

Third Catheter Insertion Device

Referring to Figs. 19-20C, in some versions, catheter insertion device 800 further includes cap 880. Cap 880 is configured to cover a portion of the needle housing 818 proximate to the second end 826 to reduce the likelihood of unwanted or uncontrolled movement of the needle housing 818 relative to the needle hub 820 by the user or clinician's palm or inside of their hand during catheter insertion.

In one version, the cap 880 is tubular in shape and has a first end 882 and a second end 884. In one version, the cap 880 tapers slightly from the first end 882 to the second end 884. Second end 884 can include a wall 886 extending radially inward to effectively close off the second end 884. In one version, the wall 886 can include an aperture 888 for venting of the interior of the cap 880.

First end 882 can be coupled to the needle hub 820, so as to move along with the needle hub 820 and cover a portion of the needle housing 818. In one version, the needle hub 820 includes an arcuate rib 890, and the cap 880 includes a recess or groove 892 sized to receive the rib 890, so that the cap 880 can be coupled to the moveable element 820 by joining the rib 890 to the groove 892. In other versions, the cap 880 and the needle hub 820 can be attached by adhesive, ultrasonic bonding, or any other method.

In one version, the needle 860 includes a notch 894 defined proximate to the sharpened tip 868. Notch 894 can be in fluid communication with the needle lumen 863. In one version, the catheter 302 is constructed of a transparent or translucent material, so that blood or other body fluid can be visible in the notch 894 when the needle 860 has pierced a vein.

In some versions, catheter insertion device 600, 700, and 800 can include at least one of a protective needle sheath, a self-contained antiseptic swab, and a tourniquet for treatment and/or preparation of a biological site of a patient. Various catheter insertion devices having protective needle sheaths, a self-contained antiseptic swabs, and/or tourniquets are disclosed in a concurrently filed application entitled "Antiseptic Sheath with Site Preparation Provisions," Attorney Docket No. 4176.179US02, which is incorporated by reference herein.

Operation of the Intravenous Catheter Assembly

In operation, placement of intravenous catheter assembly 100, 200, or 300 generally includes preparation of the biological site of the patient. Often a tourniquet is applied proximal to the biological site and a variety of techniques can be used to dilate the patient's vein. While wearing disposable gloves, the clinician cleanses the biological site and a vein is retracted or anchored by placing a thumb over the vein about fifty to seventy-five mm distal to the site. The needle 760 for instance and catheter 302 for instance are introduced into the vein by inserting the bevel of the sharpened tip 768 into the vein at about a twenty to thirty degree angle with the bevel facing up in order to pierce one wall of the vein. In some versions, during this process the clinician grips the needle hub 720 for optimum control.

If successful, blood from the vein will flow through the lumen of the needle 760 and into the flashback chamber 774, thereby indicating that the vein has been entered. To finish

placement, the safety catheter assembly 600, 700 or 800 is lowered towards the skin to decrease the entry angle, and the catheter 302 is advanced slightly into the vein. The needle 760 is loosened and the catheter 302 is gently advanced farther up into the vein until the catheter hub 304 is against the biological site.

The tourniquet is loosened and the needle 760 is withdrawn from the catheter 302. As needle 760 is withdrawn, the sharpened tip 768 is withdrawn through catheter lumen 308, internal fluid passageway 316 and valve or septum 314. As the sharpened tip 768 passes through the valve or septum 314, the self-sealing nature of the valve or septum 314 closes any void left by the needle to create a fluid tight barrier.

The catheter hub 304 can be secured to the biological site by gauze and adhesive tape. In some versions, the added surface area of the catheter hub wings 484 is used when securing the catheter 302 to the biological site. The various versions of the disclosure enable an IV fluid supply line 558 to be connected prior to catheterization. Once the catheter assembly 100, 200 or 300 is in place, clamp 546 can be manipulated as desired to open or close the fluid path to IV fluid supply line 558.

Persons of ordinary skill in the relevant arts will recognize that embodiments may comprise fewer features than illustrated in any individual embodiment described above. The embodiments described herein are not meant to be an exhaustive presentation of the ways in which the various features may be combined. Accordingly, the embodiments are not mutually exclusive combinations of features; rather, embodiments can comprise a combination of different individual features selected from different individual embodiments, as understood by persons of ordinary skill in the art. Moreover, elements described with respect to one embodiment can be implemented in other embodiments even when not described in such embodiments unless otherwise noted. Although a dependent claim may refer in the claims to a specific combination with one or more other claims, other embodiments can also include a combination of the dependent claim with the subject matter of each other dependent claim or a combination of one or more features with other dependent or independent claims. Such combinations are proposed herein unless it is stated that a specific combination is not intended. Furthermore, it is intended also to include features of a claim in any other independent claim even if this claim is not directly made dependent to the independent claim.

Any incorporation by reference of documents above is limited such that no subject matter is incorporated that is contrary to the explicit disclosure herein. Any incorporation by reference of documents above is further limited such that no claims included in the documents are incorporated by reference herein. Any incorporation by reference of documents above is yet

further limited such that any definitions provided in the documents are not incorporated by reference herein unless expressly included herein.

For purposes of interpreting the claims, it is expressly intended that the provisions of Section 112, sixth paragraph of 35 U.S.C. are not to be invoked unless the specific terms "means for" or "step for" are recited in a claim.

CLAIMS

What is claimed is:

1. An intravenous catheter assembly, comprising:

a catheter having a first end for insertion into a biological site, a second end and a flexible wall defining a lumen extending therebetween; and

a catheter hub including —

a catheter hub body having a first end operably coupled to the second end of the catheter, a second end, and an internal wall defining an internal fluid passageway therebetween, the internal wall further defining a transition step within the internal fluid passageway between a smaller diameter portion of the internal fluid passageway proximal to the first end and a larger diameter portion of the internal fluid passageway proximal to the second end;

a septum having a first end and a second end, wherein the septum is positioned within the internal fluid passageway such that the first end of the septum abuts up against the transition step; and

a septum retainer at least partially insertable within the internal fluid passageway of the catheter hub body and configured to secure the septum in position within the internal fluid passageway, the septum retainer having a outer wall shaped and sized to interlock with the internal wall of the catheter hub body.

2. The intravenous catheter assembly of claim 1, wherein the internal wall of the catheter body further defines a side port, wherein the side port is in fluid communication with the internal fluid passageway.

3. The intravenous catheter assembly of claim 2, wherein the side port is configured to be connected to one or more lengths of hollow tubing so that the inside of the hollow tubing is in fluid communication with the internal fluid passageway.

4. The intravenous catheter assembly of claim 3, further including hollow tubing connected to the side port, the tubing including a tube connector configured to be connected to an IV fluid supply line.

5. The intravenous catheter assembly of claim 1, wherein the septum has an internal surface defining a slit passing from the first end to the second end, the slit configured to enable an insertion needle to pass therethough.

6. The intravenous catheter assembly of claim 1, wherein the septum has an internal surface defining an aperture passing from the first end to the second end, the aperture configured to enable an insertion needle to pass therethough.

7. The intravenous catheter assembly of claim 1, wherein the septum has an internal surface defining an aperture originating at the first end and passing through a first thickness, and a slit originating at the termination of the aperture and passing through the second end, the aperture and slit together configured to enable an insertion needle to pass therethough.

8. The intravenous catheter assembly of claim 1, wherein the catheter hub includes one or more wings extending radially outward from the catheter hub.

9. The intravenous catheter assembly of claim 8, wherein the wings are integrally molded onto the catheter hub.

10. The intravenous catheter assembly of claim 8, wherein the wings are coupled to catheter hub via a collar that at least partially surrounds the catheter hub.

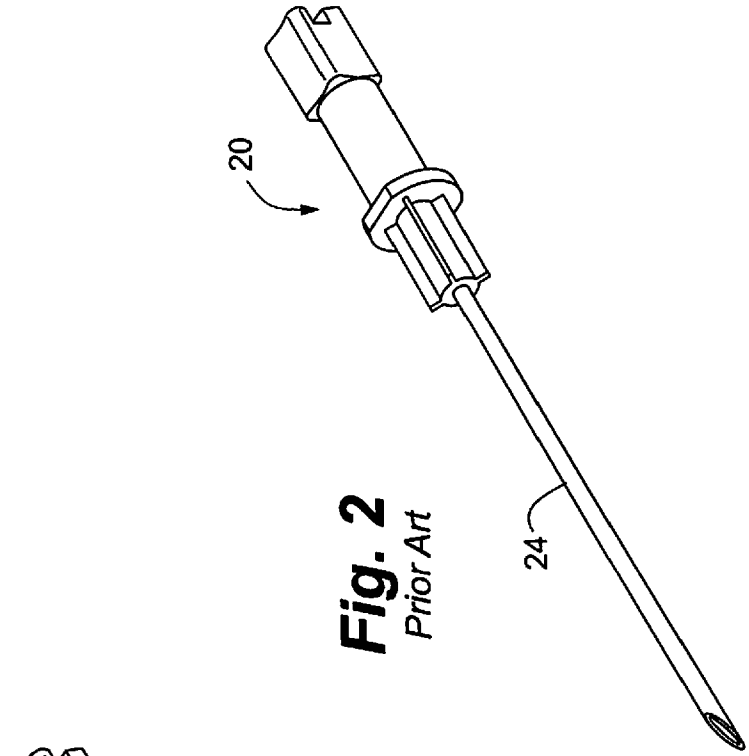


Fig. 2
Prior Art

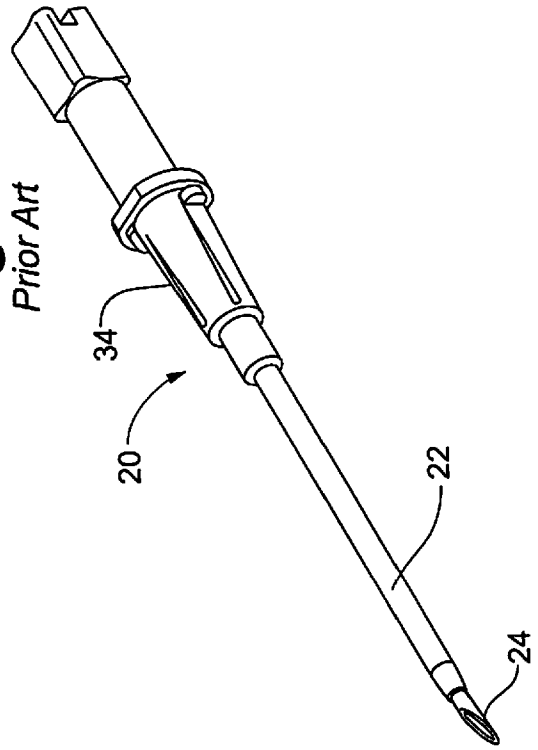


Fig. 1
Prior Art

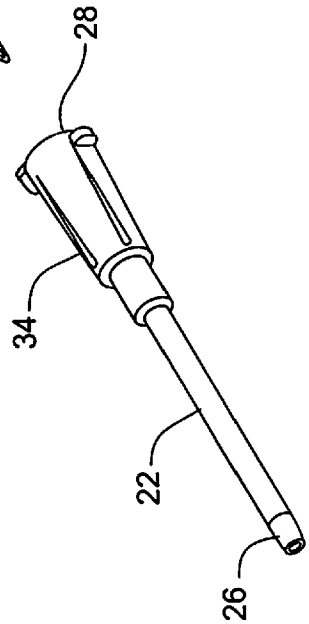


Fig. 3

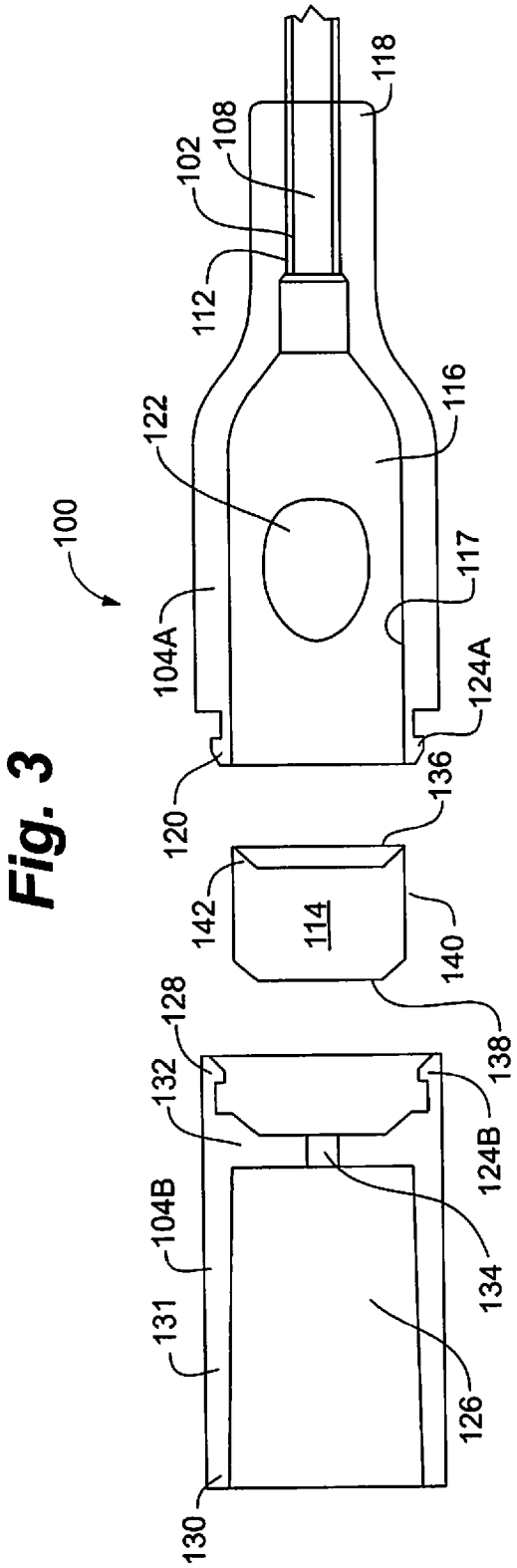
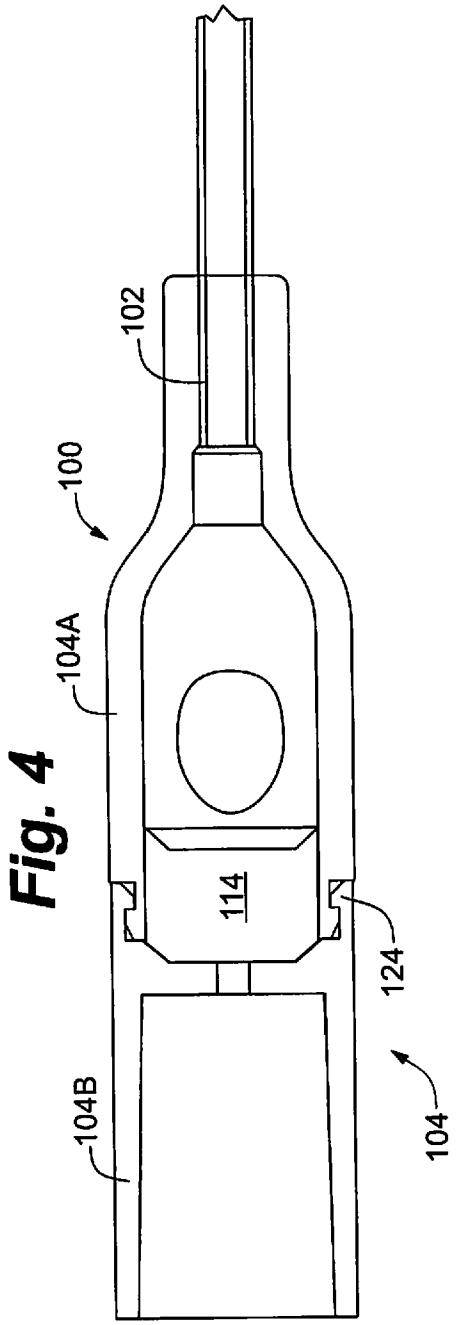

100
118
108
102
112
122
116
117
104A
124A
120
136
142
114
140
138
128
132
124B
104B
134
131
126
130

Fig. 4


102
100
104A
114
124
104B
104

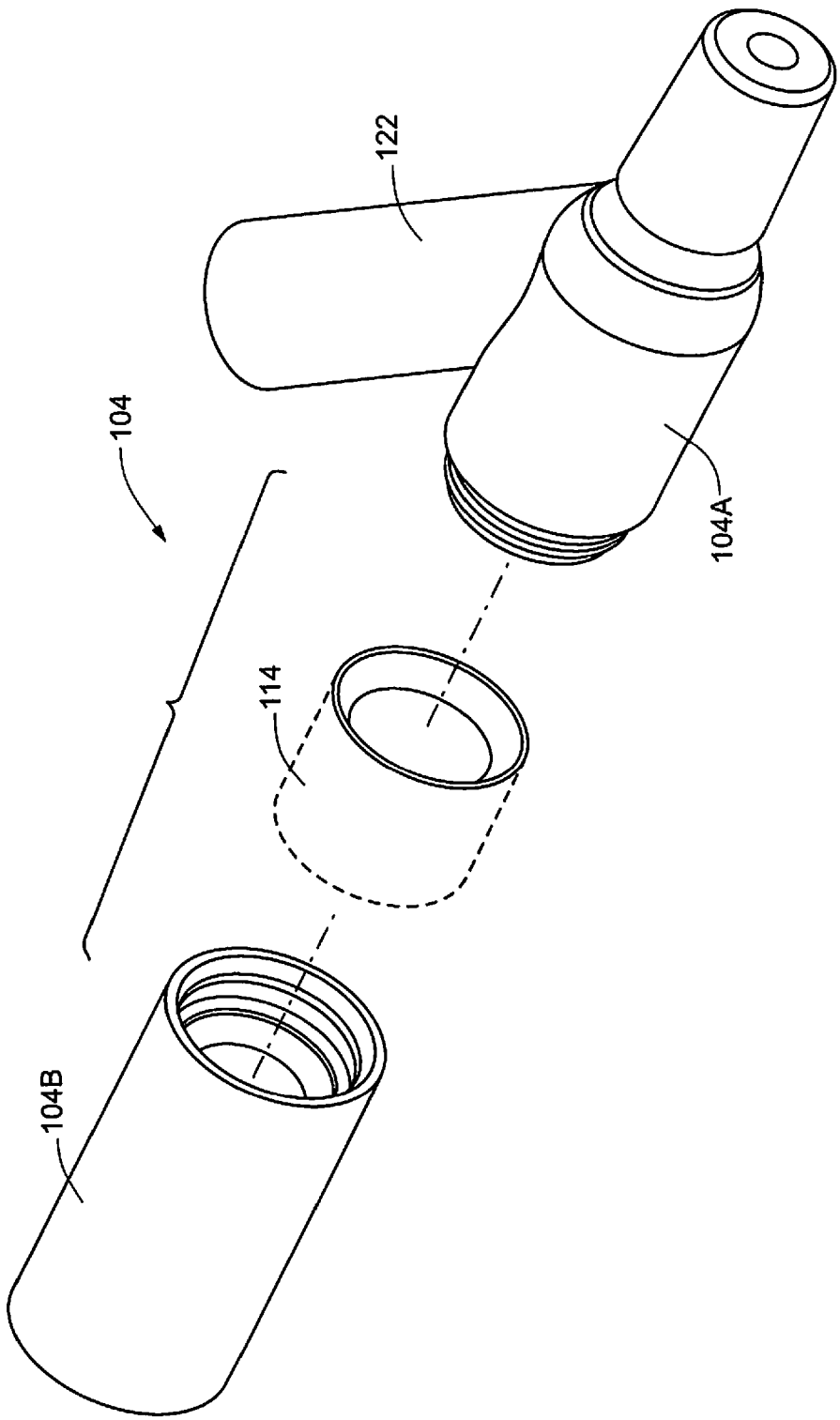


Fig. 5

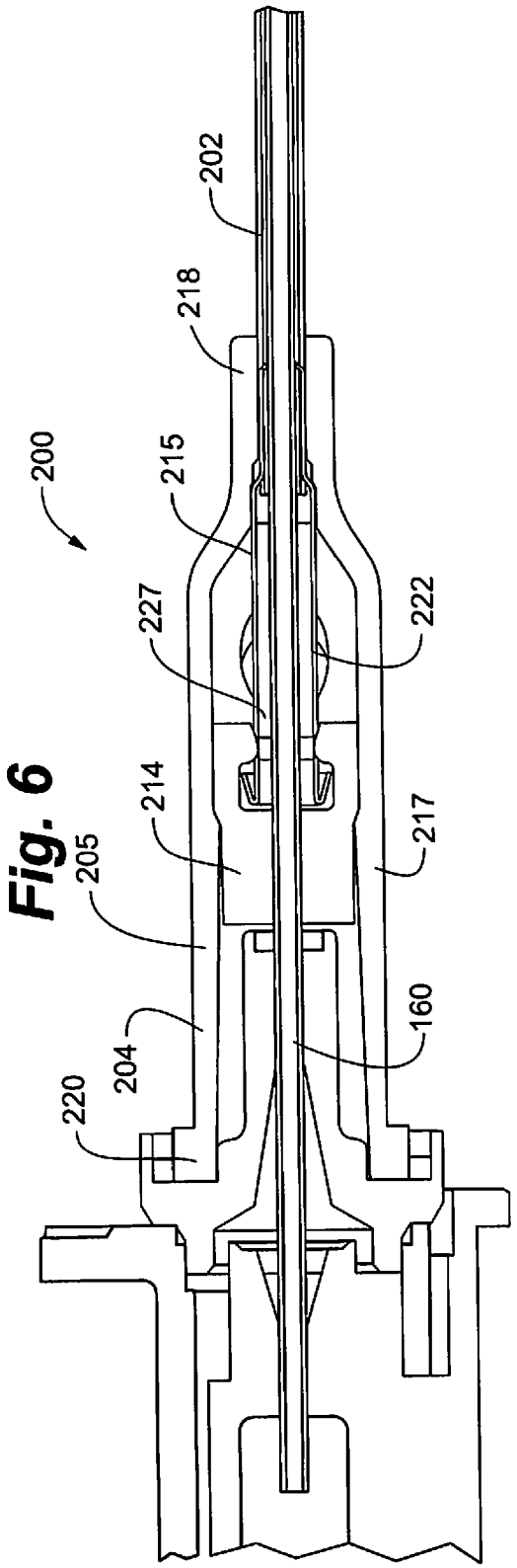

200
202
218
215
227
222
214
217
205
204
160
220

Fig. 6

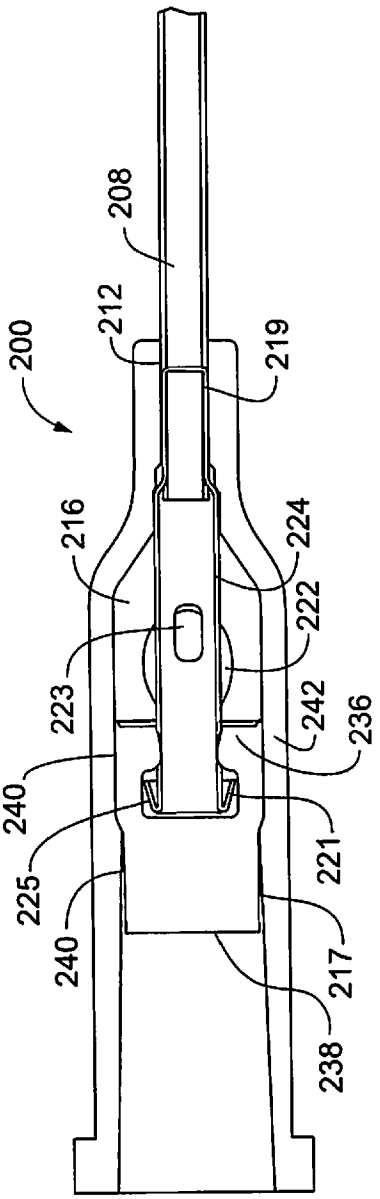

200
208
212
219
216
224
222
223
242
236
240
221
225
240
217
238

Fig. 7

Fig. 8

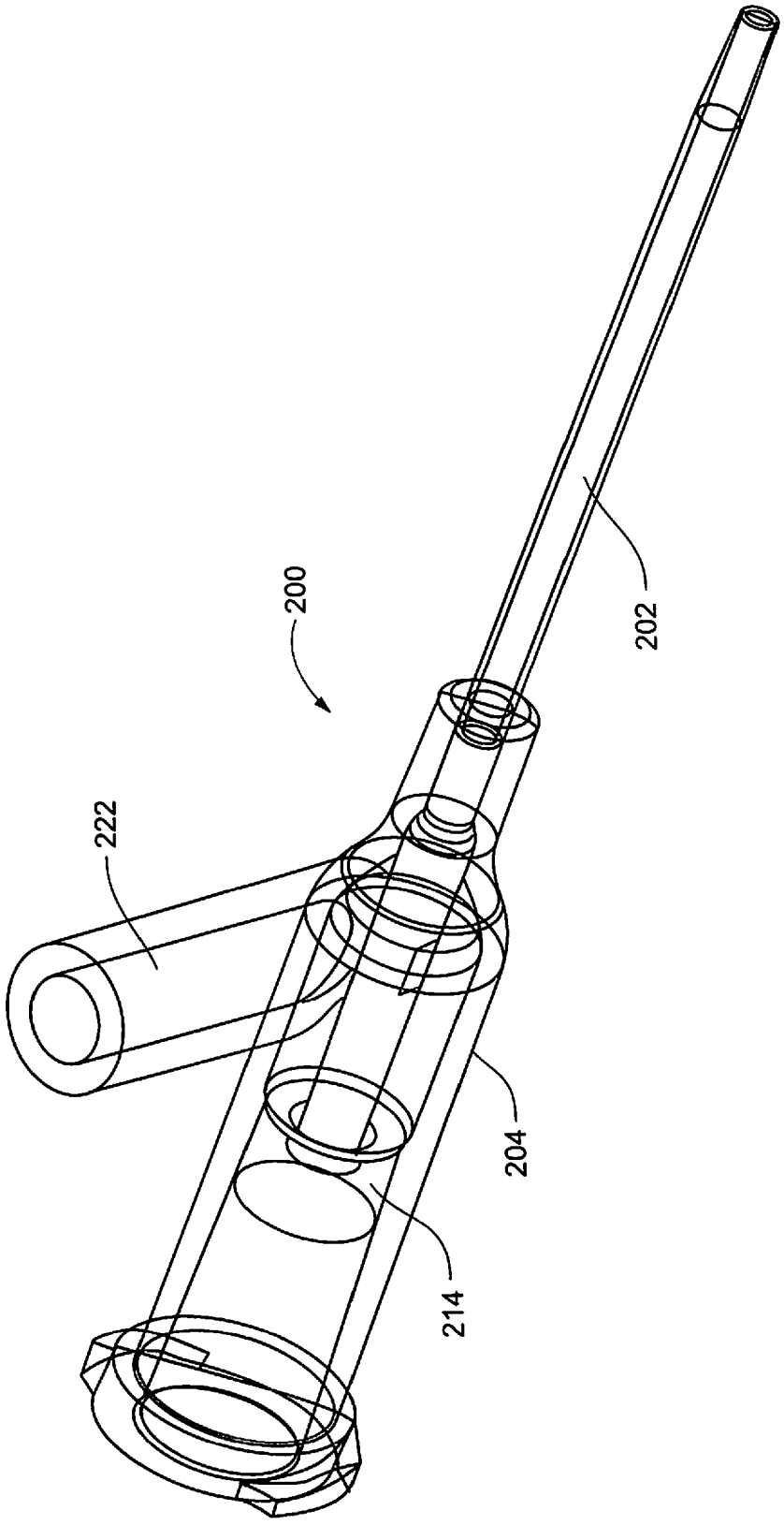


Fig. 9A

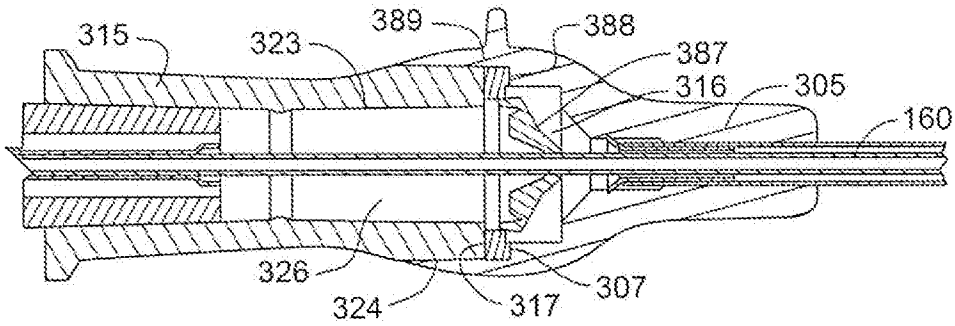


Fig. 9B

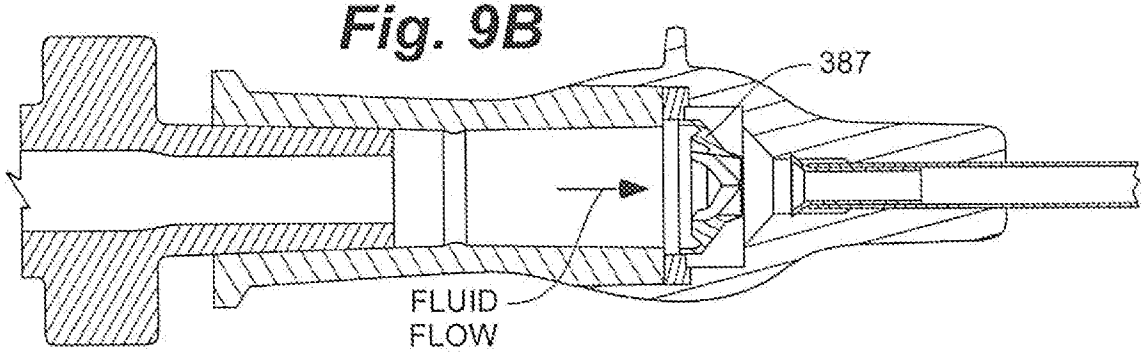


Fig. 9C

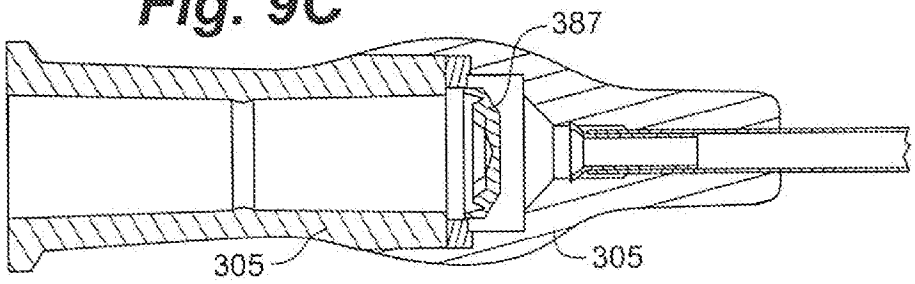


Fig. 9D

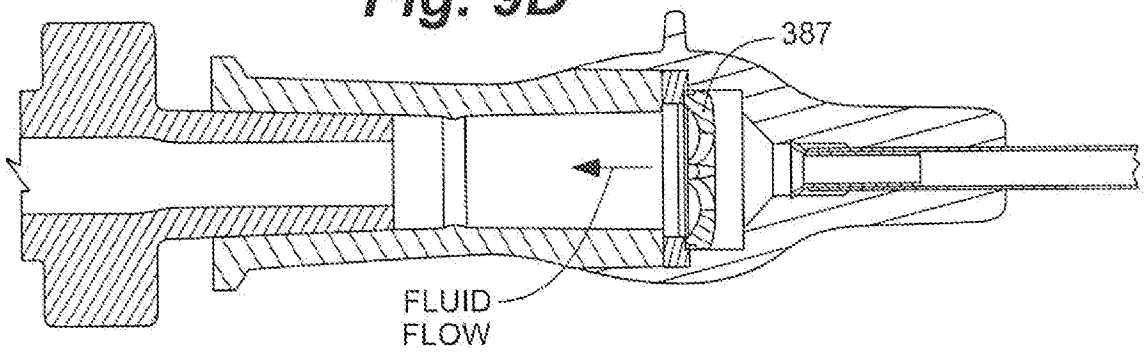


Fig. 11

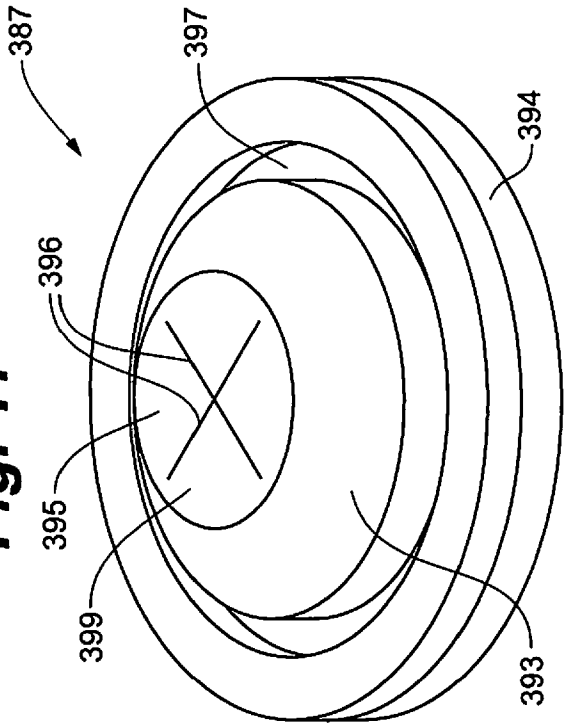
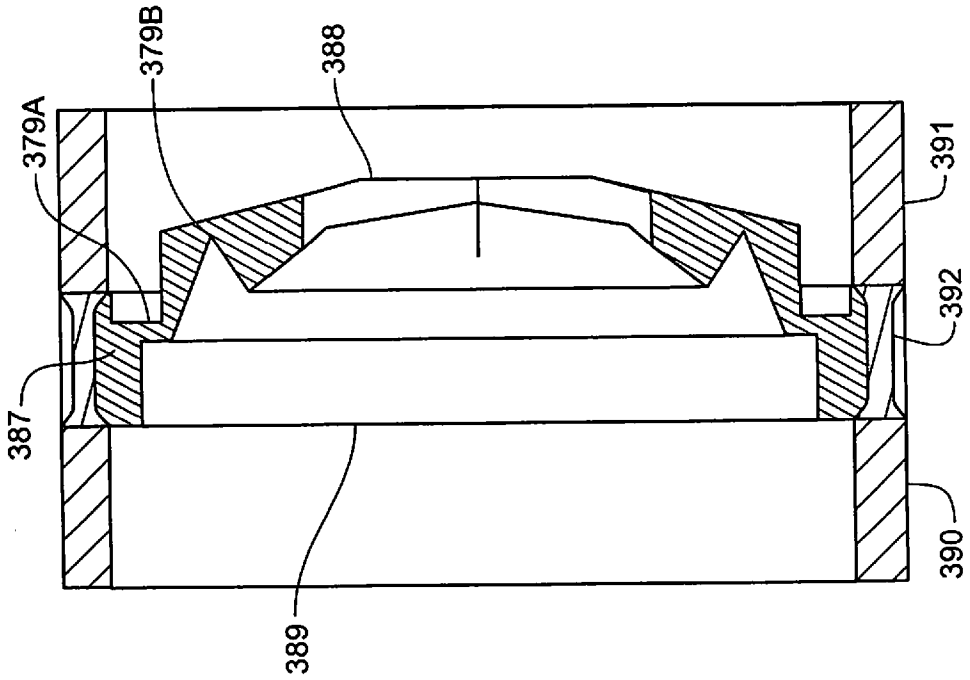


Fig. 10



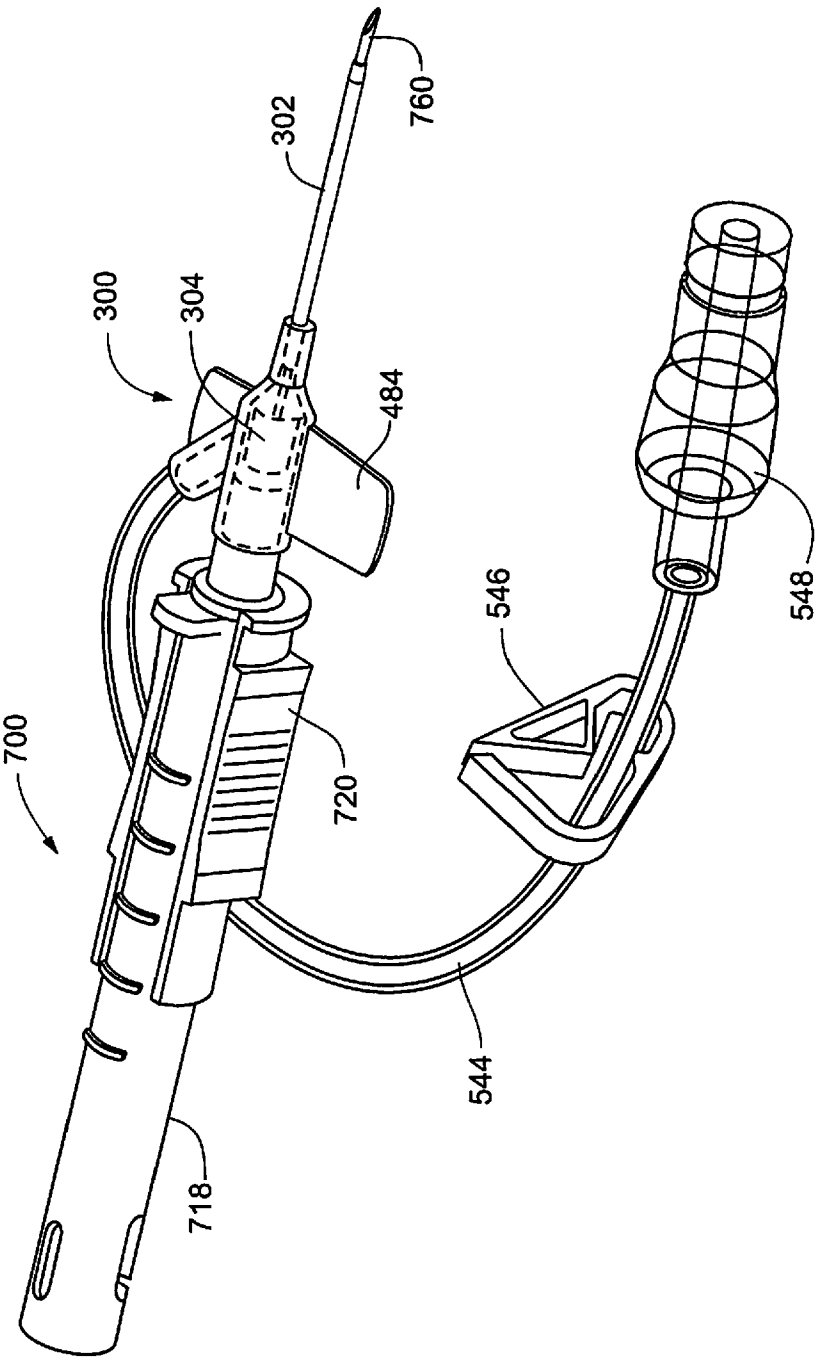


Fig. 12

Fig. 13C

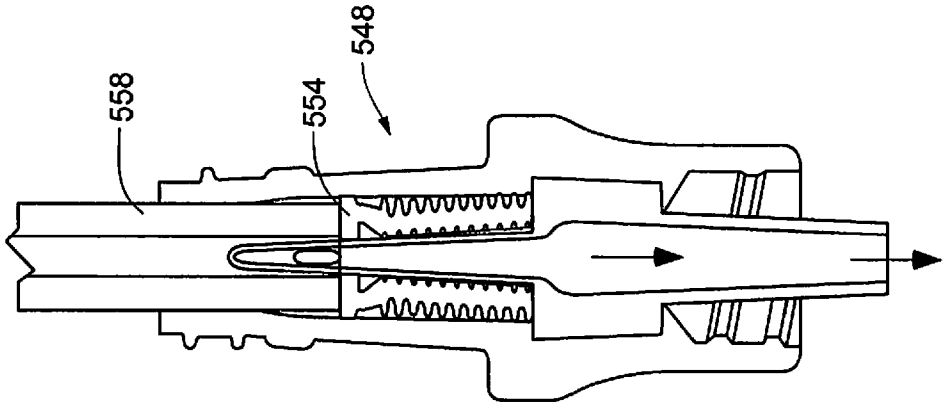


Fig. 13B

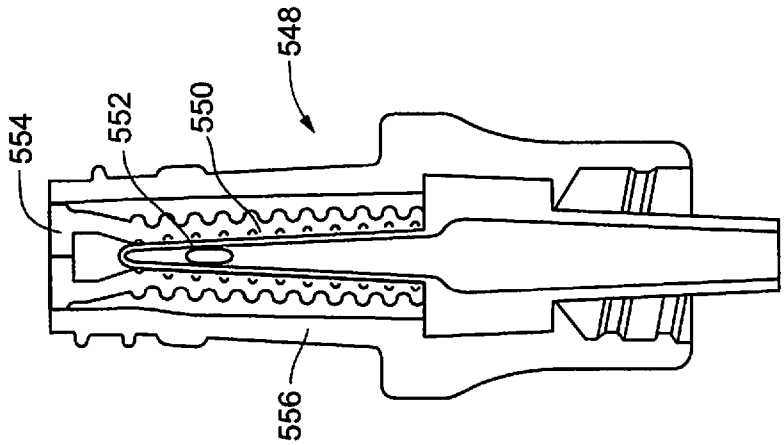
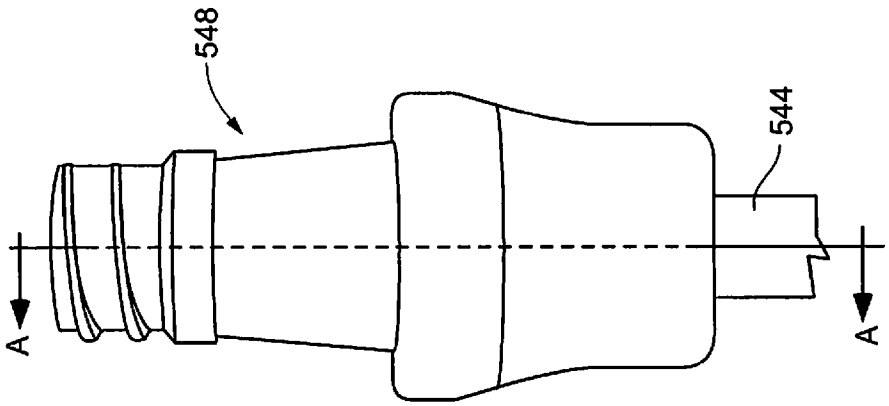


Fig. 13A



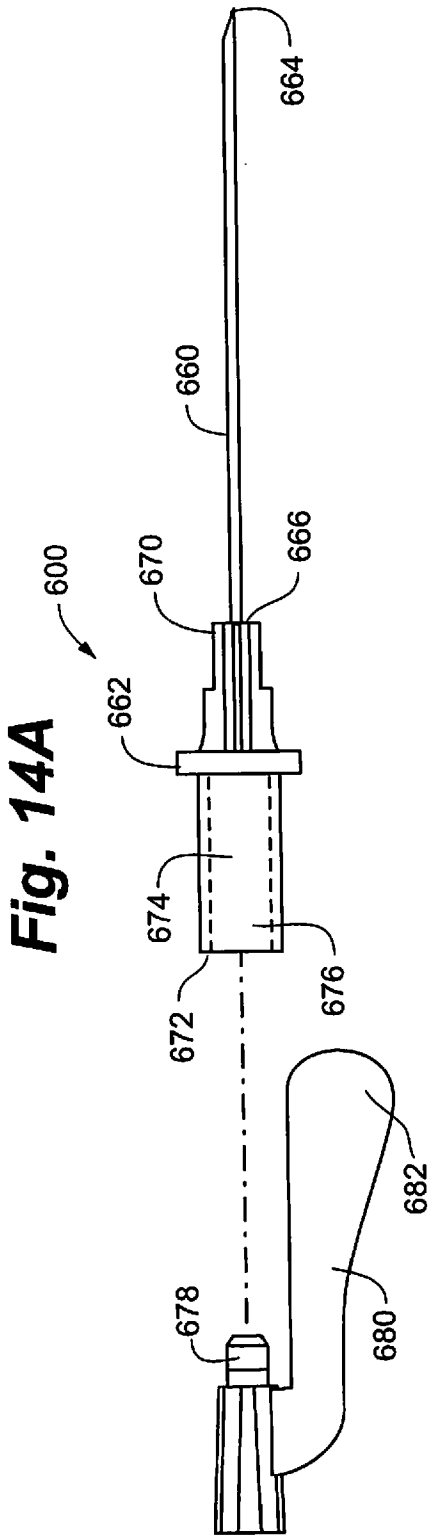


Fig. 14A

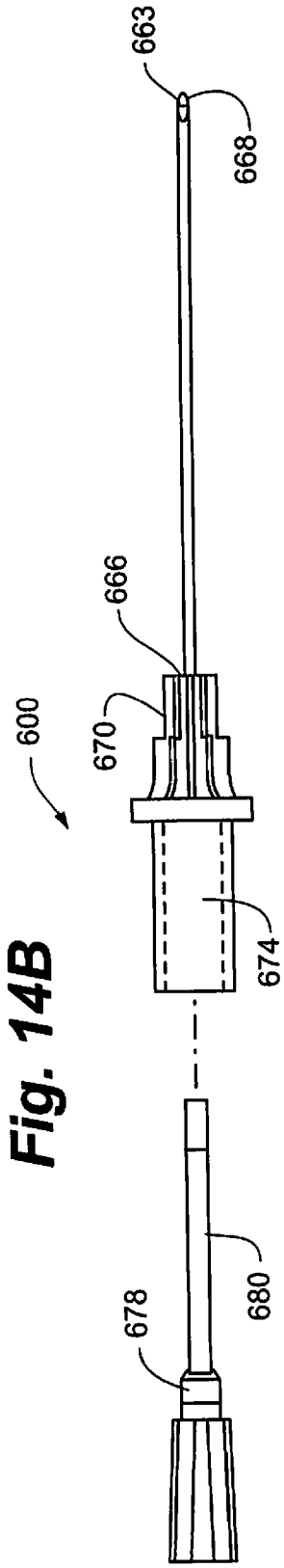


Fig. 14B

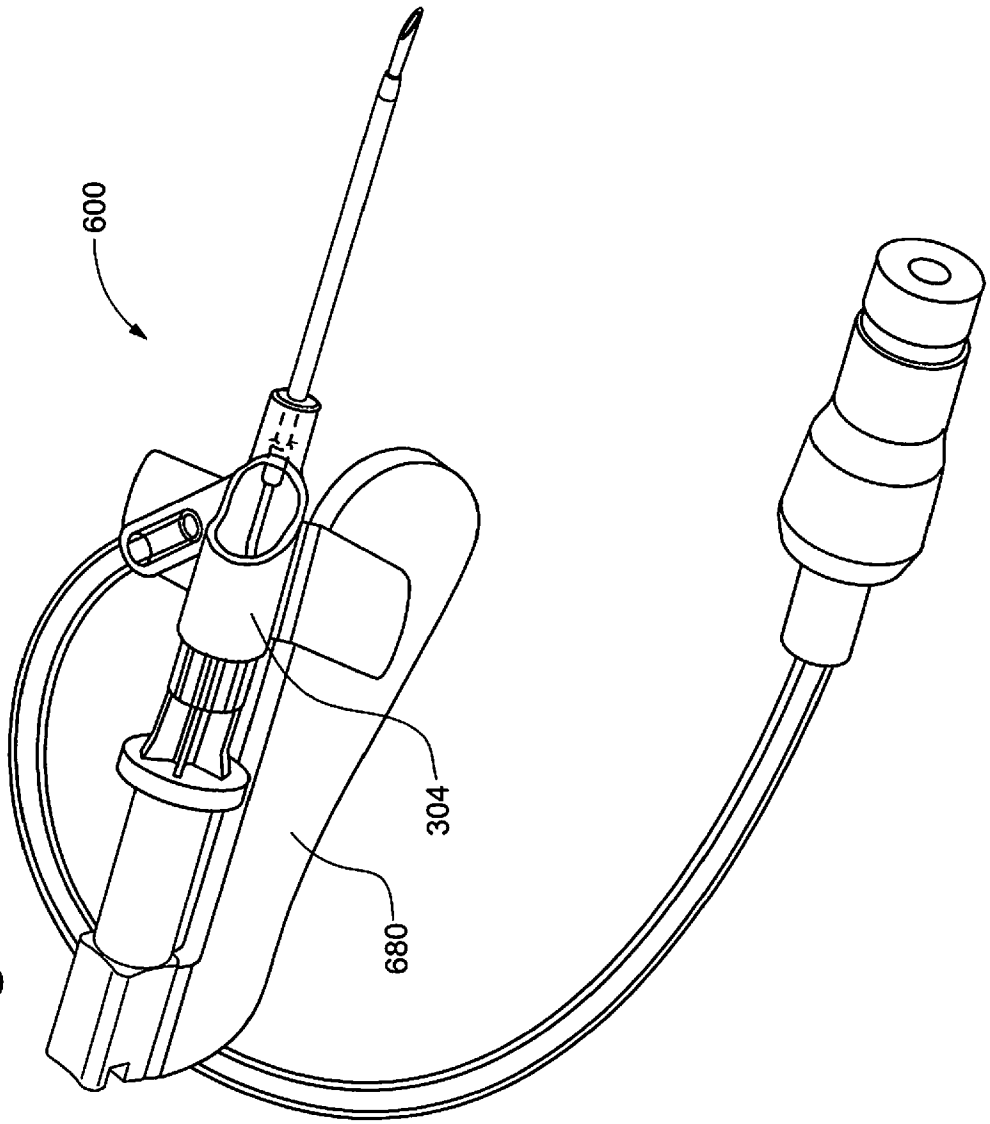


Fig. 15

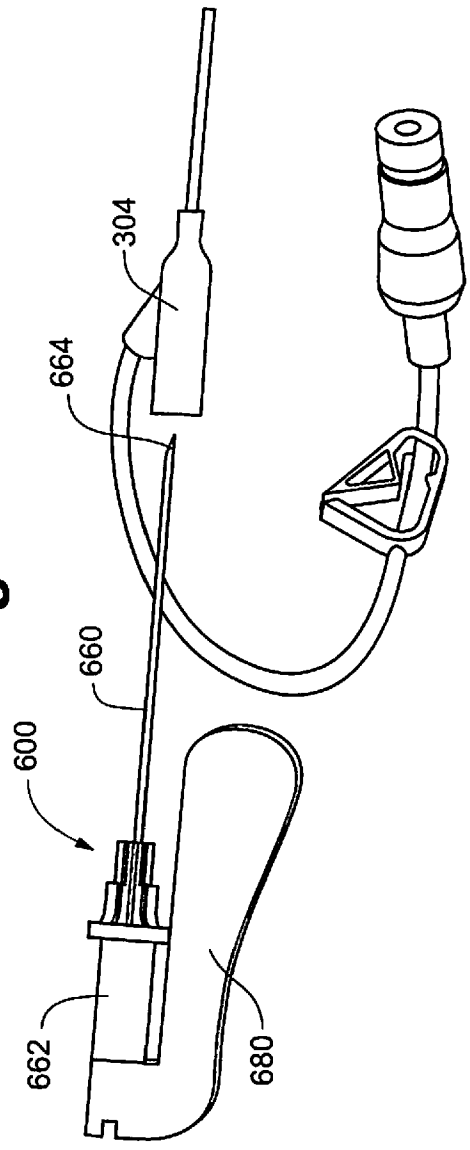


Fig. 16A

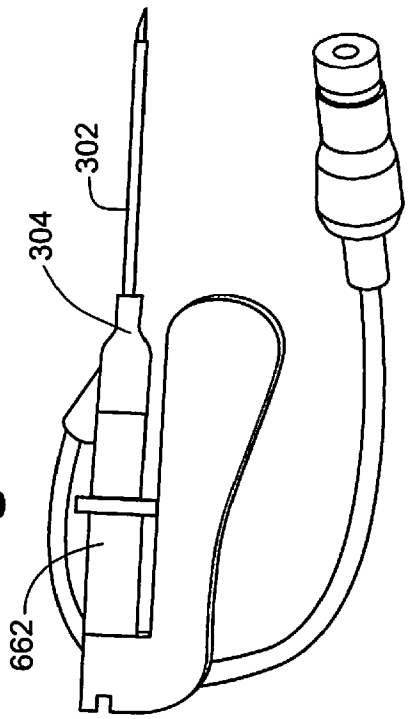


Fig. 16B

Fig. 17A

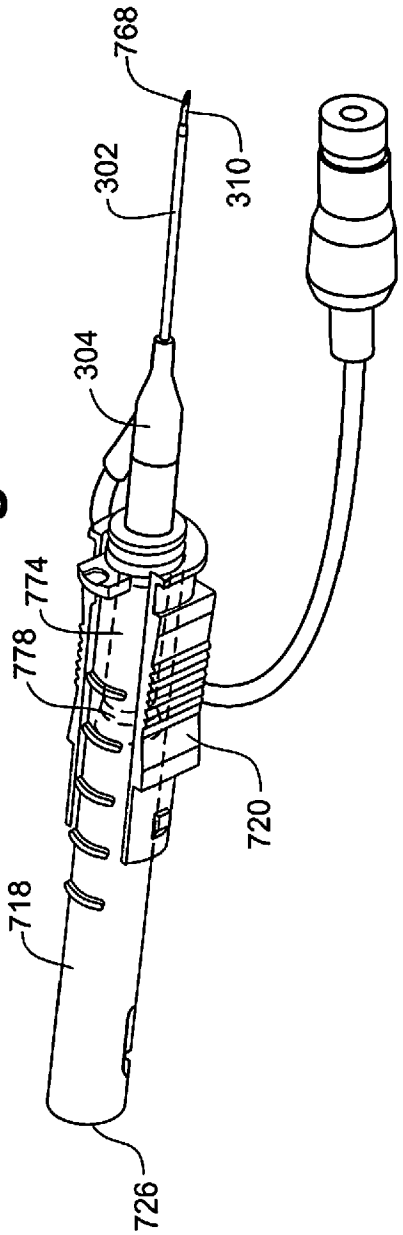
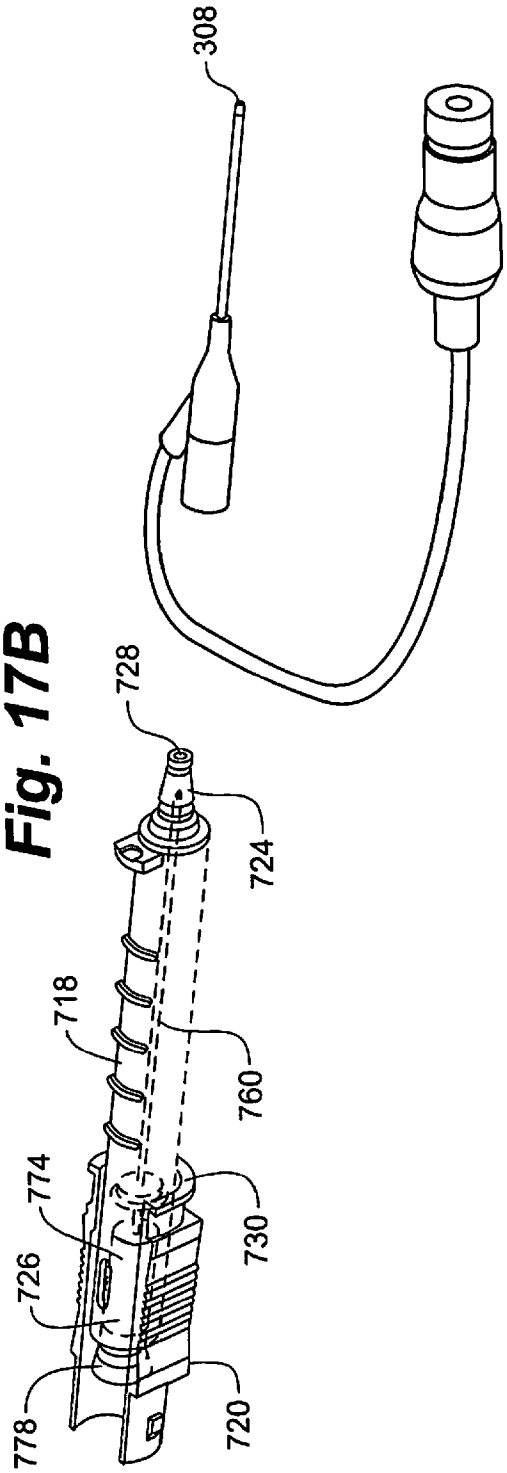


Fig. 17B



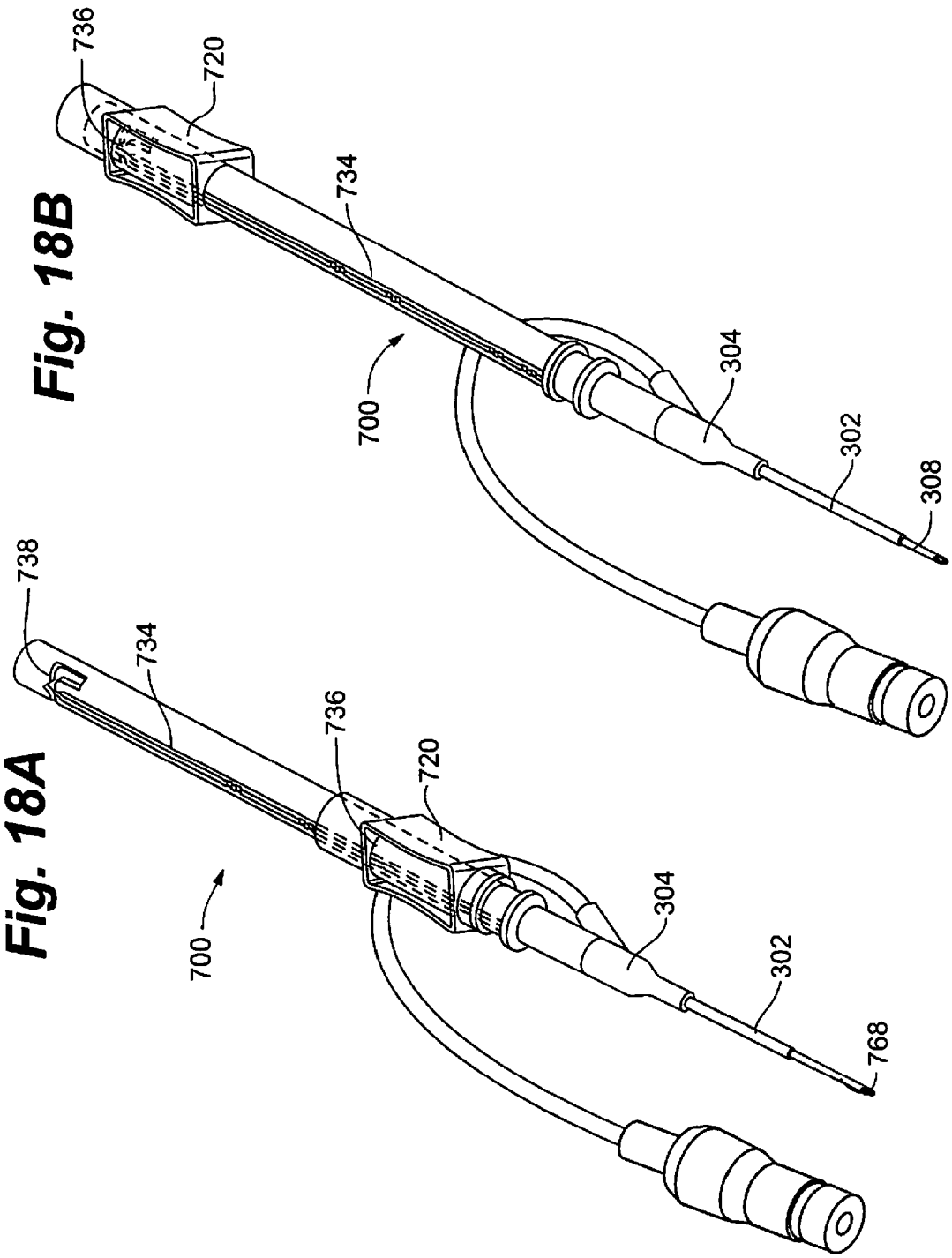


Fig. 18B

Fig. 18A

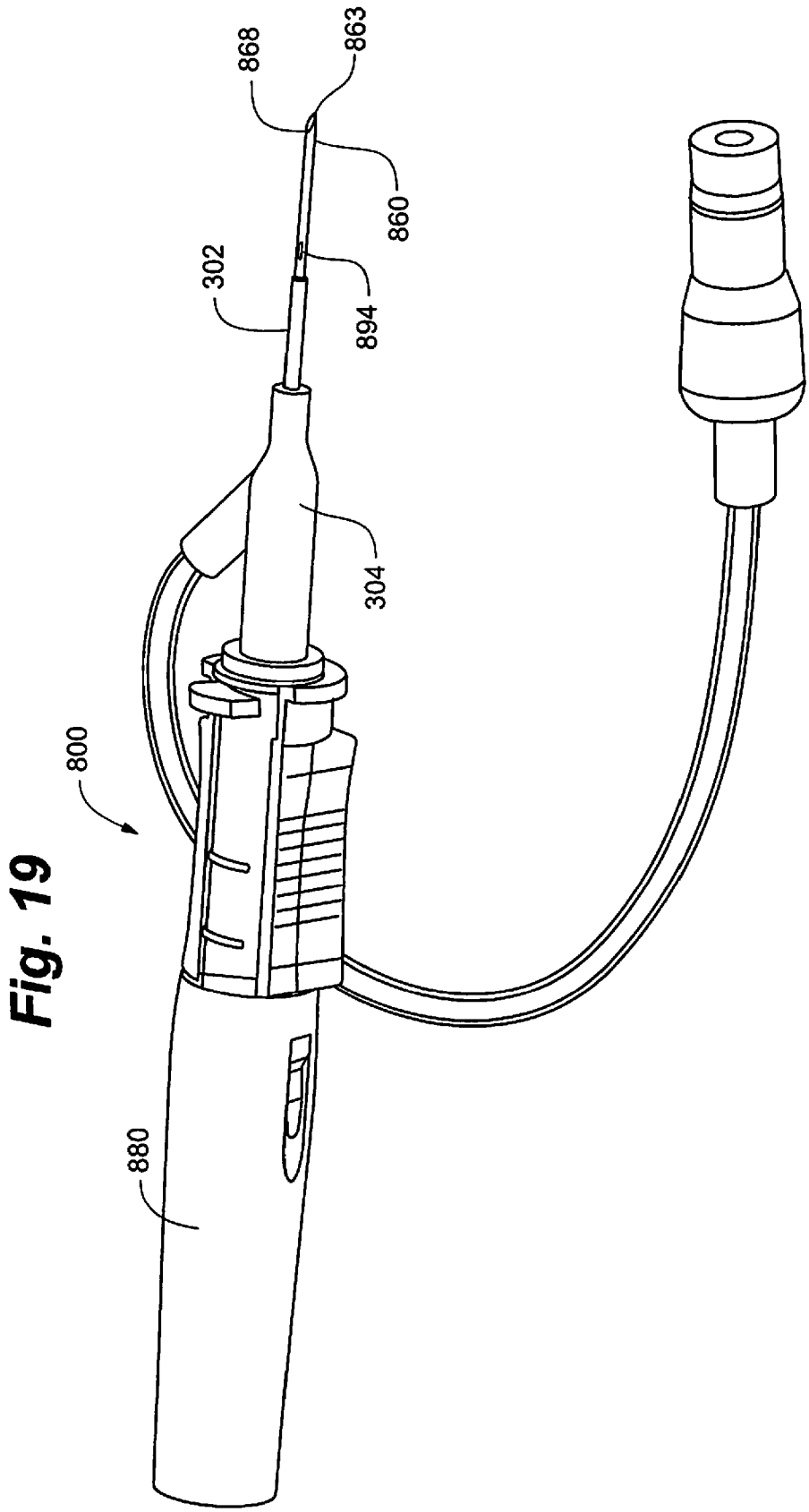


Fig. 19

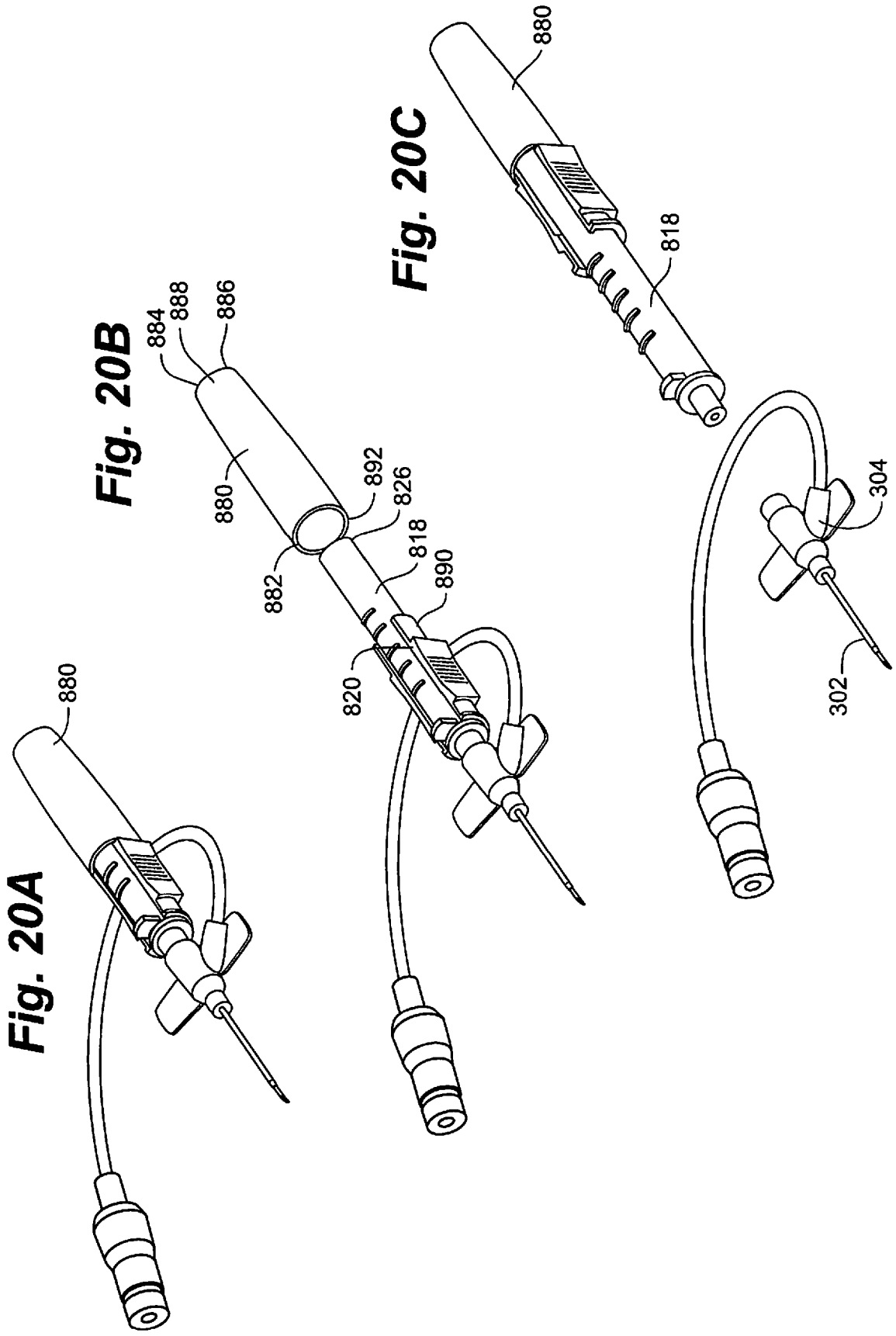


Fig. 20A
880
Fig. 20B
884
888
886
880
892
826
818
882
890
820
Fig. 20C
880
818
304
302

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/015965

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/01(2006.01)i, A61M 5/32(2006.01)i, A61M 25/00(2006.01)i

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)
A61M 25/01; A61M 19/00; A61M 39/06; A61M 31/00; A61M 25/00; A61M 5/178; A61M 1/00; A61M 1/36; A61M 25/06; A61M 5/32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: catheter, hub, assembly, septum, membrane, side port

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007-0250037 A1 (BRIMHALL, G. L. et al.) 25 October 2007 See abstract; claim 5; paragraphs [0043]-[0052]; figures 1-22.	1-10
X	WO 2012-036916 A1 (BECTON, DICKINSON AND COMPANY et al.) 22 March 2012 See abstract; claim 1; paragraphs [0028]-[0033]; figures 1A-10.	1-4
A	US 8690833 B2 (BELSON, A.) 08 April 2014 See entire document.	1-10
A	US 2006-0149189 A1 (DIAMOND, J. P. et al.) 06 July 2006 See entire document.	1-10
A	US 2014-0128820 A1 (COVIDIEN LP) 08 May 2014 See entire document.	1-10

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

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent 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
31 May 2016 (31.05.2016)	**08 June 2016 (08.06.2016)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer
Han, Inho
Telephone No. +82-42-481-3362

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2016/015965

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0250037 A1	25/10/2007	AU 2003-284115 A1	04/05/2004
		EP 1572262 A2	14/09/2005
		EP 1572262 A3	21/12/2005
		EP 1572262 B1	10/03/2010
		US 2005-0043709 A1	24/02/2005
		US 2007-0250021 A1	25/10/2007
		US 7713256 B2	11/05/2010
		US 7713257 B2	11/05/2010
		WO 2004-032995 A2	22/04/2004
		WO 2004-032995 A3	03/11/2005
WO 2012-036916 A1	22/03/2012	AU 2011-302463 A1	04/04/2013
		AU 2011-302463 B2	22/05/2014
		CA 2811175 A1	22/03/2012
		EP 2616127 A1	24/07/2013
		JP 2013-540486 A	07/11/2013
		US 2012-0065612 A1	15/03/2012
		US 8932259 B2	13/01/2015
US 8690833 B2	08/04/2014	EP 2670468 A1	11/12/2013
		JP 2014-509222 A	17/04/2014
		US 2012-0197200 A1	02/08/2012
		US 2014-0180250 A1	26/06/2014
		WO 2012-106266 A1	09/08/2012
US 2006-0149189 A1	06/07/2006	US 2006-0149214 A1	06/07/2006
		US 7931619 B2	26/04/2011
US 2014-0128820 A1	08/05/2014	CA 2602300 A1	28/03/2008
		EP 1905478 A2	02/04/2008
		EP 1905478 A3	04/06/2008
		US 2008-0082079 A1	03/04/2008
		US 2012-0203187 A1	09/08/2012
		US 8454565 B2	04/06/2013