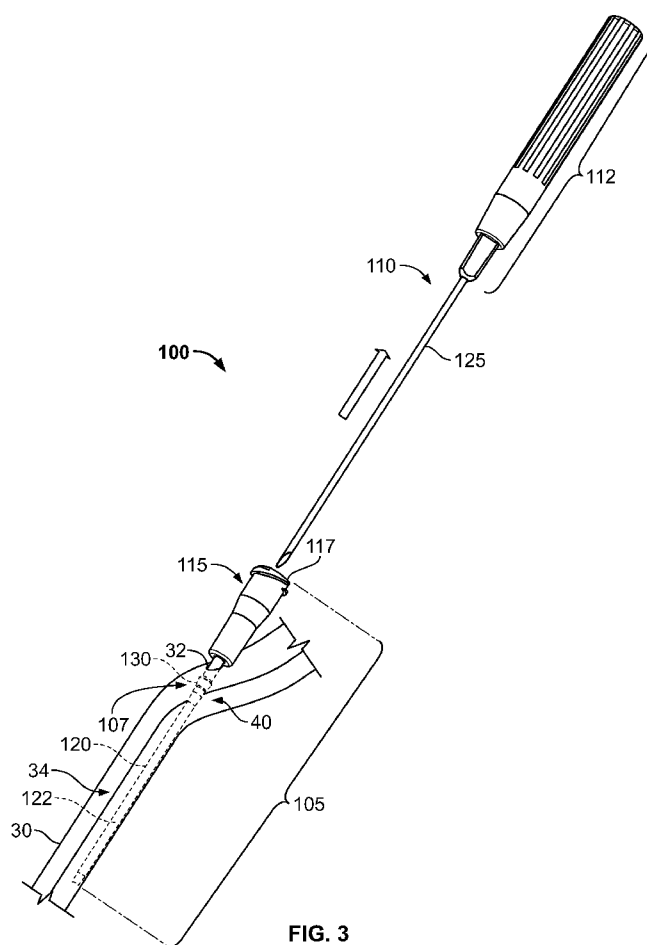




- (51) International Patent Classification:  
*A61M 25/06* (2006.01) *A61M 5/14* (2006.01)  
*A61B 17/34* (2006.01)
- (21) International Application Number:  
PCT/US2013/026340
- (22) International Filing Date:  
15 February 2013 (15.02.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
13/399,290 17 February 2012 (17.02.2012) US
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- (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, IS, JP, KE, KG, KM, KN, KP,  
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,  
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,  
NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU,  
RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ,

[Continued on next page]

(54) Title: ANCHORING AN INTRAVENOUS CANNULA



(57) Abstract: Some embodiments of a medical system include a subcutaneous anchor device that extends outwardly from side wall of an intravenous cannula so as to secure the intravenous cannula in a position relative to a skin penetration point.



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, 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, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

**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))

## Anchoring An Intravenous Cannula

### **CROSS-REFERENCE TO RELATED APPLICATION**

This application claims priority to U.S. Application Serial No. 13/399,290, filed on February 17, 2012, entitled ANCHORING AN INTRAVENOUS CANNULA, the disclosure of which is incorporated herein by reference.

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### **TECHNICAL FIELD**

This document relates to a medical device having an integrated anchor system for securing a portion of the medical device in a subcutaneous region underlying the skin.

### **BACKGROUND**

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Some medical devices are configured to provide intravenous therapy in which an intravenous infusion of a fluid is administered through an intravenous cannula. The intravenous cannula normally includes a distal tip region that is configured to insert through a skin opening and into a selected body vessel (e.g., a vein in a patient's arm or leg) while a proximal hub remains external to skin opening for connection with a separate medicinal fluid line. This type of intravenous infusion therapy provides a direct route to the bloodstream which allows for hydration, administration of blood or blood products and administration of medications. Medications that are administered intravenously can achieve therapeutic effects more rapidly and, in some cases, using a lower dose.

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Typical intravenous cannulas may extend for several inches in length and normally include a fluid lumen that extends to a distal port and the tip of the cannula. In some version, the intravenous cannula may include large, flat "wings" or "tabs" that remain external to the skin and are equipped to adhere to the outer surface of the patient's skin. In other circumstances, the intravenous cannula may be secured to the skin penetration site using adhesive tape that is wrapped around an outer circumferential surface region of the intravenous cannula and around an adjacent portion of the patient's arm or leg.

## SUMMARY

Some embodiments of a medical system include a subcutaneous anchor device that extends outwardly from side wall of an intravenous cannula so as to secure the intravenous cannula in a position relative to a skin penetration point. In some  
5 circumstances, the subcutaneous anchor device can be integrally formed as a unitary structure with the side wall of the intravenous cannula so that the subcutaneous anchor device is positioned along a central region of the intravenous cannula (e.g., at a position that is proximal of the distal tip portion configured to penetrate into a targeted vein or other vessel, and that is distal of the proximal connector hub  
10 configured to releasably mate with a separate fluid line). As such, the subcutaneous anchors may engage with fatty tissue or other tissue inside the subcutaneous layer immediately underlying the skin near the skin penetration point, thereby providing an anchoring effect without necessarily requiring adhesives applied external to the skin.

Some embodiments described herein include a medical system for anchoring  
15 an intravenous cannula device in a subcutaneous region along an underside of a skin layer. The medical system may include an intravenous cannula device and an inserter tool removably coupled to the intravenous cannula device. The intravenous cannula device may include a flexible catheter, a proximal connector hub, and a subcutaneous anchor integrally formed as a unitary structure with an outer wall of the flexible  
20 catheter. The flexible catheter may include a lumen and also may extend distally of the proximal connector hub. The proximal connector hub may optionally include a thread pattern configured to releasably connect with an external fluid line. The inserter tool may be removably coupled to the intravenous cannula device so as to insert the flexible catheter of the intravenous cannula device through a skin  
25 penetration point and into a targeted vessel. The inserter tool may optionally include a handle and an insertion needle extending distally from the handle. The insertion needle may be slidably engaged with the lumen of the flexible catheter of the intravenous cannula device. The inserter tool may be removable from the intravenous cannula device when the insertion needle is proximally withdrawn from the lumen of  
30 the flexible catheter. The subcutaneous anchor of the intravenous cannula device may be positioned between a distal tip of the flexible catheter and the proximal connector hub. The subcutaneous anchor may include at least one surface to engage tissue in a

subcutaneous region along an underside of a skin layer when the flexible catheter of the intravenous cannula device is inserted through a skin penetration point and into a targeted vessel.

Particular embodiments include a method of using an intravenous cannula device. The method may include inserting a needle portion of an inserter tool through a skin penetration point and into a targeted vessel. An intravenous cannula device may be removably coupled to the inserter tool such that a flexible catheter of the intravenous cannula device is advanced through the skin penetration point and into the targeted vessel while a subcutaneous anchor integrally formed as a unitary structure with an outer wall of the flexible catheter is positioned in a subcutaneous region along an underside of a skin layer. The method may also include removing the inserter tool from the intravenous cannula device such that the needle portion of the inserter tool is slidably withdrawn from a lumen of the flexible catheter while the flexible catheter remains in the targeted vessel and the subcutaneous anchor remains in the subcutaneous region along the underside of the skin layer. Optionally, the method may include threadably engaging an external fluid line to a proximal connector hub of the intravenous cannula device while the flexible catheter remains in the targeted vessel and the subcutaneous anchor remains in the subcutaneous region along the underside of the skin layer. The subcutaneous anchor may be positioned between a distal tip of the flexible catheter and the proximal connector hub. The subcutaneous anchor may include at least one surface to engage tissue in the subcutaneous region proximate to the skin penetration point.

In other embodiments, a medical system for anchoring an intravenous cannula device in a subcutaneous region along an underside of a skin layer may include an intravenous cannula device. The intravenous cannula device may include a flexible catheter, a proximal connector hub, and a subcutaneous anchor positioned between a distal tip of the flexible catheter and the proximal connector hub. The system may also include an inserter tool removably coupled to the intravenous cannula device. The inserter tool may optionally include a handle and an insertion needle extending distally from the handle. The insertion needle may be slidably engaged with a lumen of the flexible catheter. The subcutaneous anchor may include at least one surface to

engage tissue in a subcutaneous region along an underside of a skin layer when the flexible catheter of the intravenous cannula device is into a targeted vessel.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

### DESCRIPTION OF DRAWINGS

FIGs. 1-3 are perspective views of an intravenous cannula system having a subcutaneous anchor, in accordance with some embodiments.

FIGs. 4A and 4B are perspective and side views of an intravenous cannula system having a subcutaneous anchor including a circumferential ring, in accordance with some alternative embodiments.

FIGs. 5A and 5B are perspective and side views of an intravenous cannula system having subcutaneous anchors including a multiple circumferential ring, in accordance with some alternative embodiments.

FIGs. 6A and 6B are perspective and side views of an intravenous cannula system having subcutaneous anchors including a pair of recessed tabs, in accordance with some alternative embodiments.

FIGs. 7A and 7B are perspective and side views of an intravenous cannula system having subcutaneous anchors including multiple pairs of recessed tabs, in accordance with some alternative embodiments.

FIGs. 8A and 8B are perspective and side views of an intravenous cannula system having a subcutaneous anchor including a slotted circumferential ring, in accordance with some alternative embodiments.

FIGs. 9A and 9B are perspective and side views of an intravenous cannula system having subcutaneous anchors including multiple slotted circumferential rings, in accordance with some alternative embodiments.

FIGs. 10A and 10B are perspective and side views of an intravenous cannula system having a subcutaneous anchor including an anchor flap, in accordance with some alternative embodiments.

FIGs. 11A and 11B are perspective and side views of an intravenous cannula system having subcutaneous anchors including multiple anchor flaps, in accordance with some alternative embodiments.

5 FIGs. 12A and 12B are perspective and side views of an intravenous cannula system having a subcutaneous anchor including a tapered circumferential ring, in accordance with some alternative embodiments.

FIGs. 13A and 13B are perspective and side views of an intravenous cannula system having subcutaneous anchors including multiple tapered circumferential rings, in accordance with some alternative embodiments.

10 FIGs. 14A and 14B are perspective and side views of an intravenous cannula system having subcutaneous anchors including textured cutouts, in accordance with some alternative embodiments.

FIGs. 15A and 15B are perspective and side views of an intravenous cannula system having a subcutaneous threaded anchor, in accordance with some alternative  
15 embodiments.

FIGs. 16A and 16B are perspective and side views of an intravenous cannula system having a subcutaneous anchor including a wedge, in accordance with some alternative embodiments.

Like reference symbols in the various drawings indicate like elements.

## 20 DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Referring to FIGS. 1-3, a medical system 100 includes an intravenous cannula device 105 that is equipped with a subcutaneous anchor 130 so as to secure the intravenous cannula device 105 in a position relative to a skin penetration point 32. In this embodiment, the subcutaneous anchor 130 can be integrally formed as a unitary  
25 structure with the side wall of the intravenous cannula device 105. The intravenous cannula device 105 can include a distal section having a flexible catheter 120 and a proximal connector hub 115 configured to releasably connect with an external fluid line (not shown in FIGS. 1-3). As described in more detail below, the subcutaneous anchor 130 can be positioned along a central region of the intravenous cannula 105  
30 such that the anchor 130 is arranged proximal to a distal tip 122 of the catheter 120 and is arranged distal to the proximal connector hub 115. In particular embodiments, the subcutaneous anchor 130 is located in the central region 107 and extends radially

outward of a cylindrical wall the catheter 120 so that the subcutaneous anchor 130 may engage with fatty tissue or other tissue inside the subcutaneous layer 34 immediately underlying the skin 30 near the skin penetration point 32, thereby providing an anchoring effect without necessarily requiring adhesives applied external to the skin 30.

The system 100 depicted in FIGs. 1-3 also includes an inserter tool 110 (FIG. 3) that is detachably connected to the intravenous cannula device 105. In this embodiment, the inserter tool 110 includes a handle 112 configured to be grasped by a user in order to control the insertion of the intravenous cannula device 105 through the skin penetration point 32. As described in more detail below, the inserted tool 110 is removably coupled to the intravenous cannula device 105 so that an insertion needle 125 of the inserter tool 110 provides support to the flexible catheter 120 during insertion of the distal tip 122 of the flexible catheter 120 into a targeted body vessel 40. After the inserter tool 110 is used to facilitate placement of the intravenous cannula device 105, the inserter tool 110 can be removed from the intravenous cannula device 105 while the distal tip 122 of the flexible catheter 120 remains in the targeted body vessel 40, thereby providing a fluid communication line between the proximal connector hub 115 and the targeted body vessel 40 via the flexible catheter 120.

Still referring to FIGs. 1-3, the proximal connector hub 115 of the intravenous cannula device 105 includes a fluid fitting 117 that is configured to releasably mate with an external fluid line. For example, the fluid fitting 117 may provide a luer connector, which includes a threaded region and a sealing face at the proximal-most end region of the proximal connector hub 115, for purposes of detachably coupling to an external fluid line (e.g., a supply of intravenous fluid, a medicine delivery line, a blood infusion line, a blood withdrawal line, or the like). The proximal connector hub 115 includes a generally rigid body having an outer radius that is substantially larger than the outer radius of the flexible catheter 120. In this embodiment, the outer radius of the proximal connector hub 115 is also larger than the skin penetration point 32 such that the proximal connector hub 115 remains external to the skin 30 during use. The proximal connector hub 115 includes a central lumen that is in fluid communication with a corresponding lumen of the flexible catheter 120. Accordingly,



in the embodiment depicted in FIGs. 1-3, the catheter 120 can be inserted into through the penetration point 32, to the underside of the skin 30, and into a vein 40 or other targeted vessel to provide vascular access for intravenous infusion or withdrawal of a fluid.

5 In some embodiments, the catheter 120 may be flexible. For example, the catheter 120 can be configured to flexibly contour with the curvatures of the targeted vessel 40. As previously described, the catheter 120 can be supported by the insertion needle 125 on the inserter tool 110 during the initial placement of the flexible catheter 120 into the targeted vessel 40. In such embodiments, the insertion needle 125  
10 removably occupies the lumen of the catheter 120, and provides support for the catheter 120 against bending or bucking during insertion into the targeted vessel 40. In some implementations, the insertion needle 125 is equipped with a sharp tip 127 that protrudes from the distal tip of the catheter 120 (refer to FIGs. 1-2) such that the inserter tool 110 provides the initial penetration path through the skin 32 and into the  
15 targeted vessel 40.

The catheter 120 can be configured to have an axial length which is substantially greater than the axial length of the proximal connector hub 115. For example, in some embodiments, the axial length of the catheter 20 (extending from the junction with the proximal connector hub 115 to the distal-most end of the  
20 catheter tip) can be about 25mm to about 150mm, about 40 mm to about 70 mm, and preferably about 50 mm. The catheter may also include an outer diameter of about 12-gauge to about 28-gauge, and preferable about 14-gauge to about 24-gauge sizes. Such an axial length and diameter size can be advantageous for providing access to the targeted vessel 40 while not necessary requiring advancement deep into the  
25 vasculature. Also, the overall axial length of the intravenous cannula device 105 (extending from the proximal end of the proximal connector hub 115 to the distal-most end of the catheter tip) can be about 45 mm to about 170 mm, about 60 mm to about 90 mm, and preferably about 70 mm. Such an axial length can be advantageous for providing access to the targeted vessel while also maintaining the proximal  
30 connector hub 115 at a location external to the skin and near the skin penetration point 32.

Still referring to FIGs. 1-3, the flexible catheter 120 can extend distally from the proximal connector hub 115, and the proximal portion of the flexible catheter can define the central region 107 of the intravenous cannula device 105 at which the subcutaneous anchor 130 is located. In this embodiment, the subcutaneous anchor 130 is formed about the periphery of the catheter 120 at a position that is substantially closer to the proximal connector hub 115 than to the distal tip 122 of the catheter 120. The subcutaneous anchor 130 is positioned to reside in the subcutaneous layer 34 along the underside of the skin 30 and near the skin penetration point 32.

Accordingly, while the catheter 120 can penetrate into the targeted vessel 40, the subcutaneous anchor 130 is positioned along to the intravenous cannula device 105 to reside external to the vessel 40 but under the skin 30 in the subcutaneous layer 34. Furthermore, while the subcutaneous anchor 130 is positioned in the subcutaneous layer 34, the proximal connector hub 115 remains external to the skin 30 so as to receive a connection with an external fluid line.

As described in more detail below, the subcutaneous anchor 130 can be directed to penetrate through the same penetration point 32 as the catheter 120 to maintain a position of the subcutaneous anchor 130 in the subcutaneous layer 34 along the underside of the skin 30. As such, the subcutaneous anchor 130 can secure the catheter 120 in the operative position relative to the penetration point 32 without necessarily requiring adhesives bonded to the skin. In some embodiments, the subcutaneous anchor 130 can be integrally formed with the catheter 120 as a unitary such that the subcutaneous anchor 130 and the catheter 120 share a common material. The subcutaneous anchor 130 can include one or more structures that extend outwardly from outer circumference of the catheter 120. For example, the subcutaneous anchor 130 can include one or more rings, flexible flaps, spirals, flexible tabs, tines, barbs, or the like that, after insertion, are deployed in the subcutaneous region 34 so as to secure the position of the intravenous cannula device 105 relative to the skin penetration point 32. Various examples of the subcutaneous anchor 130 are described below in connection with FIGs. 4-16.

In use, the system 100 can be manipulated by a user so as to deliver the distal tip of intravenous cannula device 105 into the targeted vessel 40, and then the system 100 can be adjusted to provide a fluid communication line to the targeted vessel 40.

For example, as shown in FIG. 1, the handle 112 of the inserter tool 110 can be grasped by the user so as to forcibly advance the sharp tip 127 of the insertion needle 125 through the skin 30 and into the targeted vessel 40. In doing so, the flexible catheter 120 of the intravenous cannula device 105 (which is slidably received on the insertion needle 125) is also advanced through the penetration point 32 and into the targeted vessel 40.

As shown in FIG. 2, the system 100 can be further advanced after the skin penetration point 32 is formed so that the subcutaneous anchor 130 is likewise advanced through the skin penetration point 32. In such circumstances, the subcutaneous anchor 130 is positioned external to the vessel 40 but under the skin 30 in the subcutaneous layer 34. The subcutaneous anchor 130 includes one or more structures that are configured to engage the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 105 from the skin penetration point 32. Thus, the intravenous cannula device 105 is anchored in the operative position relative to the penetration point 32 so that the distal tip of the flexible catheter 120 resides in the targeted vessel 40 while the proximal connector hub 115 resides external to the skin 30. Preferably, the proximal connector hub 115 comprises a substantially transparent polymer material so that the user can directly visualize blood return filling into an internal chamber at the hub when the distal end of the catheter 120 is positioned within the vessel 40.

After the intravenous cannula device 105 is anchored in the operative position, the inserter tool 110 of the system can be released from the intravenous cannula device 105. For example, the inserter tool 110 can be frictionally or threadably engaged with the intravenous cannula device 105. If the inserter tool 110 is engaged with the intravenous cannula device 105 by a friction fit, the user can apply a withdrawal force to the handle 112 of the inserter tool 110 relative to the intravenous cannula device 105. If the inserter tool is threadably engaged with the intravenous cannula device 105, the user can applied a rotational motion to the handle 112 of the inserter tool 110 relative to the intravenous cannula device 105 so as to decouple to the two components. In the illustrated example in FIG. 2, the inserter tool 110 can be released from the intravenous cannula device 105 by twisting (e.g., unscrewing) the handle 112 relative to the intravenous cannula device 105.

As shown in FIG. 3, after the intravenous cannula device 105 is anchored in the operative position, the inserter tool 110 can be fully removed from the intravenous cannula device 105. In the illustrated example, the needle 125, which had occupied the interior space of the catheter 120 in FIGs. 1 and 2, has been longitudinally withdrawn from the catheter 120 through the proximal connector hub 115. As such, the needle 125 no longer reinforces the flexible catheter 120, and allows the catheter 120 to flexibly comply with curvatures of the vein 40 (e.g., in the event of patient movement). Furthermore, the central lumen of the catheter 120 is then free to provide fluid communication between the proximal connector portion 115 and the targeted vessel 40. Accordingly, the proximal connector hub 115 can be mated with an external fluid line, such as an IV drip line or a medicine infusion line.

In some alternative embodiments, the inserter tool 110 can be equipped with a retractable needle (rather than the fixed needle 125 that can receive a safety cap after removal). The retractable needle of the inserter tool may be retractable relative to the handle 112, which can improve user safety and reduce the likelihood of inadvertent needle wounds. For example, the retractable needle may have a length that is similar to the needle 124 depicted in FIG. 3, but the retractable needle can be spring-loaded to ejected proximally away from the lumen of the flexible catheter and into an internal receiving chamber defined inside the handle 112 when the inserter tool is withdrawn from the intravenous cannula device 105. In such circumstances, the handle may have a greater length than the embodiment depicted in FIG. 3 so as to fully receive the retracted needle). Alternatively or additionally, the inserter tool can be equipped with a protective cap piece that is movable to cover the tip of the needle (either the fixed needle 125 or the spring-biased retractable needle) when the inserter tool is withdrawn from the intravenous cannula device 105.

In the embodiment depicted in FIGs. 1-3, the subcutaneous anchor 130 is integrally formed with the outer wall of the flexible catheter 120. The shape of the anchor device 130 can be selected to provide improved anchoring or withdrawal benefits depending upon the configuration of the catheter 120 and the selected location of the skin penetration point along a patient's body. For example, as shown in FIGs. 1-3, the subcutaneous anchor 130 can include a tapered ring structure that extends around the circumference of the catheter 120 and provides a substantially

greater outer diameter size than the generally cylindrical body portion of the catheter 120. The tapered ring structure can have a tapered wall that extends toward the distal tip 122 of the catheter 120 so as to facilitate insertion through the skin penetration point 32, while a proximal-facing ridge of the subcutaneous anchor device 130 resists withdrawal of the intravenous cannula device 105 while the subcutaneous anchor device 130 resides in the subcutaneous layer 34. In some alternative embodiments, the subcutaneous anchor device 130 can be provided in different forms along the central region 107 of the intravenous cannula device 105.

Referring now to FIGs. 4A-4B, some alternative embodiments of a medical system 400 may include a subcutaneous anchor 430 having a different configuration, for example, in the shape of a flexible circumferential ring. In this embodiment, the medical system 400 can be similar to the medical system 100 of FIGs. 1-3. For example, the medical system 400 includes an intravenous cannula device 405 and an inserter tool 410 that is detachably coupled to the intravenous cannula device 405.

The intravenous cannula device 405 can include a distal section having a flexible catheter 420 and a proximal connector hub 415 configured to releasably connect with an external fluid line (not shown in FIGs. 4A-4B). In this embodiment, the flexible circumferential ring 430 is integrally formed as a unitary structure with the side wall of the flexible catheter 420, and the flexible circumferential ring 430 is positioned along a central region of the intravenous cannula device 405 (e.g., proximal to a distal tip of the catheter 420 and distal to the proximal connector hub 415).

The flexible circumferential ring 430 is formed radially about the catheter 420 at a location near to the proximal connector hub 415. The flexible circumferential ring 430 can be directed to penetrate through the same penetration point 32 as the catheter 420 for positioning in the subcutaneous layer 34 along the underside of the skin 30. As such, the flexible circumferential ring 430 can secure the catheter 420 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. In some embodiments, the flexible circumferential ring 430 can be integrally formed with the flexible catheter 420 such that the flexible circumferential ring 430 and the catheter 420 share a common flexible polymer material. Accordingly, during insertion through the skin penetration point, the flexible circumferential ring 430 can flexibly adjust in a first direction so

that the outer rim of the flexible circumferential ring 430 is shifted toward the circumferential wall of the catheter 420 (in a proximal direction toward the proximal connector hub 415). After insertion of the flexible circumferential ring 430 through the skin penetration point and into the subcutaneous layer 34, the flexible  
5 circumferential ring 430 can be biased to extend outwardly from the circumferential wall of the catheter 420. In doing so, the flexible circumferential ring 430 can operate as a subcutaneous anchor that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 405 from the skin penetration point 32. Thus, the intravenous cannula  
10 device 405 can be anchored in the operative position relative to the penetration point 32 so that the distal tip of the flexible catheter 420 resides in the targeted vessel 40 while the proximal connector hub 415 resides external to the skin 30.

Referring to FIG. 4B, during removal of the intravenous cannula device 405, the flexible circumferential ring 430 can flexibly adjust in a second direction so that  
15 the outer rim of the flexible circumferential ring 430 is shifted toward the circumferential wall of the catheter 420 (in a distal direction away the proximal connector hub 415). Thus, the flexible circumferential ring 430 can be configured to prolapse in response to a removal force 440 applied to the intravenous cannula device 405 during withdrawal of the intravenous cannula device 405 from the skin  
20 penetration point.

Referring now to FIGs. 5A-5B, some alternative embodiments of a medical system 500 may include an intravenous cannula device 505 that is similar to the device 405 illustrated in FIGS. 4A-4B, except that intravenous cannula device 505 is equipped with multiple subcutaneous anchors 530 in the shape of flexible  
25 circumferential rings. Similar to previously described embodiments herein, the medical system 500 includes the intravenous cannula device 505 and an inserter tool 510 that is detachably coupled to the intravenous cannula device 505. The intravenous cannula device 505 can include a distal section having a flexible catheter 520 and a proximal connector hub 515 configured to releasably connect with an  
30 external fluid line. In this embodiment, each of the flexible circumferential rings 530 is integrally formed as a unitary structure with the side wall of the flexible catheter 520, and the flexible circumferential rings 530 are positioned in series along a central

region of the intravenous cannula device 505 (e.g., proximal to a distal tip of the catheter 520 and distal to the proximal connector hub 515).

Similar to the embodiments previously described in connection with FIGs. 4A-4B, one or more of the flexible circumferential rings 530 can be directed to  
5 penetrate through the same penetration point 32 as the catheter 520 for positioning in  
in the subcutaneous layer 34 along the underside of the skin 30. As such, one or more  
of the flexible circumferential rings 530 can secure the catheter 520 in the operative  
position relative to the penetration point 32 without necessarily requiring adhesive  
tapes bonded to the skin. Each of the flexible circumferential rings 530 inserted  
10 through the skin penetration point 32 can flexibly adjust in a first direction so that the  
outer rim of the respective circumferential ring 530 is shifted toward the  
circumferential wall of the catheter 520 (in a proximal direction toward the proximal  
connector hub 515). After insertion of the respective circumferential ring 530 through  
the skin penetration point 32 and into the subcutaneous layer 34, the respective  
15 circumferential ring 530 can be biased to extend outwardly from the circumferential  
wall of the catheter 520. In doing so, the respective circumferential ring 530 can  
operate as a subcutaneous anchor that engages the underside of the skin 30, the fatty  
tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the  
intravenous cannula device 505 from the skin penetration point 32. Thus, the  
20 intravenous cannula device 505 can be anchored in the operative position relative to  
the penetration point 32 so that the distal tip of the flexible catheter 520 resides in the  
targeted vessel 40 while the proximal connector hub 515 resides external to the skin  
30.

Referring to FIG. 5B, during removal of the intravenous cannula device 505,  
25 each of the flexible circumferential rings 530 passing through the skin penetration  
point 32 can flexibly adjust in a second direction so that the outer rim of the  
respective circumferential ring 530 is shifted toward the circumferential wall of the  
catheter 520 (in a distal direction away the proximal connector hub 515). Thus, the  
respective circumferential ring 530 withdrawing through the skin penetration point 32  
30 can be configured to prolapse in response to a removal force 540 applied to the  
intravenous cannula device 505 during withdrawal of the intravenous cannula device  
505 from the skin penetration point. Any of the flexible circumferential rings 530 that

are withdrawn through the skin penetration point 32 or are otherwise positioned external to the skin 30 can return to its non-prolapsed condition in which the flexible circumferential ring 530 is biased to extend generally radially outward from the circumferential wall of the catheter 520.

5 Referring now to FIGs. 6A-6B, some alternative embodiments of a medical system 600 may include a subcutaneous anchor 630 having a different configuration, for example, in the shape of a pair of recessed tabs. In this embodiment, the medical system 600 can be similar to the medical system 100 of FIGs. 1-3. For example, the medical system 600 includes an intravenous cannula device 605 and an inserter tool  
10 610 that is detachably coupled to the intravenous cannula device 605. The intravenous cannula device 605 can include a distal section having a flexible catheter 620 and a proximal connector hub 615 configured to releasably connect with an external fluid line. In this embodiment, each of the recessed tabs 630 are integrally formed as a unitary structure with the side wall of the flexible catheter 620, and the  
15 recessed tabs 630 are positioned along a central region of the intravenous cannula device 605 (e.g., proximal to a distal tip of the catheter 620 and distal to the proximal connector hub 615).

Each recessed tab 630 can include a corresponding cavity 632 that is shaped to receive the respective recessed tab 630 during insertion through the skin penetration  
20 point 32. Also, the pair of recessed tabs 630 can be arranged diametrically opposite from one another about the central axis of the catheter 620 at a location near to the proximal connector hub 615. In this embodiment, each of the recessed tabs 630 includes a curved shape in which a concave major surface faces generally toward the distal end of the catheter 620 while a convex minor surface faces generally toward the  
25 proximal connector hub 615. The pair of recessed tabs 630 can be directed to penetrate through the same penetration point 32 as the catheter 620 for positioning in in the subcutaneous layer 34 along the underside of the skin 30. As such, the pair of recessed tabs 630 can secure the catheter 620 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin.

30 In some embodiments, the pair of recessed tabs 630 can be integrally formed with the flexible catheter 620 such that the pair of recessed tabs 630 and the catheter 420 share a common flexible polymer material. Accordingly, during insertion through



the skin penetration point, each of the recessed tabs 630 can flexibly adjust in a first direction (toward the proximal connector hub 615) so that each tab 630 nests within its corresponding cavity 632. After insertion of the recessed tabs 630 through the skin penetration point 32 and into the subcutaneous layer 34, the recessed tabs 630 can be  
5 biased to extend outwardly from the circumferential wall of the catheter 620. In doing so, the pair of recessed tabs 630 can operate as subcutaneous anchors that engage the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 605 from the skin penetration point 32. Thus, the intravenous cannula device 605 can be anchored in  
10 the operative position relative to the penetration point 32 so that the distal tip of the flexible catheter 620 resides in the targeted vessel 40 while the proximal connector hub 615 resides external to the skin 30.

Referring to FIG. 6B, during removal of the intravenous cannula device 605, each of the recessed tabs 630 can flexibly adjust in a second direction to bend or  
15 prolapse (in a distal direction away the proximal connector hub 615). Thus, the recessed tabs 630 can be configured to prolapse in response to a removal force 640 applied to the intravenous cannula device 605 during withdrawal of the intravenous cannula device 605 from the skin penetration point. Optionally, each of the recessed tabs 630 can include a second cavity (not shown) positioned distal of the respective  
20 tab 630 so as to receive at least a portion of the tab 630 during removal through the skin penetration point 32.

Referring now to FIGs. 7A-7B, some alternative embodiments of a medical system 700 may include an intravenous cannula device 705 that is similar to the device 605 illustrated in FIGS. 6A-6B, except that intravenous cannula device 705 is  
25 equipped with multiple pairs of recessed tabs 730 that are operable to provide subcutaneous anchoring. Similar to previously described embodiments herein, the medical system 700 includes the intravenous cannula device 705 and an inserter tool 710 that is detachably coupled to the intravenous cannula device 705. The intravenous cannula device 705 can include a distal section having a flexible catheter  
30 720 and a proximal connector hub 715 configured to releasably connect with an external fluid line. In this embodiment, each of the recessed tabs 730 is integrally formed as a unitary structure with the side wall of the flexible catheter 720, and the

pairs of recessed tabs 730 are positioned in series along a central region of the intravenous cannula device 705 (e.g., proximal to a distal tip of the catheter 720 and distal to the proximal connector hub 715).

Similar to the embodiments previously described in connection with FIGs. 6A-6B, one or more of the pairs of recessed tabs 730 can be directed to penetrate through the same penetration point 32 as the catheter 720 for positioning in the subcutaneous layer 34 along the underside of the skin 30. As such, one or more of the pairs of recessed tabs 730 can secure the catheter 720 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. Each of the recessed tabs 730 inserted through the skin penetration point 32 can flexibly adjust in a first direction (toward the proximal connector hub 715) so that each tab 730 nests within its corresponding cavity 732. After insertion of the respective pair of recessed tabs 730 through the skin penetration point 32 and into the subcutaneous layer 34, the respective pair of recessed tabs 730 can be biased to extend outwardly from the circumferential wall of the catheter 720 (similar to the previous embodiments described in connection with FIGs. 6A-6B). In doing so, the respective pair of recessed tabs 730 can operate as subcutaneous anchors that engage the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 705 from the skin penetration point 32. Thus, the intravenous cannula device 705 can be anchored in the operative position relative to the penetration point 32 so that the distal tip of the flexible catheter 720 resides in the targeted vessel 40 while the proximal connector hub 715 resides external to the skin 30.

Referring to FIG. 7B, during removal of the intravenous cannula device 705, each of the pairs of recessed tabs 730 passing through the skin penetration point 32 can flexibly adjust in a second direction to bend or prolapse (in a distal direction away from the proximal connector hub 715). Thus, the respective pair of recessed tabs 730 (when withdrawing through the skin penetration point 32) can be configured to prolapse in response to a removal force 740 applied to the intravenous cannula device 705 during withdrawal of the intravenous cannula device 705 from the skin penetration point 32. Any of the recessed tabs 730 that are withdrawn through the skin penetration point 32 or are otherwise positioned external to the skin 30 can return

to their non-prolapsed condition in which the recessed tabs 730 are biased to extend generally outward from the respective cavities 732. Optionally, each of the recessed tabs 730 can include a second cavity (not shown) positioned distal of the respective tab 730 so as to receive at least a portion of the tab 730 during removal through the skin penetration point 32.

Referring now to FIGs. 8A-8B, some alternative embodiments of a medical system 800 may include a subcutaneous anchor 830 having a different configuration, for example, in the shape of a slotted circumferential ring. In this embodiment, the medical system 800 can be similar to the medical system 100 of FIGs. 1-3. For example, the medical system 800 includes an intravenous cannula device 805 and an inserter tool 810 that is detachably coupled to the intravenous cannula device 805. The intravenous cannula device 805 can include a distal section having a flexible catheter 820 and a proximal connector hub 815 configured to releasably connect with an external fluid line. In this embodiment, the slotted circumferential ring 830 is integrally formed as a unitary structure with the side wall of the flexible catheter 820, and the slotted circumferential ring 830 is positioned along a central region of the intravenous cannula device 805 (e.g., proximal to a distal tip of the catheter 820 and distal to the proximal connector hub 815).

The slotted circumferential ring 830 is formed radially about the catheter 820 at a location near to the proximal connector hub 815. The slotted circumferential ring 830 can be directed to penetrate through the same penetration point 32 as the catheter 820 for positioning in the subcutaneous layer 34 along the underside of the skin 30. Accordingly, the slotted circumferential ring 830 can secure the catheter 820 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. In some embodiments, the slotted circumferential ring 830 can be integrally formed with the flexible catheter 820 such that the slotted circumferential ring 830 and the catheter 820 share a common flexible polymer material. Accordingly, during insertion through the skin penetration point, the slotted circumferential ring 830 can flexibly adjust in a first direction so that the outer edge segments of the slotted circumferential ring 830 are shifted toward the circumferential wall of the catheter 820 (in a proximal direction toward the proximal connector hub 815). After insertion of the slotted circumferential ring 830 through the skin

penetration point 32 and into the subcutaneous layer 34, the slotted circumferential ring 830 can be biased so that the outer edge segments extend generally radially outward from the circumferential wall of the catheter 830. In doing so, the slotted circumferential ring 830 can operate as a subcutaneous anchor that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 805 from the skin penetration point 32. The intravenous cannula device 805 can be anchored in the operative position relative to the penetration point 32 so that the distal tip of the flexible catheter 820 resides in the targeted vessel 40 while the proximal connector hub 815 resides external to the skin 30.

Referring to FIG. 8B, during removal of the intravenous cannula device 805, the slotted circumferential ring 830 can flexibly adjust in a second direction so that the outer edge segments of the slotted circumferential ring 830 are shifted toward the circumferential wall of the catheter 820 (in a distal direction away the proximal connector hub 815). As such, the flexible circumferential ring 830 can be configured to prolapse in response to a removal force 840 applied to the intravenous cannula device 805 during withdrawal of the intravenous cannula device 805 from the skin penetration point 32.

Referring now to FIGS. 9A-9B, some alternative embodiments of a medical system 900 may include an intravenous cannula device 905 that is similar to the device 805 illustrated in FIGS. 8A-8B, except that intravenous cannula device 905 is equipped with multiple subcutaneous anchors 930 in the shape of slotted circumferential rings. Similar to previously described embodiments herein, the medical system 900 includes the intravenous cannula device 905 and an inserter tool 910 that is detachably coupled to the intravenous cannula device 905. The intravenous cannula device 905 can include a distal section having a flexible catheter 920 and a proximal connector hub 915 configured to releasably connect with an external fluid line. In this embodiment, each of the slotted circumferential rings 930 is integrally formed as a unitary structure with the side wall of the flexible catheter 920, and the slotted circumferential rings 930 are positioned in series along a central region of the intravenous cannula device 905 (e.g., proximal to a distal tip of the catheter 920 and distal to the proximal connector hub 915).

Similar to the embodiments previously described in connection with FIGs. 8A-8B, one or more of the slotted circumferential rings 930 can be directed to penetrate through the same penetration point 32 as the catheter 920 for positioning in the subcutaneous layer 34 along the underside of the skin 30. As such, one or more of the slotted circumferential rings 930 can secure the catheter 920 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. Each of the slotted circumferential rings 930 inserted through the skin penetration point 32 can flexibly adjust in a first direction so that the outer edge segments of the respective slotted ring 930 is shifted toward the circumferential wall of the catheter 920 (in a proximal direction toward the proximal connector hub 915). After insertion of the respective slotted ring 930 through the skin penetration point 32 and into the subcutaneous layer 34, the respective slotted ring 930 can be biased so that the outer edge segments extend generally radially outward from the circumferential wall of the catheter 920. In doing so, the respective slotted ring 930 can operate as a subcutaneous anchor that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 505 from the skin penetration point 32. Thus, the intravenous cannula device 905 can be anchored in the operative position relative to the penetration point 32 so that the distal tip of the flexible catheter 920 resides in the targeted vessel 40 while the proximal connector hub 915 resides external to the skin 30.

Referring to FIG. 9B, during removal of the intravenous cannula device 905, each of the slotted circumferential rings 930 passing through the skin penetration point 32 can flexibly adjust in a second direction so that the outer edge segments of the respective slotted ring 930 are shifted toward the circumferential wall of the catheter 920 (in a distal direction away the proximal connector hub 915). Thus, the respective slotted ring 930 withdrawing through the skin penetration point 32 can be configured to prolapse in response to a removal force 940 applied to the intravenous cannula device 905 during withdrawal of the intravenous cannula device 905 from the skin penetration point 32. Any of the slotted circumferential rings 930 that are withdrawn through the skin penetration point 32 or are otherwise positioned external to the skin 30 can return to its non-prolapsed condition in which the slotted

circumferential ring 930 is biased to extend generally radially outward from the circumferential wall of the catheter 920.

Referring now to FIGs. 10A-10B, some alternative embodiments of a medical system 1000 may include a subcutaneous anchor 1030 having a different configuration, for example, in the shape of an anchor flap. In this embodiment, the medical system 1000 can be similar to the medical system 100 of FIGs. 1-3. For example, the medical system 1000 includes an intravenous cannula device 1005 and an inserter tool 1010 that is detachably coupled to the intravenous cannula device 1005. The intravenous cannula device 1005 can include a distal section having a flexible catheter 1020 and a proximal connector hub 1015 configured to releasably connect with an external fluid line. In this embodiment, the anchor flap 1030 is integrally formed as a unitary structure with the side wall of the flexible catheter 1020, and the anchor flap 1030 is positioned along a central region of the intravenous cannula device 1005 (e.g., proximal to a distal tip of the catheter 1020 and distal to the proximal connector hub 1015).

Each recessed tab 1030 can include a corresponding cavity 1032 that is shaped to receive the anchor flap 1030 during insertion through the skin penetration point 32. In this embodiment, the anchor flap 1030 includes a generally flat shape that extends transversely from the longitudinal axis of the catheter 1020. The anchor flap 1030 can be directed to penetrate through the same penetration point 32 as the catheter 1020 for positioning in the subcutaneous layer 34 along the underside of the skin 30. As such, the anchor flap 1030 can secure the catheter 1020 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin.

In some embodiments, the anchor flap 1030 can be integrally formed with the flexible catheter 1020 such that the anchor flap 1030 and the catheter 1020 share a common flexible polymer material. Accordingly, during insertion through the skin penetration point, the anchor flap 1030 can flexibly adjust in a first direction (toward the proximal connector hub 1015) so that the anchor flap 1030 nests within its corresponding cavity 1032. After insertion of the anchor flap 1030 through the skin penetration point 32 and into the subcutaneous layer 34, the anchor flap 1030 can be biased to extend outwardly from the circumferential wall of the catheter 1020. In

doing so, the anchor flap 1030 can operate as subcutaneous anchors that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 1005 from the skin penetration point 32.

5 Referring to FIG. 10B, during removal of the intravenous cannula device 1005, the anchor flap 1030 can flexibly adjust in a second direction to prolapse (in a distal direction away the proximal connector hub 1015). Thus, the anchor flap 1030 can be configured to prolapse in response to a removal force 1040 applied to the intravenous cannula device 1005 during withdrawal of the intravenous cannula device 1005 from  
10 the skin penetration point 32. Optionally, the anchor flap 1030 can include a second cavity (not shown) positioned distal of the anchor flap 1030 so as to receive at least a portion of the anchor flap 1030 during removal through the skin penetration point 32.

Referring now to FIGs. 11A-11B, some alternative embodiments of a medical system 1100 may include an intravenous cannula device 1105 that is similar to the  
15 device 1005 illustrated in FIGS. 10A-10B, except that intravenous cannula device 1105 is equipped with multiple anchor flaps 1130 that are operable to provide subcutaneous anchoring. Similar to previously described embodiments herein, the medical system 1100 includes the intravenous cannula device 1105 and an inserter tool 1110 that is detachably coupled to the intravenous cannula device 1105. The  
20 intravenous cannula device 1105 can include a distal section having a flexible catheter 1120 and a proximal connector hub 1115 configured to releasably connect with an external fluid line. In this embodiment, each of the anchor flaps 1130 is integrally formed as a unitary structure with the side wall of the flexible catheter 1120, and the anchor flaps 1130 are positioned in series along a central region of the intravenous  
25 cannula device 1105 (e.g., proximal to a distal tip of the catheter 1120 and distal to the proximal connector hub 1115).

Similar to the embodiments previously described in connection with FIGs. 10A-10B, one or more of the anchor flaps 1130 can be directed to penetrate through the same penetration point 32 as the catheter 1120 for positioning in in the  
30 subcutaneous layer 34 along the underside of the skin 30. In doing so, one or more of the anchor flaps 1130 can secure the catheter 1120 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the

skin. Each of the anchor flaps 1130 inserted through the skin penetration point 32 can flexibly adjust in a first direction (toward the proximal connector hub 1115) so that each of the respective flaps 1130 nests within its corresponding cavity 1132. After insertion of the respective anchor flap 1130 through the skin penetration point 32 and  
5 into the subcutaneous layer 34, the respective anchor flap 1130 can be biased to extend outwardly from the circumferential wall of the catheter 1120 (similar to the previous embodiments described in connection with FIGs. 6A-6B). In doing so, the respective anchor flap 1130 can operate as a subcutaneous anchor that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to  
10 resist withdrawal of the intravenous cannula device 1105 from the skin penetration point 32.

Referring to FIG. 11B, during removal of the intravenous cannula device 1105, each of the anchor flaps 1130 passing through the skin penetration point 32 can flexibly adjust in a second direction to bend or prolapse (in a distal direction away the  
15 proximal connector hub 1115). Thus, the respective anchor flap 1130 withdrawing through the skin penetration point 32 can be configured to prolapse in response to a removal force 1140 applied to the intravenous cannula device 1105 during withdrawal of the intravenous cannula device 1105 from the skin penetration point 32. Any of the anchor flaps 1130 that are withdrawn through the skin penetration point 32 or are  
20 otherwise positioned external to the skin 30 can return to their non-prolapsed condition in which the anchor flaps 1130 are biased to extend transversely to the longitudinal axis of the catheter 1120. Optionally, each of the anchor flaps 1130 can include a second cavity (not shown) positioned distal of the respective anchor flap 1130 so as to receive at least a portion of the respective anchor flap 1130 during  
25 removal through the skin penetration point 32.

Referring now to FIGs. 12A-12B, some alternative embodiments of a medical system 1200 may include a subcutaneous anchor 1230 having a different configuration, for example, in the shape of a tapered circumferential ring. Similar to previously described embodiments, the medical system 1200 can include an  
30 intravenous cannula device 1205 and an inserter tool 1210 that is detachably coupled to the intravenous cannula device 1205. The intravenous cannula device 1205 can include a distal section having a flexible catheter 1220 and a proximal connector hub



1215 configured to releasably connect with an external fluid line. In this embodiment, the tapered circumferential ring 1230 is integrally formed as a unitary structure with the side wall of the flexible catheter 1220, and the tapered circumferential ring 1230 is positioned along a central region of the intravenous cannula device 1205 (e.g., proximal to a distal tip of the catheter 1220 and distal to the proximal connector hub 1215).

The tapered circumferential ring 1230 can be directed to penetrate through the same penetration point 32 as the catheter 1220 for positioning in in the subcutaneous layer 34 along the underside of the skin 30. As such, the tapered circumferential ring 1230 can secure the catheter 1220 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. In some embodiments, the tapered circumferential ring 1230 may be asymmetrical along its axis. For example, the tapered circumferential ring 1230 may include a proximal tapered face 1236 at a proximal end nearest to the proximal connector hub 1215. The proximal tapered face 1236 may expand distally from an initial diameter (e.g., substantially equal to the diameter of the catheter 1220) at the proximal end of the tapered circumferential ring 1230 to a maximum diameter of the tapered circumferential ring 1230 along the distal border of the proximal tapered face 1236. The diameter of the tapered circumferential ring 1230 then reduces along one or more distal tapered sections 1237, 1238, and 1239. In general, the slope of the proximal tapered face 1236 may be substantially greater (e.g., steeper) than the aggregate slopes of the tapered sections 1237, 1238, and 1239. In some embodiments, such longitudinally asymmetrical configurations may reduce the relative insertion resistance while also increasing the relative withdrawal resistance of the tapered circumferential ring 1230 through the penetration point 32.

After insertion of the tapered circumferential ring 1230 through the skin penetration point 32 and into the subcutaneous layer 34, the tapered circumferential ring 1230 can operate as a subcutaneous anchor that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 1205 from the skin penetration point 32. During removal of the intravenous cannula device 1205 (FIG. 12B), the tapered circumferential rings 1230 withdrawing through the skin penetration point 32 can be

configured to pass through the skin penetration point 32 in an atraumatic manner when a removal force 1240 is applied to the intravenous cannula device 1205.

Referring now to FIGs. 13A-13B, some alternative embodiments of a medical system 1300 may include an intravenous cannula device 1305 that is similar to the device 1205 illustrated in FIGS. 12A-12B, except that intravenous cannula device 1305 is equipped with multiple tapered circumferential rings 1330 positioned in a series. Similar to previously described embodiments herein, the medical system 1300 includes the intravenous cannula device 1305 and an inserter tool 1310 that is detachably coupled to the intravenous cannula device 1305. The intravenous cannula device 1305 can include a distal section having a flexible catheter 1320 and a proximal connector hub 1315 configured to releasably connect with an external fluid line. In this embodiment, each of the tapered circumferential rings 1330 is integrally formed as a unitary structure with the side wall of the flexible catheter 1320, and the tapered circumferential rings 1330 are positioned in series along a central region of the intravenous cannula device 1305 (e.g., proximal to a distal tip of the catheter 1320 and distal to the proximal connector hub 1315).

Similar to the embodiments previously described in connection with FIGs. 12A-12B, one or more of the tapered circumferential rings 1330 can be directed to penetrate through the same penetration point 32 as the catheter 1320 for positioning in the subcutaneous layer 34 along the underside of the skin 30. In doing so, one or more of the tapered circumferential rings 1330 can secure the catheter 1320 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. Each of the tapered circumferential rings 1330 can include a proximal tapered face that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 1305 from the skin penetration point 32. During removal of the intravenous cannula device 1305 (FIG. 13B), the respective tapered circumferential rings 1330 withdrawing through the skin penetration point 32 can be configured to pass through the skin penetration point 32 in an atraumatic manner when a removal force 1340 is applied to the intravenous cannula device 1305.

Referring now to FIGs. 14A-14B, some alternative embodiments of a medical system 1400 may include an intravenous cannula device 1405 that is similar to the

device 105 illustrated in FIGS. 1-3, except that intravenous cannula device 1405 is equipped with multiple textured cutouts 1430. Similar to previously described embodiments herein, the medical system 1400 includes the intravenous cannula device 1405 and an inserter tool 1410 that is detachably coupled to the intravenous cannula device 1405. The intravenous cannula device 1405 can include a distal section having a flexible catheter 1420 and a proximal connector hub 1415 configured to releasably connect with an external fluid line. In this embodiment, the textured cutouts 1430 include sidewalls integrally formed as a unitary structure with the side wall of the flexible catheter 1320, and the textured cutouts 1430 are positioned in series along a central region of the intravenous cannula device 1405 (e.g., proximal to a distal tip of the catheter 1420 and distal to the proximal connector hub 1415). In the depicted embodiment, the textured cutouts 1430 may be formed in the sidewall of the flexible catheter 1420 as a set of scalloped cavities configured to anchor within the subcutaneous layer. Some or all of the textured cutouts 1430 can be directed to penetrate through the same penetration point 32 as the catheter 1420 for positioning in the subcutaneous layer 34 along the underside of the skin 30. In doing so, one or more of the textured cutouts 1430 can secure the catheter 1420 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. Each of the textured cutouts 1430 can include a least one cavity sidewall that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 1405 from the skin penetration point 32. During removal of the intravenous cannula device 1405 (FIG. 14B), the respective textured cutouts 1430 withdrawing through the skin penetration point 32 can be configured to pass through the skin penetration point 32 in an atraumatic manner when a removal force 1440 is applied to the intravenous cannula device 1405.

Referring now to FIGs. 15A-15B, some alternative embodiments of a medical system 1500 may include an intravenous cannula device 1505 that is similar to the device 105 illustrated in FIGS. 1-3, except that intravenous cannula device 1505 is equipped with a threaded anchor 1530. Similar to previously described embodiments herein, the medical system 1500 includes the intravenous cannula device 1505 and an inserter tool 1510 that is detachably coupled to the intravenous cannula device 1505.

The intravenous cannula device 1505 can include a distal section having a flexible catheter 1520 and a proximal connector hub 1515 configured to releasably connect with an external fluid line. In this embodiment, the threaded anchor 1530 include at least one thread pattern formed as a unitary structure with the side wall of the flexible catheter 1520, and the threaded anchor 1530 is positioned along a central region of the intravenous cannula device 1505 (e.g., proximal to a distal tip of the catheter 1520 and distal to the proximal connector hub 1515). In the depicted embodiment, the threaded anchor 1530 may be spiral around the side wall of the flexible catheter 1520 so that the thread is configured to anchor within the subcutaneous layer. The threaded anchor 1530 can be directed to penetrate through the same penetration point 32 as the catheter 1520 for positioning in in the subcutaneous layer 34 along the underside of the skin 30. For example, during insertion of the intravenous cannula device 1505, the user can twist the inserter tool 1510 to “screw” the anchor thread through the skin penetration point 32. In doing so, the threaded anchor 1530 can secure the catheter 1520 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. The threaded anchor 1530 can include a least one thread wall surface that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 1505 from the skin penetration point 32. During removal of the intravenous cannula device 1505 (FIG. 15B), the threaded anchor can be removed through the skin penetration point 32 by twisting the proximal connector hub 1515 with a removing force 1540 so as to “unscrew” the threaded anchor 1530 out of the skin penetration point 32 in an atraumatic manner.

Referring now to FIGs. 16A-16B, some alternative embodiments of a medical system 1600 may include an intravenous cannula device 1605 that is similar to the device 105 illustrated in FIGS. 1-3, except that intravenous cannula device 1605 is equipped with a wedge anchor 1630. Similar to previously described embodiments herein, the medical system 1600 includes the intravenous cannula device 1605 and an inserter tool 1610 that is detachably coupled to the intravenous cannula device 1605.

The intravenous cannula device 1605 can include a distal section having a flexible catheter 1620 and a proximal connector hub 1615 configured to releasably connect with an external fluid line. The wedge anchor 1630 can be positioned along a central

region of the intravenous cannula device 1605 (e.g., proximal to a distal tip of the catheter 1620 and distal to the proximal connector hub 1615). In the depicted embodiment, the wedge anchor 1630 is asymmetrical in shape. For example, in a cross sectional view taken parallel to the longitudinal axis of the catheter 1620, the wedge anchor 1630 may appear generally trapezoidal in shape, in which the upper and lower sides of the trapezoid are substantially parallel to the axis of the catheter 1620, and a proximal side has a steeper angle than a distal side. In some embodiments, this longitudinally asymmetrical configuration can reduce the relative insertion resistance while also increasing the relative extraction resistance of the wedge anchor 1630 through the penetration point 32.

The wedge anchor 1630 can be directed to penetrate through the same penetration point 32 as the catheter 1620 for positioning in in the subcutaneous layer 34 along the underside of the skin 30. In doing so, the wedge anchor 1630 can secure the catheter 1620 in the operative position relative to the penetration point 32 without necessarily requiring adhesive tapes bonded to the skin. The wedge anchor 1630 can include a least one sidewall (e.g., the aforementioned steep proximal side wall) that engages the underside of the skin 30, the fatty tissues in the subcutaneous layer 34, or both so as to resist withdrawal of the intravenous cannula device 1605 from the skin penetration point 32. During removal of the intravenous cannula device 1605 (FIG. 16B), the user can lightly move the intravenous cannula device 1605 in a back-and-forth lateral movement while applying a longitudinal withdrawal force 1640 so that the wedge anchor 1630 passes through the skin penetration point 32 in an atraumatic manner.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

**WHAT IS CLAIMED IS:**

1 1. A medical system for anchoring an intravenous cannula device in a subcutaneous  
2 region along an underside of a skin layer, comprising:

3 an intravenous cannula device including a flexible catheter, a proximal  
4 connector hub, and a subcutaneous anchor integrally formed as a unitary structure  
5 with an outer wall of the flexible catheter, the flexible catheter including a lumen and  
6 extending distally of the proximal connector hub, and the proximal connector hub  
7 including a thread pattern configured to releasably connect with an external fluid line;  
8 and

9 an inserter tool removably coupled to the intravenous cannula device so as to  
10 insert the flexible catheter of the intravenous cannula device through a skin  
11 penetration point and into a targeted vessel, the inserter tool including a handle and an  
12 insertion needle extending distally from the handle, the insertion needle being slidably  
13 engaged with the lumen of the flexible catheter of the intravenous cannula device,  
14 wherein the inserter tool is removable from the intravenous cannula device when the  
15 insertion needle is proximally withdrawn from the lumen of the flexible catheter,

16 wherein the subcutaneous anchor is positioned between a distal tip of the  
17 flexible catheter and the proximal connector hub, and wherein the subcutaneous  
18 anchor includes at least one surface to engage tissue in a subcutaneous region along  
19 an underside of a skin layer when the flexible catheter of the intravenous cannula  
20 device is inserted through a skin penetration point and into a targeted vessel.

21  
22 2. The system of claim 1, wherein the subcutaneous anchor comprises one or more  
23 flexible circumferential rings integrally formed as a unitary structure with the outer  
24 wall of the flexible catheter.

25  
26 3. The system of claim 1, wherein each of the one or more flexible circumferential  
27 rings are configured to prolapse and extend toward a distal end of the flexible catheter  
28 during removal through the skin penetration point.

29  
30 4. The system of claim 1, wherein the subcutaneous anchor comprises one or more  
31 pairs of recessed tabs integrally formed as a unitary structure with the outer wall of

1 the flexible catheter, wherein each respective recessed tab includes a corresponding  
2 cavity to receive the recessed tab during insertion through the skin penetration point.

3  
4 5. The system of claim 1, wherein each of the one or more pairs of recessed tabs are  
5 configured to prolapse such that free ends of the recessed tabs extend toward a distal  
6 end of the flexible catheter during removal through the skin penetration point.

7  
8 6. The system of claim 1, wherein each of the one or more pairs of recessed tabs are  
9 configured to provide a generally curved shape in which a convex surface faces  
10 generally toward the proximal connector hub.

11  
12 7. The system of claim 1, wherein the subcutaneous anchor comprises one or more  
13 slotted circumferential rings integrally formed as a unitary structure with the outer  
14 wall of the flexible catheter.

15  
16 8. The system of claim 1, wherein each of the one or more slotted circumferential  
17 rings are configured to prolapse and extend toward a distal end of the flexible catheter  
18 during removal through the skin penetration point.

19  
20 9. The system of claim 1, wherein the subcutaneous anchor comprises one or more  
21 anchor flaps integrally formed as a unitary structure with the outer wall of the flexible  
22 catheter, wherein each of the one or more anchor flaps comprises a generally straight  
23 body that extends transversely to a longitudinal axis of the flexible catheter.

24  
25 10. The system of claim 1, wherein each of the one or more anchor flaps are flexible  
26 and configured to prolapse such that free ends of the one or more anchor flaps extend  
27 toward a distal end of the flexible catheter during removal through the skin  
28 penetration point.

29  
30 11. The system of claim 1, wherein the subcutaneous anchor comprises one or more  
31 tapered circumferential rings integrally formed as a unitary structure with the outer

1 wall of the flexible catheter, wherein each of the tapered circumferential rings have an  
2 asymmetric shape in which a proximal face is steeper than a distal tapered face.

3  
4 12. The system of claim 1, wherein the subcutaneous anchor comprises a set of  
5 textured cutouts integrally formed as a unitary structure with the outer wall of the  
6 flexible catheter, wherein each of the textured cutouts are defined by cavity walls  
7 formed in the outer wall of the flexible catheter.

8  
9 13. The system of claim 1, wherein the subcutaneous anchor comprises a threaded  
10 anchor integrally formed as a unitary structure with the outer wall of the flexible  
11 catheter, wherein the threaded anchor comprises a raised thread pattern helically  
12 extending around the outer wall of the flexible catheter.

13  
14 14. The system of claim 1, wherein the subcutaneous anchor comprises a wedge  
15 anchor integrally formed as a unitary structure with the outer wall of the flexible  
16 catheter, wherein the wedge anchor comprises an asymmetric shape having a  
17 proximal face and a distal face, the proximal face defines an incline relative to the  
18 outer wall of the flexible catheter that is greater than an incline defined by the distal  
19 face.

20  
21 15. A method of using an intravenous cannula device, comprising:  
22 inserting a needle portion of an inserter tool through a skin penetration point  
23 and into a targeted vessel, wherein an intravenous cannula device is removably  
24 coupled to the inserter tool such that a flexible catheter of the intravenous cannula  
25 device is advanced through the skin penetration point and into the targeted vessel  
26 while a subcutaneous anchor integrally formed as a unitary structure with an outer  
27 wall of the flexible catheter is positioned in a subcutaneous region along an underside  
28 of a skin layer;  
29 removing the inserter tool from the intravenous cannula device such that the  
30 needle portion of the inserter tool is slidably withdrawn from a lumen of the flexible  
31 catheter while the flexible catheter remains in the targeted vessel and the



1 subcutaneous anchor remains in the subcutaneous region along the underside of the  
2 skin layer; and

3 threadably engaging an external fluid line to a proximal connector hub of the  
4 intravenous cannula device while the flexible catheter remains in the targeted vessel  
5 and the subcutaneous anchor remains in the subcutaneous region along the underside  
6 of the skin layer, wherein the subcutaneous anchor is positioned between a distal tip  
7 of the flexible catheter and the proximal connector hub, and wherein the subcutaneous  
8 anchor includes at least one surface to engage tissue in the subcutaneous region  
9 proximate to the skin penetration point.

10  
11 16. The method of claim 15, further comprising infusing a fluid from the proximal  
12 connector hub through the lumen of the flexible catheter and into the targeted vessel.

13  
14 17. The method claim 15, further comprising applying a withdrawal force to the  
15 proximal connector hub of the intravenous cannula device so as to withdrawal the  
16 subcutaneous anchor through the skin penetration point.

17  
18 18. A medical system for anchoring an intravenous cannula device in a subcutaneous  
19 region along an underside of a skin layer, comprising:

20 an intravenous cannula device including a flexible catheter, a proximal  
21 connector hub, and a subcutaneous anchor positioned between a distal tip of the  
22 flexible catheter and the proximal connector hub; and

23 an inserter tool removably coupled to the intravenous cannula device, the  
24 inserter tool including a handle and an insertion needle extending distally from the  
25 handle, the insertion needle being slidably engaged with a lumen of the flexible  
26 catheter,

27 wherein the subcutaneous anchor includes at least one surface to engage tissue  
28 in a subcutaneous region along an underside of a skin layer when the flexible catheter  
29 of the intravenous cannula device is into a targeted vessel.

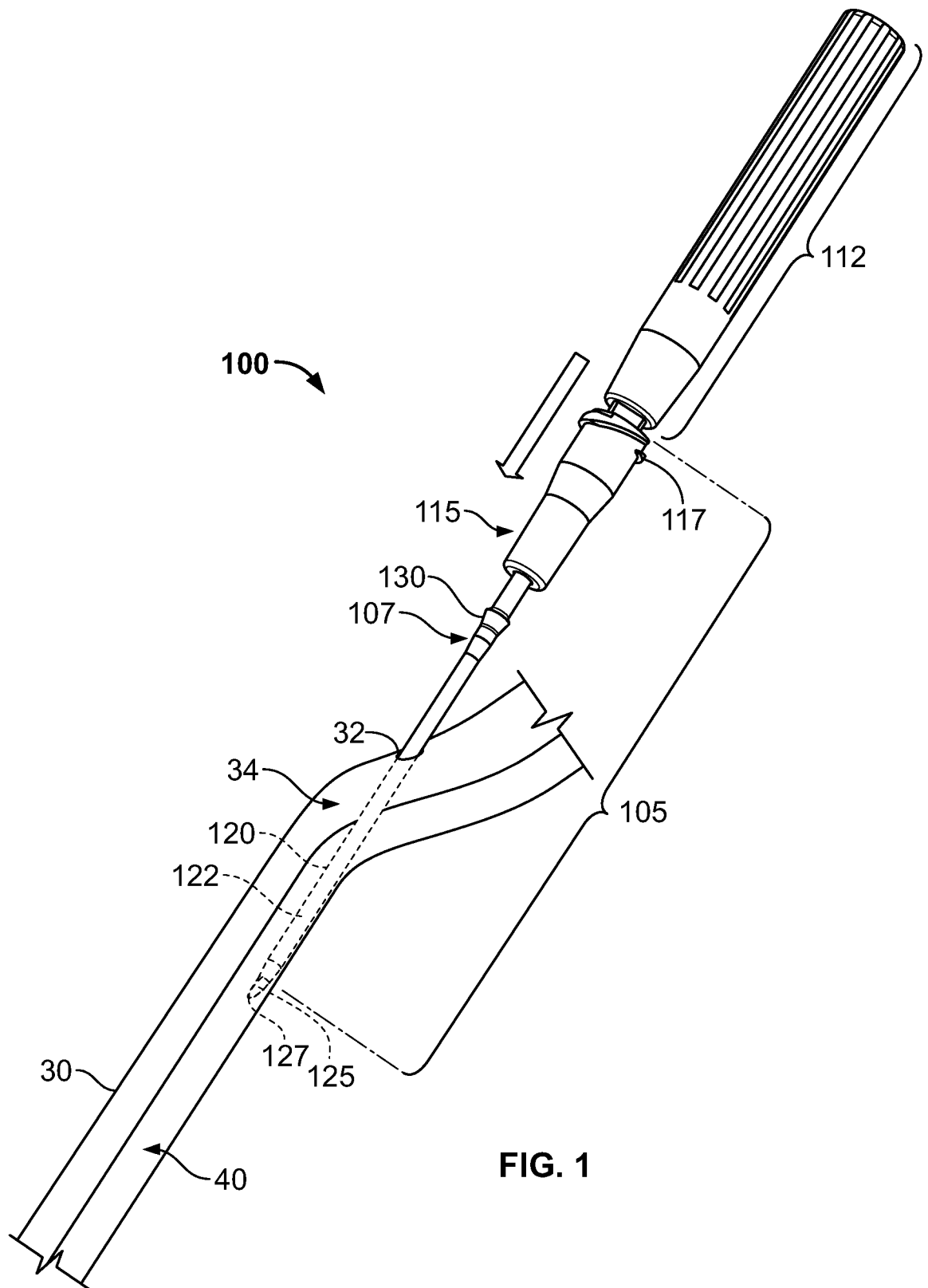
30  
31 19. The system of claim 18, wherein the subcutaneous anchor comprises at least one  
32 of: one or more flexible circumferential rings, one or more pairs of recessed tabs, one

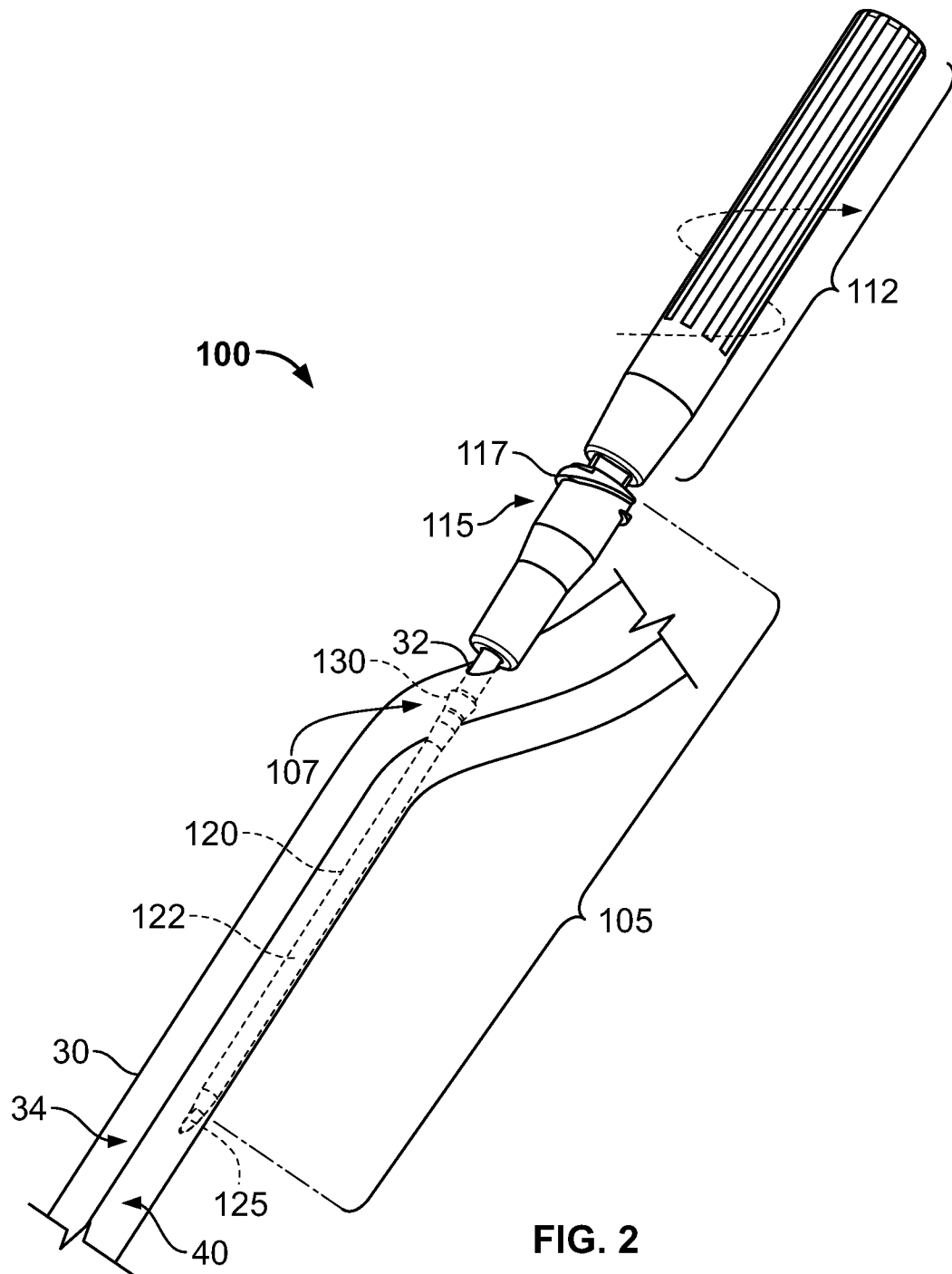
1 or more slotted circumferential rings, one or more anchor flaps, one or more tapered  
2 circumferential rings, a set of textured cutouts, a threaded anchor, and a wedge  
3 anchor.

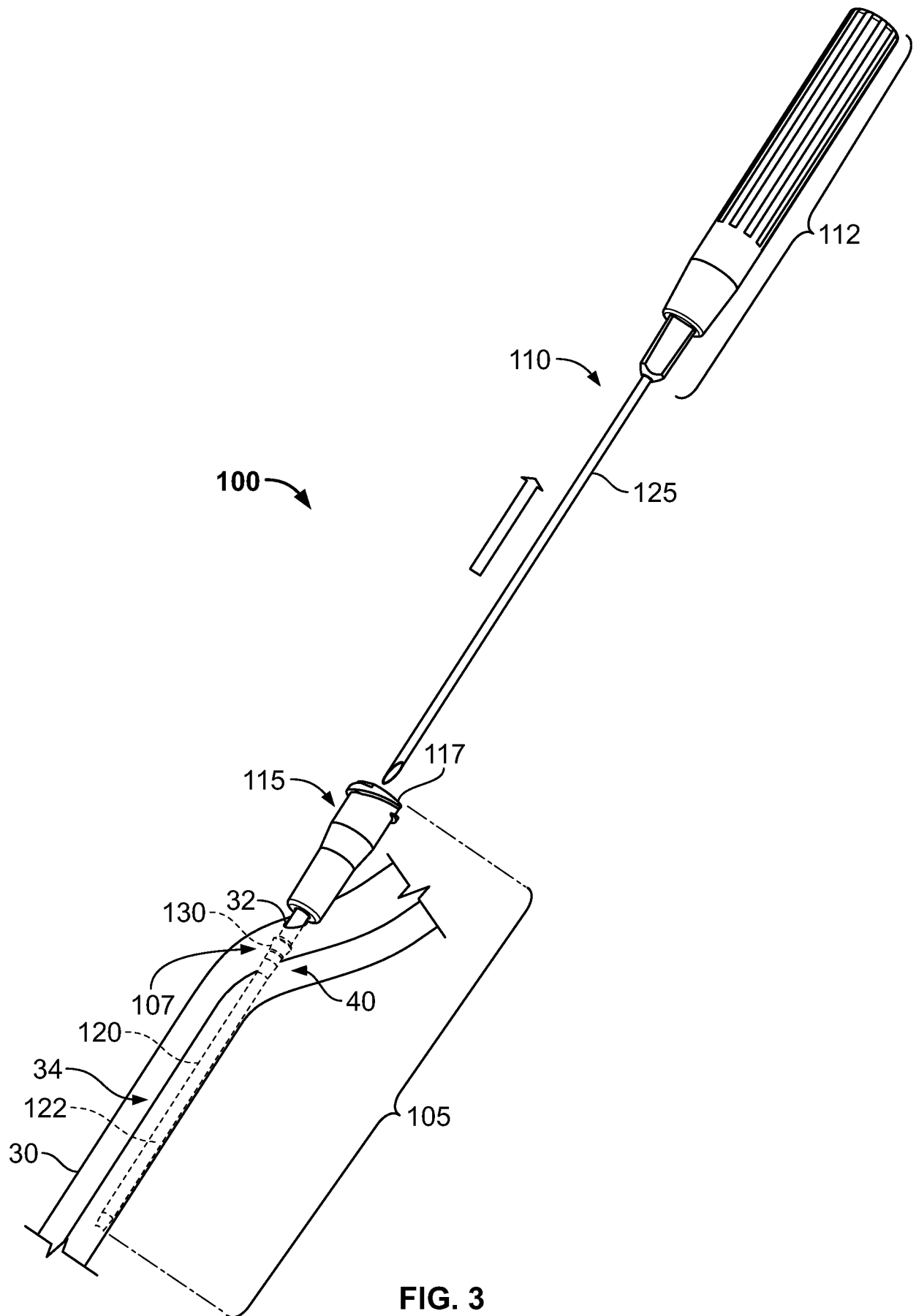
4

5 20. The system of claim 18, wherein the insertion needle is fixedly positioned relative  
6 to the handle of the inserter tool.

7







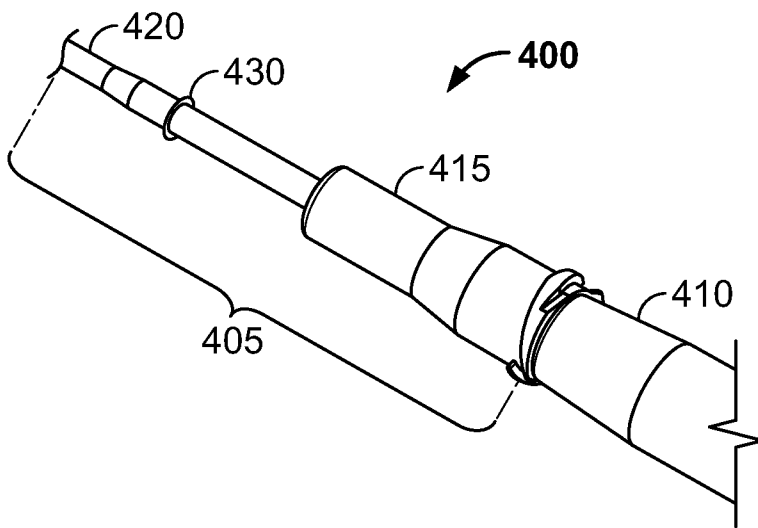


FIG. 4A

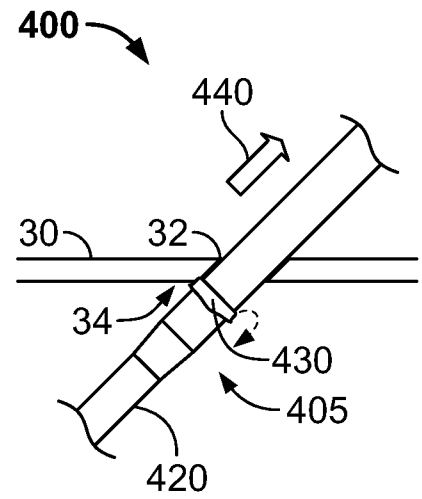


FIG. 4B

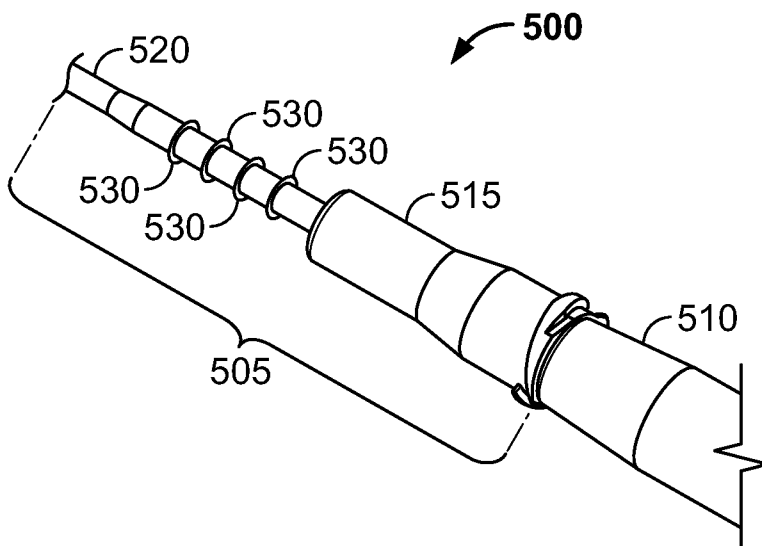


FIG. 5A

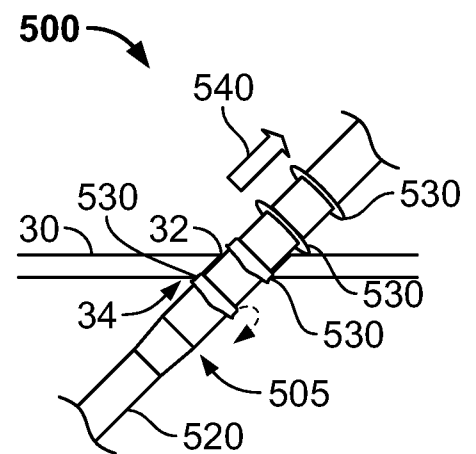


FIG. 5B

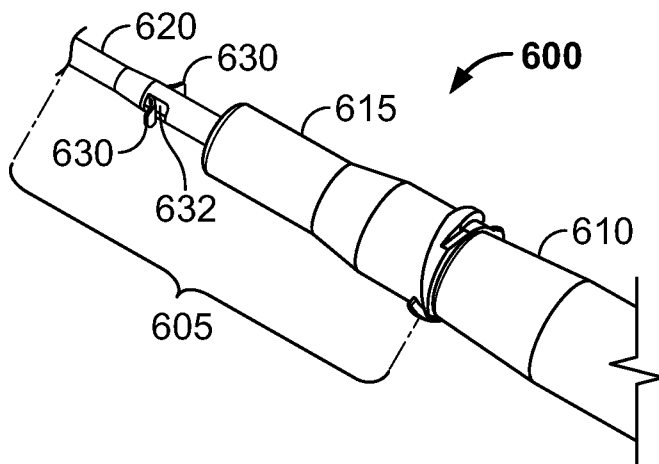


FIG. 6A

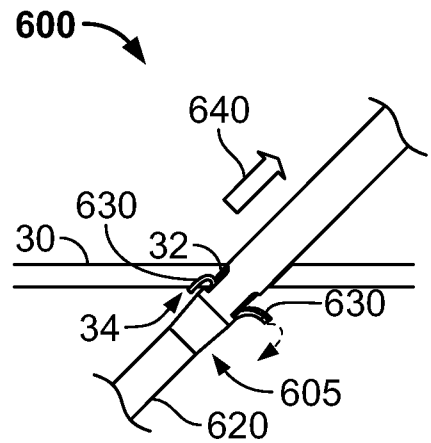


FIG. 6B

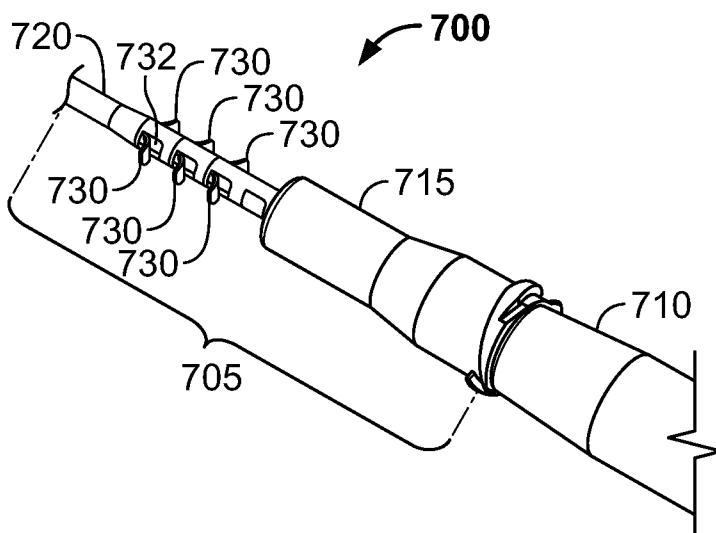


FIG. 7A

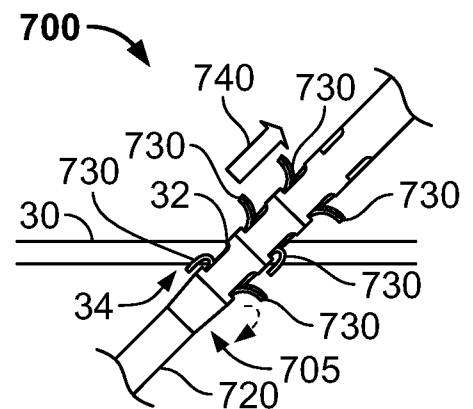


FIG. 7B

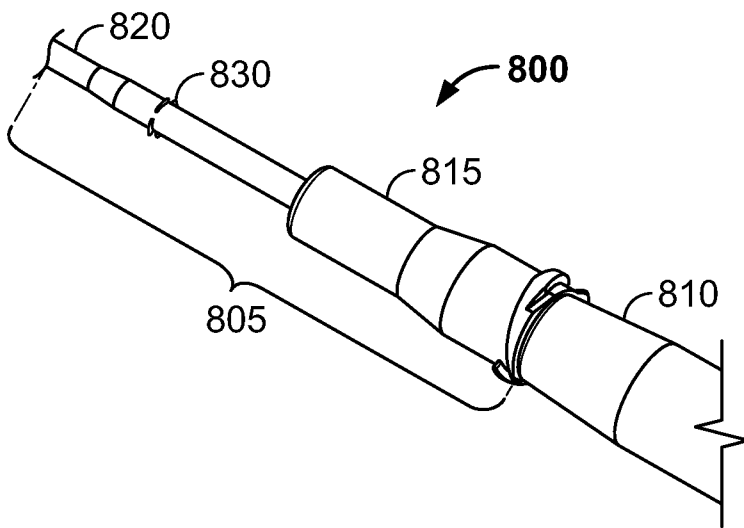


FIG. 8A

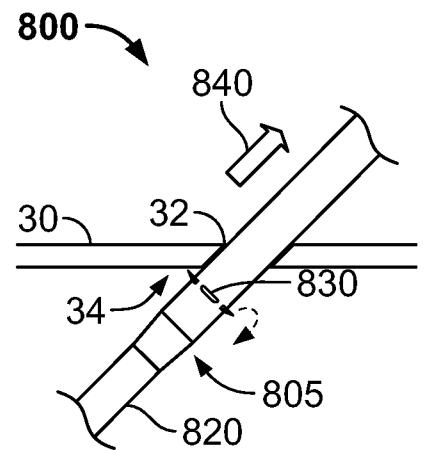


FIG. 8B

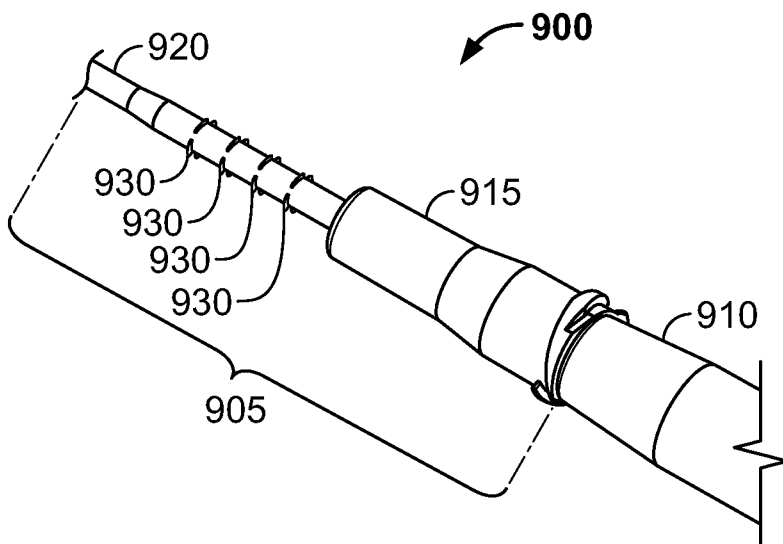


FIG. 9A

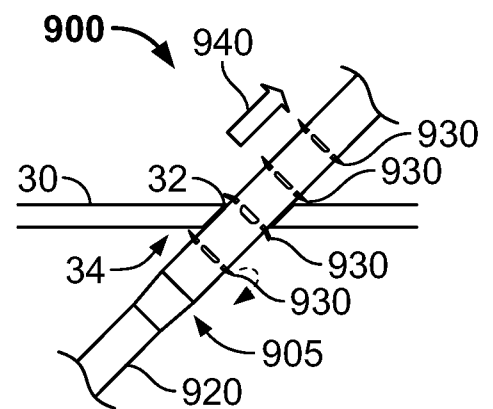


FIG. 9B



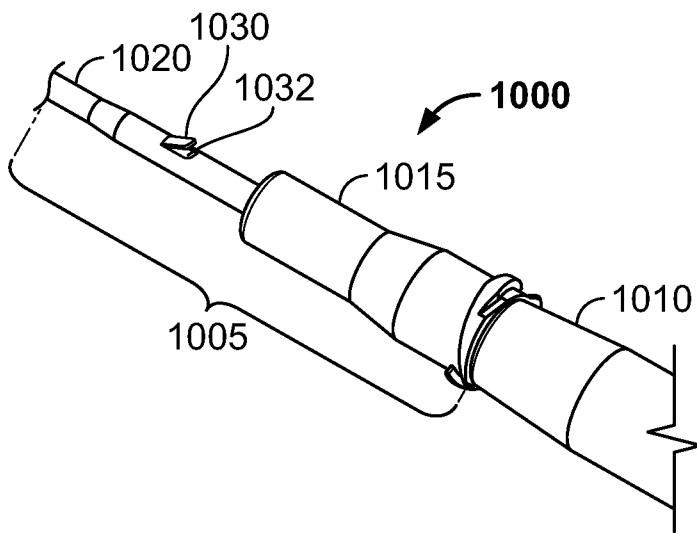


FIG. 10A

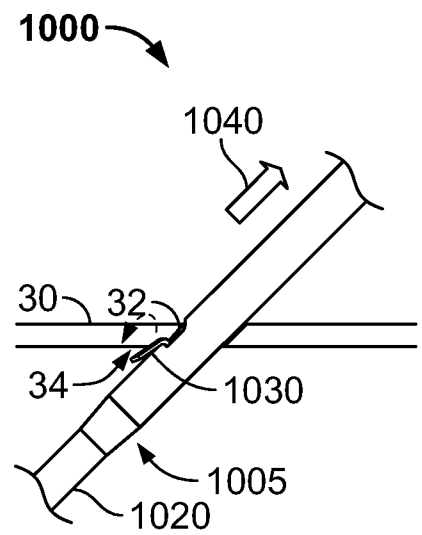


FIG. 10B

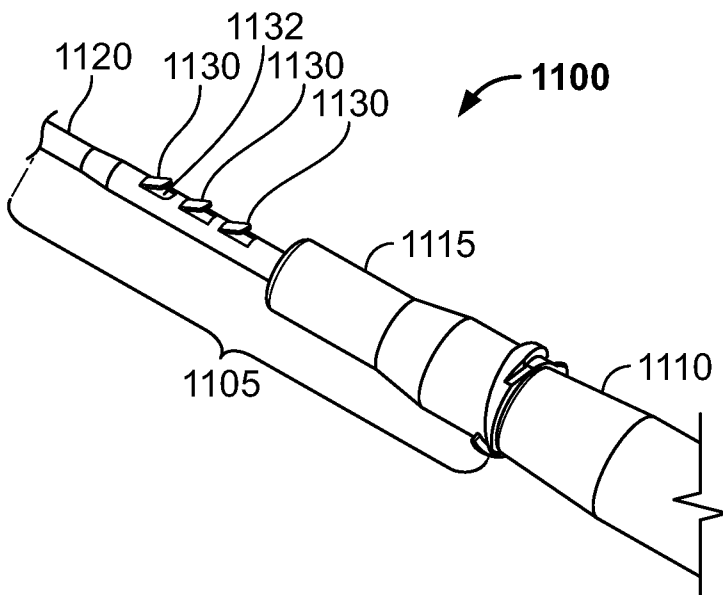


FIG. 11A

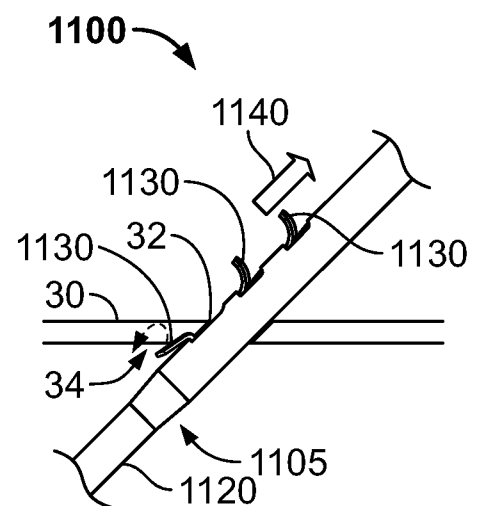


FIG. 11B

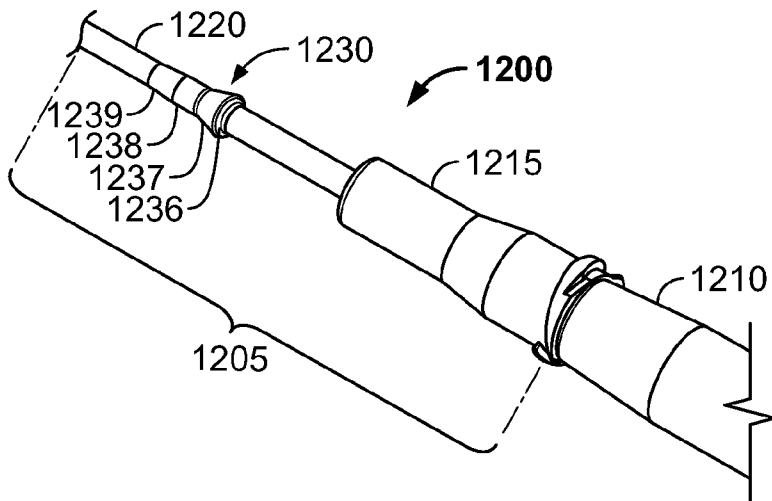


FIG. 12A

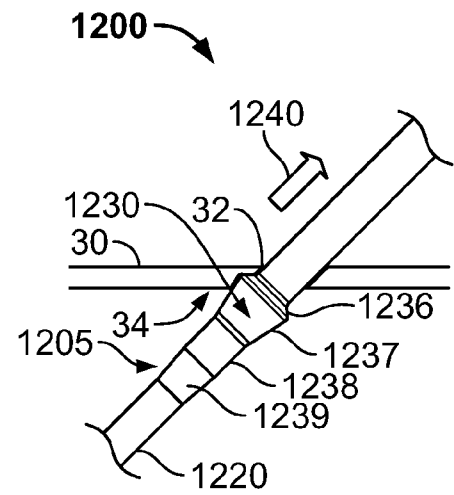


FIG. 12B

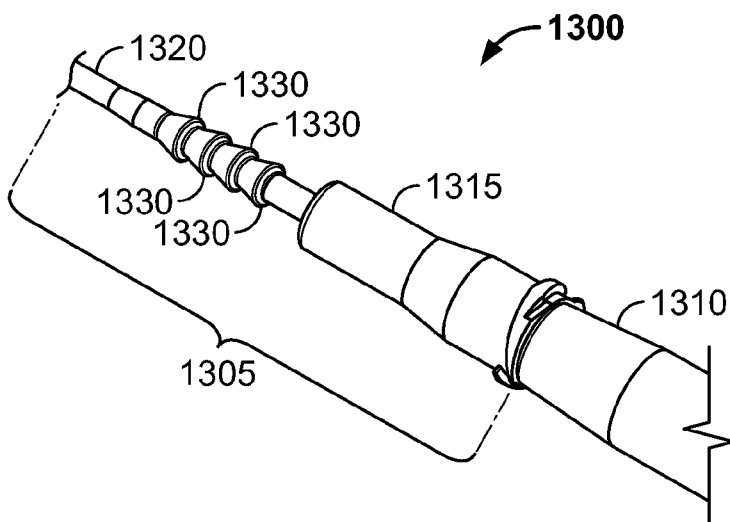


FIG. 13A

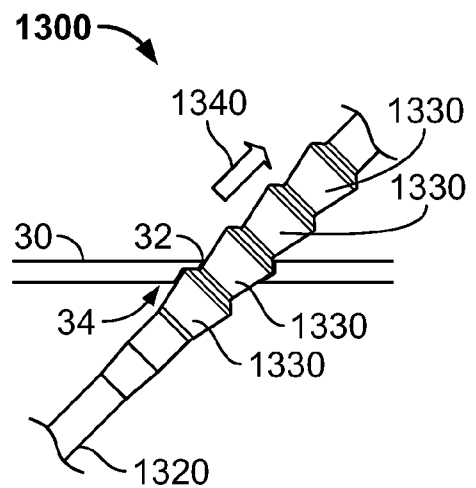
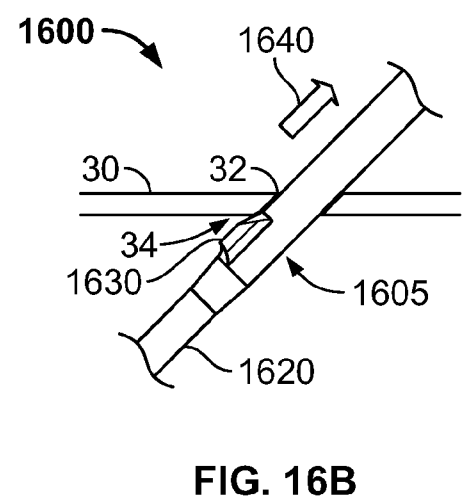
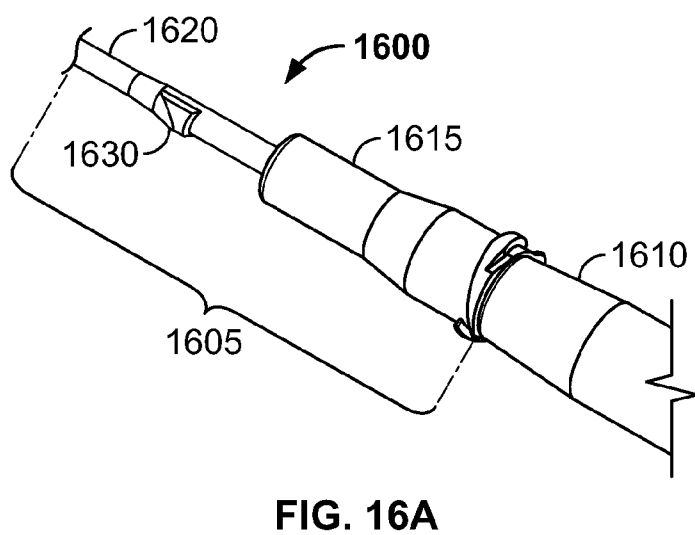
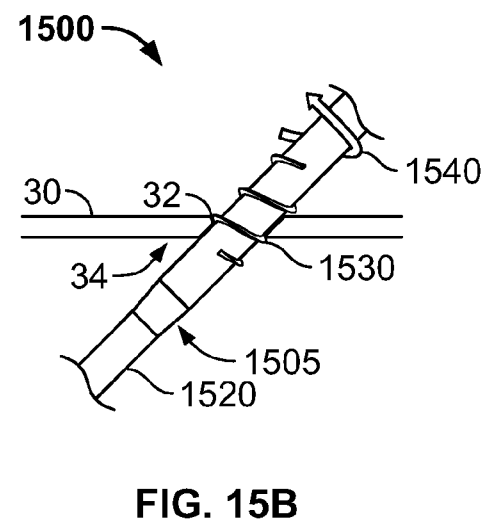
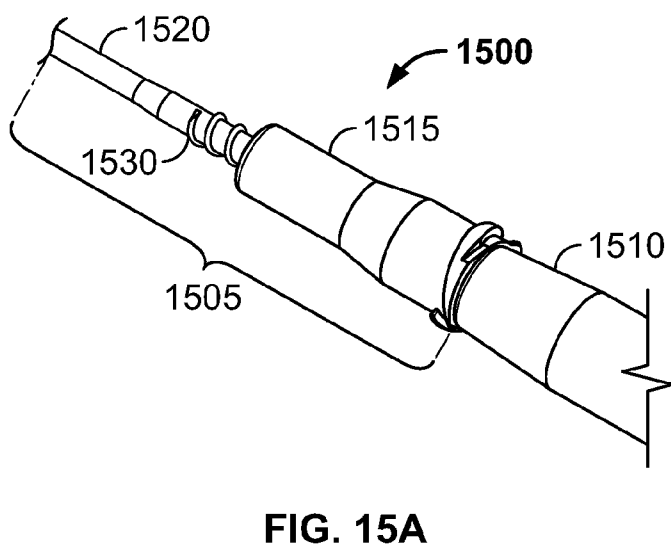
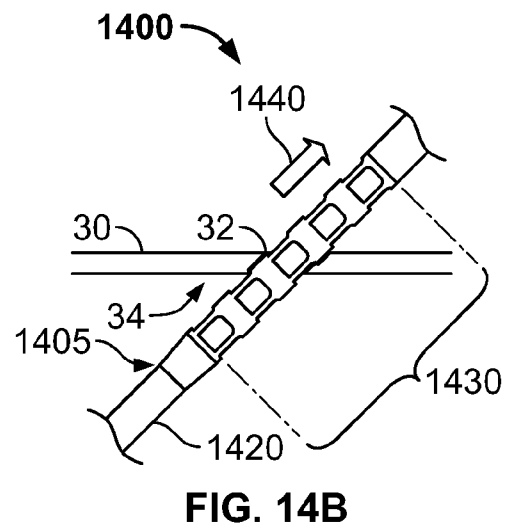
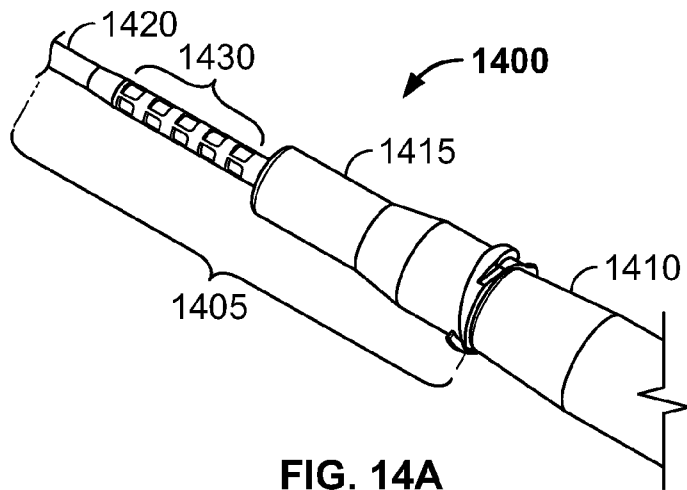


FIG. 13B



## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2013/026340****A. CLASSIFICATION OF SUBJECT MATTER****A61M 25/06(2006.01)i, A61B 17/34(2006.01)i, A61M 5/14(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 25/06; A61M 39/02; A61M 25/01; A61M 29/00; A61B 10/00; A61M 25/02

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: intravenous cannula, catheter, flexible catheter, connector, hub, skin layer, subcutaneous anchor, tab, flap, ring, cuff, thread, wedge****C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006-0129134 A1 (KERR, A.) 15 June 2006 See abstract; claim 12; paragraphs [0056], [0062], [0064]-[0067]; figures 1A, 7, 9, 11-15.	1-3, 5, 7-8, 10-14 , 18-20
Y		4, 6, 9
Y	US 6958044 B2 (BURBANK, F. H. et al.) 25 October 2005 See abstract; claim 1; figures 2, 11-12.	4, 6, 9
A		1-3, 5, 7-8, 10-14 , 18-20
A	US 6896665 B2 (PICHA, G. J. et al.) 24 May 2005 See abstract; claim 1; figure 3.	1-14, 18-20
A	US 7056286 B2 (RAVENSCROFT, A. et al.) 6 June 2006 See abstract; claim 1; figure 3.	1-14, 18-20
A	WO 2010-059714 A2 (INTERRAD MEDICAL, INC.) 27 May 2010 See abstract; claim 1; figures 1-3.	1-14, 18-20



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 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search

20 June 2013 (20.06.2013)

Date of mailing of the international search report

**21 June 2013 (21.06.2013)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office  
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302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

HAN, In Ho

Telephone No. 82-42-481-3362



# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2013/026340**

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15-17  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 15-17 pertain to methods for treatment of the human and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

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International application No.

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