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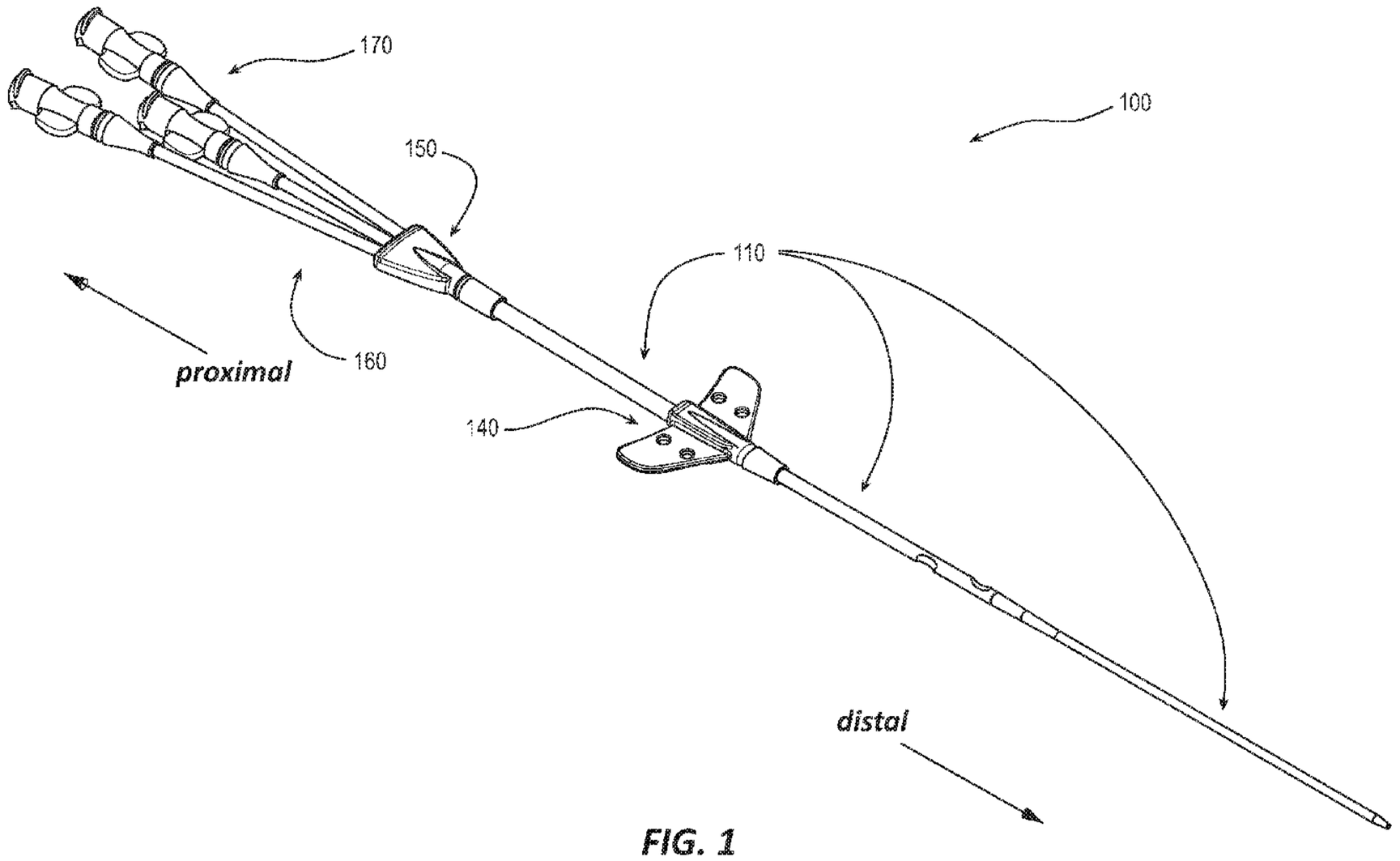


FIG. 1

(57) Abstract: Rapidly insertable central catheters ("RICC") and methods thereof are disclosed. In an example, a RICC includes a catheter tube, a suture wing disposed over a medial portion of the catheter tube, a hub coupled to a proximal-end portion of the catheter tube, and a number of extension legs extending from the hub. The catheter tube can include a first section in a distal portion of the catheter tube formed of a first polymeric material having a first durometer. The catheter tube can also include a second section proximal of the first section of the catheter tube formed of a second polymeric material having a second durometer less than the first durometer. The catheter tube can have a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and advanced through a vasculature of a patient without use of the Seldinger technique.

[Continued on next page]

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RAPIDLY INSERTABLE CENTRAL CATHETERS AND METHODS THEREOF

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 62/924,582 filed October 22, 2019, which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] A central venous catheter ("CVC") is formed of a material having a relatively low durometer, which contributes to the CVC having a lack of column strength. Due to the lack of column strength, CVCs are commonly introduced into patients and advanced through vasculatures thereof by way of the Seldinger technique. The Seldinger technique utilizes a number of steps and medical devices (e.g., a needle, a scalpel, a guidewire, an introducer sheath, a dilator, a CVC, etc.). While the Seldinger technique is effective, the number of steps are time consuming, handling the number of medical devices is awkward, and both of the foregoing can lead to patient trauma. In addition, there is a relatively high potential for touch contamination due to the number of medical devices that need to be interchanged during the number of steps of the Seldinger technique. As such, there is a need to reduce the number of steps and medical devices involved in introducing a catheter into a patient and advancing the catheter through a vasculature thereof.

[0003] Disclosed herein are rapidly insertable central catheters ("RICCs") and methods thereof that address the foregoing.

SUMMARY

[0004] Disclosed herein is a RICC including, in some embodiments, a catheter tube, a suture wing disposed over a medial portion of the catheter tube, a hub coupled to a proximal-end portion of the catheter tube, and a number of extension legs extending from the hub. The catheter tube includes a first section in a distal portion of the catheter tube formed of a first polymeric material having a first durometer. The catheter tube also includes a second section proximal of the first section of the catheter tube formed of a second polymeric material having a second durometer less than the first durometer. The catheter tube has a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and

advanced through a vasculature of a patient. The number of extension legs extending from the hub is equal to a number of lumens extending through the RICC.

[0005] In some embodiments, the catheter tube between the suture wing and the hub is a single catheter tube configured to abate bacterial ingress between a dressing applied over the suture wing and skin of the patient. Being a single catheter tube enables the dressing to be pinched more tightly around the catheter tube than possible for multiple extension legs, which extend from suture wing-hub combinations common to existing central venous catheters or peripherally inserted central catheters.

[0006] In some embodiments, the catheter tube between the suture wing and the hub is configured to mitigate patient discomfort from proximity of the number or extension legs to a head or neck of the patient. The catheter tube is flexible enough to enable the catheter tube to be bent away from the head or neck of the patient and secured to the patient.

[0007] In some embodiments, the first section of the catheter tube is polytetrafluoroethylene, polypropylene, or polyurethane.

[0008] In some embodiments, the second section of the catheter tube is bump tubing. The suture wing is disposed over a bump in the second section of the catheter tube such that the catheter tube proximal of the suture wing has a larger outer diameter than the catheter tube distal of the suture wing.

[0009] In some embodiments, the catheter tube further includes a third section proximal of the second section of the catheter tube. The third section of the catheter tube has a larger outer diameter than the second section of the catheter tube. The suture wing is disposed over a proximal-end portion of the second section of the catheter tube and a distal-end portion of the third section of the catheter tube.

[0010] In some embodiments, the third section of the catheter tube is polyvinyl chloride, polyethylene, polyurethane, or silicone.

[0011] In some embodiments, the second section of the catheter tube is polyvinyl chloride, polyethylene, polyurethane, or silicone.

[0012] In some embodiments, the RICC is a triluminal catheter including a trifurcated hub having three extension legs extending from the trifurcated hub. Each extension leg of the

three extension legs includes a Luer connector coupled to a proximal-end portion of the extension leg.

[0013] In some embodiments, the RICC includes a first lumen extending from an opening in a proximal end of a first Luer connector to an opening in a distal end of the first section of the catheter tube. The RICC also includes a second lumen extending from an opening in a proximal end of a second Luer connector to a first eyelet in the second section of the catheter tube. The RICC also includes a third lumen extending from an opening in a proximal end of a third Luer connector to a second eyelet in the second section of the catheter tube.

[0014] In some embodiments, the RICC is a diluminal catheter including a bifurcated hub having two extension legs extending from the bifurcated hub. Each extension leg of the two extension legs includes a Luer connector coupled to a proximal-end portion of the extension leg.

[0015] In some embodiments, the RICC includes a first lumen extending from an opening in a proximal end of a first Luer connector to an opening in a distal end of the first section of the catheter tube. The RICC also includes a second lumen extending from an opening in a proximal end of a second Luer connector to an eyelet in the second section of the catheter tube.

[0016] Also disclosed herein is a RICC including, in some embodiments, a catheter tube, a suture wing disposed over a medial portion of the catheter tube, a hub coupled to a proximal-end portion of the catheter tube, and three extension legs extending from the hub. The catheter tube includes a first section in a distal portion of the catheter tube formed of a first polymeric material having a first durometer. The catheter tube also includes a second section proximal of the first section of the catheter tube formed of bump tubing of a second polymeric material having a second durometer less than the first durometer. The catheter tube has a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and advanced through a vasculature of a patient without the Seldinger technique. The suture wing is disposed over a bump in the second section of the catheter tube such that the catheter tube proximal of the suture wing has a larger outer diameter than the catheter tube distal of the suture wing. Each extension leg of the three extension legs has a Luer connector coupled to a proximal-end portion of the extension leg.

[0017] In some embodiments, the RICC includes a first lumen extending from an opening in a proximal end of a first Luer connector to an opening in a distal end of the first section of the catheter tube. The RICC also includes a second lumen extending from an opening in a proximal end of a second Luer connector to a first eyelet in the second section of the catheter tube. The RICC also includes a third lumen extending from an opening in a proximal end of a third Luer connector to a second eyelet in the second section of the catheter tube.

[0018] In some embodiments, the catheter tube between the suture wing and the hub is configured to abate bacterial ingress between a dressing applied over the suture wing and skin of the patient. The catheter tube enables the dressing to be pinched more tightly around the catheter tube than possible for multiple extension legs, which extend from suture wing-hub combinations common to existing central venous catheters or peripherally inserted central catheters.

[0019] In some embodiments, the catheter tube between the suture wing and the hub is configured to mitigate patient discomfort from proximity of the number or extension legs to a head or neck of the patient. The catheter tube is flexible enough to enable the catheter tube to be bent away from the head or neck of the patient and secured to the patient.

[0020] Also disclosed herein is a method of a RICC including, in some embodiments, a creating step of creating an insertion site to access a vasculature of a patient with a needle disposed within a lumen of the RICC. The RICC includes a catheter tube having a first section in a distal portion of the catheter tube and a second section proximal of the first section of the catheter tube. The first section of the catheter tube is formed of a first polymeric material with a first durometer and the second section of the catheter tube is formed of a second polymeric material with a second durometer less than the first durometer. The method further includes an inserting step of inserting a distal-end portion of the catheter tube into the insertion site. The method further includes an advancing step of advancing the catheter tube through the vasculature of the patient. The advancing step further includes inserting the catheter tube farther into the insertion site without having to use a Seldinger technique. The Seldinger technique need not be used due to the catheter tube having a column strength sufficient to prevent buckling of the catheter tube when inserted into the insertion site and advanced through the vasculature of the patient.

[0021] In some embodiments, the method further includes a withdrawing step of withdrawing the needle from the lumen of the RICC after creating the insertion site and inserting at least some of the first section of the catheter tube into the insertion site.

[0022] In some embodiments, the insertion site is at a right subclavian vein or a right internal jugular vein.

[0023] In some embodiments, the advancing step further includes advancing the first section of the catheter tube through the right subclavian vein or the right internal jugular vein, a right brachiocephalic vein, and into a superior vena cava.

[0024] Also disclosed herein is a RICC including, in some embodiments, a catheter tube, a suture wing disposed over a medial portion of the catheter tube, a hub coupled to a proximal-end portion of the catheter tube, and a number of extension legs extending from the hub. The catheter tube includes a first section in a distal portion of the catheter tube formed of a first polymeric material. The catheter tube also includes a second section proximal of the first section of the catheter tube formed of a second polymeric material having a substantially equal durometer to the first polymeric material. The catheter tube has a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and advanced through a vasculature of a patient. The number of extension legs extending from the hub is equal to a number of lumens extending through the RICC.

[0025] These and other features of the concepts provided herein will become more apparent to those of skill in the art in view of the accompanying drawings and following description, which describe particular embodiments of such concepts in greater detail.

DRAWINGS

[0026] FIG. 1 illustrates an isometric view of a RICC in accordance with some embodiments.

[0027] FIG. 2 illustrates an exploded view of the RICC in accordance with some embodiments.

[0028] FIG. 3 illustrates an exploded view of the RICC in accordance with some embodiments.

[0029] FIG. 4 illustrates a distal portion of a catheter tube of the RICC in accordance with some embodiments.

[0030] FIG. 5A illustrates a first transverse cross section of the catheter tube of the RICC in accordance with some embodiments.

[0031] FIG. 5B illustrates a second transverse cross section of the catheter tube of the RICC in accordance with some embodiments.

[0032] FIG. 5C illustrates a third transverse or fourth cross section of the catheter tube of the RICC in accordance with some embodiments.

DESCRIPTION

[0033] Before some particular embodiments are disclosed in greater detail, it should be understood that the particular embodiments disclosed herein do not limit the scope of the concepts provided herein. It should also be understood that a particular embodiment disclosed herein can have features that can be readily separated from the particular embodiment and optionally combined with or substituted for features of any of a number of other embodiments disclosed herein.

[0034] Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, "first," "second," and "third" features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as "left," "right," "top," "bottom," "front," "back," and the like are used for convenience and are not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

[0035] With respect to "proximal," a "proximal portion" or a "proximal-end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near a clinician when the catheter is used on a patient. Likewise, a "proximal length" of, for

example, the catheter includes a length of the catheter intended to be near the clinician when the catheter is used on the patient. A "proximal end" of, for example, the catheter includes an end of the catheter intended to be near the clinician when the catheter is used on the patient. The proximal portion, the proximal-end portion, or the proximal length of the catheter can include the proximal end of the catheter; however, the proximal portion, the proximal-end portion, or the proximal length of the catheter need not include the proximal end of the catheter. That is, unless context suggests otherwise, the proximal portion, the proximal-end portion, or the proximal length of the catheter is not a terminal portion or terminal length of the catheter.

[0036] With respect to "distal," a "distal portion" or a "distal-end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near or in a patient when the catheter is used on the patient. Likewise, a "distal length" of, for example, the catheter includes a length of the catheter intended to be near or in the patient when the catheter is used on the patient. A "distal end" of, for example, the catheter includes an end of the catheter intended to be near or in the patient when the catheter is used on the patient. The distal portion, the distal-end portion, or the distal length of the catheter can include the distal end of the catheter; however, the distal portion, the distal-end portion, or the distal length of the catheter need not include the distal end of the catheter. That is, unless context suggests otherwise, the distal portion, the distal-end portion, or the distal length of the catheter is not a terminal portion or terminal length of the catheter.

[0037] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art.

[0038] As set forth above, there is a need to reduce the number of steps and medical devices involved in introducing a catheter into a patient and advancing the catheter through a vasculature thereof. Disclosed herein are RICCs and methods thereof that address the foregoing.

Rapidly insertable central catheters

[0039] FIG. 1 illustrates an isometric view of a RICC 100 in accordance with some embodiments.

[0040] As shown, the RICC 100 includes a catheter tube 110, a suture wing 140, a hub 150, and a number of extension legs 160 extending from the hub 150.

[0041] The suture wing 140 is disposed over a medial portion of the catheter tube 110 between a proximal-end portion and a distal-end portion of the catheter tube 110. Depending upon a chosen method of manufacturing, the suture wing 140 can be molded with a through hole longitudinally extending through the suture wing 140 configured for insertion of the catheter tube 110 (e.g., the second section 214 of the catheter tube 110 set forth below) therethrough. (*See*, for example, FIGS. 1 and 2.) Alternatively, the suture wing 140 can be molded over a number of core pins for a number of fluid pathways longitudinally extending through the suture wing 140 configured to fluidly connect a number of catheter-tube lumens of the catheter tube 110 distal of the suture wing 140 (e.g., the second section 314 of the catheter tube 110 set forth below) to a number of catheter-tube lumens of the catheter tube 110 proximal of the suture wing 140 (e.g., the third section 318 of the catheter tube 110 set forth below). (*See*, for example, FIGS. 1 and 3.) Alternatively, the suture wing 140 can be molded over a number of cannulas longitudinally extending through the suture wing 140 configured to fluidly connect the number of catheter-tube lumens of the catheter tube 110 distal of the suture wing 140 (e.g., the second section 314 of the catheter tube 110 set forth below) to the number of catheter-tube lumens of the catheter tube 110 proximal of the suture wing 140 (e.g., the third section 318 of the catheter tube 110 set forth below). (*See*, for example, FIGS. 1 and 3.)

[0042] The suture wing 140 includes a pair of wings 342 including a number of through holes 344 for suturing the suture wing 140 to a patient. (*See* FIG. 3.) Each wing of the pair of wings 342 can include one through hole, two through holes, three through holes, or four through holes for suturing the suture wing 140 to a patient.

[0043] The hub 150 is coupled to the proximal-end portion of the catheter tube 110 such as by insertion of the proximal-end portion of the catheter tube 110 into a bore in a distal-end portion of the hub 150. While not shown, the hub 150 also includes a number of bores in a proximal-end portion of the hub 150 corresponding in number to the number of extension legs 160. The number of bores in the distal-end portion of the hub 150 are configured to accept insertion of the number of extension legs 160 into the number of bores.

[0044] As set forth in more detail below, the RICC 100 can be a monoluminal catheter or a multiluminal catheter such as a diluminal catheter or a triluminal catheter. Accordingly, the hub 150 is either not furcated for the monoluminal catheter or furcated in accordance with a number of lumens extending through the RICC 100. For example, the hub 150 can be bifurcated for the diluminal catheter or trifurcated for the triluminal catheter. Depending upon

a chosen method of manufacturing, the hub 150 can be molded over a number of core pins for a number of fluid pathways longitudinally extending through the hub 150 configured to fluidly connect the number of catheter-tube lumens of the catheter tube 110 to a number of extension-leg lumens of the number of extension legs 160. Alternatively, the hub 150 can be molded over a number of cannulas longitudinally extending through the hub 150 configured to fluidly connect the number of catheter-tube lumens of the catheter tube 110 to the number of extension-leg lumens of the number of extension legs 160.

[0045] The number of extension legs 160 extend from the hub 150 by way of their distal-end portions. The number of extension legs 160 is equal to the number of lumens extending through the RICC 100. For example: If the RICC 100 is a monoluminal catheter, one extension leg extends from the hub 150. If the RICC 100 is a diluminal catheter, two extension legs extend from the hub 150. If the RICC 100 is a triluminal catheter, three extension legs extend from the hub 150.

[0046] The RICC 100 further includes a number of Luer connectors 170 for fluidly connecting a number of medical devices to the RICC 100. Each extension leg of the number of extension legs 160 includes a Luer connector of the number of Luer connectors 170 coupled to a proximal-end portion of the extension leg. Given the foregoing, the number of Luer connectors 170 is equal to the number of extension legs 160, which number of extension legs 160, in turn, is equal to the number of lumens extending through the RICC 100. For example: If the RICC 100 is a monoluminal catheter, one extension leg extends from the hub 150 and one Luer connector is coupled to the extension leg. If the RICC 100 is a diluminal catheter, two extension legs extend from the hub 150 and two Luer connectors are respectively coupled to the two extension legs. If the RICC 100 is a triluminal catheter, three extension legs extend from the hub 150 and three Luer connectors are respectively coupled to the three extension legs.

[0047] Two genera of the catheter tube 110 are set forth below in two embodiments. Distinguishing features of a first embodiment of the catheter tube 110 are initially introduced and distinguishing features of a second embodiment of the catheter tube 110 are subsequently introduced. For expository expediency, various features of the two embodiments of the catheter tube 110 are described thereafter, some of which features are common between the two embodiments of the catheter tube 110, and some of which features are unique to the first

embodiment or the second embodiment of the catheter tube 110. Other features of the RICC 100 are described after the catheter tube 110 and elsewhere herein.

[0048] FIG. 2 illustrates an exploded view of the RICC 100 in accordance with the first embodiment of the catheter tube 110.

[0049] As shown, the first embodiment of the catheter tube 110 includes a first section 212 and a second section 214 of the catheter tube 110 with an optional section 216 therebetween depending upon the manner in which the first section 212 and the second section 214 of the catheter tube 110 are coupled during manufacturing. The manner in which the first section 212 and the second section 214 of the catheter tube 110 are coupled is described in U.S. Provisional Application No. 62/905,363, filed September 24, 2019, and in U.S. Provisional Application No. 62/898,408, filed September 10, 2019, each of which is incorporated in its entirety into this application. (*See* also U.S. Provisional Application No. 62/923,320, filed October 18, 2019, which is incorporated in its entirety into this application.) For example, any two sections of the first, second, and third sections coupled together as set forth herein can be coupled together by bonding (e.g., solvent bonding) or welding (e.g., RF welding). The third section or junction 140, 240, or 340 of the catheter tube 110, 210, or 310 in the aforementioned provisional applications corresponds to the optional section 216 between the first section 212 and the second section 214 of the first embodiment of the catheter tube 110.

[0050] FIG. 3 illustrates an exploded view of the RICC 100 in accordance with a second embodiment of the catheter tube 110.

[0051] As shown, the second embodiment of the catheter tube 110 includes the first section 212 and a second section 314 of the catheter tube 110 with a third section 318 proximal of the second section 314 of the catheter tube 110. The optional section 216 can be between the first section 212 and the second section 314 of the second embodiment of the catheter tube 110 depending upon the manner in which the first section 212 and the second section 314 of the catheter tube 110 are coupled during manufacturing. As with the first embodiment of the catheter tube 110, the manner in which the first section 212 and second section 314 of the second embodiment of the catheter tube 110 are coupled is described in the aforementioned provisional applications. The third section or junction 140, 240, or 340 of the catheter tube 110, 210, or 310 in the aforementioned provisional applications corresponds to the optional section

216 between the first section 212 and the second section 214 of the first embodiment of the catheter tube 110.

[0052] In view of the foregoing, the catheter tube 110 can include two sections up to at least four sections depending upon a chosen method of manufacturing the RICC 100. Among such embodiments of the catheter tube 110, two sections of the catheter tube 110 are common: the first section 212 in a distal portion of the catheter tube 110 and the second section 214 or 314 proximal of the first section of the catheter tube 110.

[0053] The first section 212 of the catheter tube 110 is formed of a first polymeric material (e.g., polytetrafluoroethylene, polypropylene, or polyurethane) having a first durometer, while the second section 214 or 314 is formed of a second polymeric material (e.g., polyvinyl chloride, polyethylene, polyurethane, or silicone) having a second durometer less than the first durometer. For example, each section of the first section 212 and the second section 214 or 314 of the catheter tube 110 can be made from a different polyurethane having a different durometer. Indeed, polyurethane is advantageous in that polyurethane sections of the catheter tube 110 can be relatively rigid at room-temperature but become more flexible *in vivo* at body temperature, which reduces irritation to vessel walls and phlebitis. Polyurethane is also advantageous in that can be less thrombogenic than some other polymers.

[0054] It should be understood the first durometer and the second durometer can be on different scales (e.g., Type A or Type D), so the second durometer of the second polymeric material might not be numerically less than the first durometer of the first polymeric material. That said, the hardness of the second polymeric material can still be less than the hardness of the first polymeric material as the different scales – each of which ranges from 0 to 100 – are designed for characterizing different materials in groups of the materials having a like hardness.

[0055] Notwithstanding the foregoing, the first section 212 and the second section 214 or 314 of the catheter tube 110 can be formed of a same polymeric material or different polymeric materials having substantially equal durometers provided a column strength of the catheter tube 110 is sufficient to prevent buckling of the catheter tube 110 when inserted into an insertion site and advanced through a vasculature of a patient.

[0056] The catheter tube 110 having at least the first section 212 of the first polymeric material and the second section 214 or 314 of the second polymeric material has a column strength sufficient to prevent buckling of the catheter tube 110 when the catheter tube 110 is

inserted into an insertion site and advanced through a vasculature of a patient. The column strength of the catheter tube 110 is notable in that it makes it possible to rapidly insert the catheter tube 110 into the insertion site and advance the catheter tube 110 through the vasculature of the patient without the using the Seldinger technique.

[0057] Adverting to the first embodiment of the catheter tube 110 shown in FIG. 2, the second section 214 of the catheter tube 110 includes a bumped diameter indicated by a bump 215 in a medial portion of the second section 214 of the catheter tube 110. A proximal portion of the second section 214 of the catheter tube 110 has a larger outer diameter than a distal portion of the second section 214 of the catheter tube 110. When the suture wing 140 is disposed over the bump 215 as shown in FIG. 1, the catheter tube 110 proximal of the suture wing 140 – also known as a catheter-tube extension herein – has a larger outer diameter than the catheter tube 110 distal of the suture wing 140. The larger outer diameter of the second section 214 of the catheter tube 110 proximal of the suture wing 140 provides a thicker, more kink-resistant catheter-tube wall useful for bending the hub 150 and the number of extension legs 160 away from a head or neck of a patient while the RICC 100 is in use. In addition, any lumens present in the catheter tube 110 can have a greater diameter in the second section 214 of the catheter tube 110 proximal of the suture wing 140 than distal of the suture wing 140. This prevents flow rate reduction, particularly when the second section 214 of the catheter tube 110 proximal of the suture wing 140 is bent away from a head or neck of a patient. The second section 214 of the catheter tube 110 can be formed of a single extrusion of bump tubing.

[0058] Adverting to the second embodiment of the catheter tube 110 shown in FIG. 3, the second section 314 and the third section 318 of the catheter tube 110, together, simulate the bumped diameter of the second section 214 of the first embodiment of the catheter tube 110. The third section 318 of the catheter tube 110 has a larger outer diameter than the second section 214 of the catheter tube 110. When the suture wing 140 is disposed over a proximal-end portion of the second section 314 of the catheter tube 110 and a distal-end portion of the third section 318 of the catheter tube 110, the catheter tube 110 proximal of the suture wing 140 (i.e., the third section 318 of the catheter tube 110) – also known as the catheter-tube extension – has a larger outer diameter than the catheter tube 110 distal of the suture wing 140 (i.e., the second section 314 of the catheter tube 110). Like that set forth above with respect to the second section 214 of the catheter tube 110, the larger outer diameter of the third section 318 of the catheter tube 110 proximal of the suture wing 140 provides a thicker, more kink-

resistant catheter-tube wall useful for bending the hub 150 and the number of extension legs 160 away from a head or neck of a patient while the RICC 100 is in use. In addition, any lumens present in the catheter tube 110 can have a greater diameter in the third section 318 of the catheter tube 110 than in the second section 314 of the catheter tube 110. This prevents flow rate reduction, particularly when the third section 318 of the catheter tube 110 proximal of the suture wing 140 is bent away from a head or neck of a patient. Like the second section 214 or 314 of the catheter tube 110, the third section 318 of the catheter tube 110 can be polyvinyl chloride, polyethylene, polyurethane, or silicone.

[0059] Whether of the first embodiment or the second embodiment of the catheter tube 110, the catheter tube 110 between the suture wing 140 and the hub 150 can have a reverse taper in which the larger outer diameter of the catheter tube 110 continues to increase from the suture wing 140 to the hub 150. In other words, the catheter tube 110 tapers from the hub 150 to the suture wing 140 but continues to have a larger outer diameter than the catheter tube 110 distal of the suture wing 140. In association with the continuously increasing outer diameter of the catheter tube 110 from the suture wing 140 to the hub 150, the catheter-tube wall can continuously increase in thickness, any lumens of the catheter tube 110 can continuously increase in cross-sectional area, or a combination thereof. Consequently, the catheter tube 110 between the suture wing 140 and the hub 150 can be more resistant to kinks and flow rate reduction, particularly when the catheter tube 110 proximal of the suture wing 140 is bent away from a head or neck of a patient.

[0060] The catheter tube 110 between the suture wing 140 and the hub 150, which section of the catheter tube 110 is also known as the catheter-tube extension herein, is a single catheter tube configured to abate bacterial ingress between a dressing applied over the suture wing 140 and skin of a patient. Existing CVCs or peripherally inserted central catheters ("PICCs") have multiple extension legs extending from suture wing-hub combinations common to the CVCs and PICCs. The multiple extension legs in the CVCs or PICCs provide multiple pathways under the dressing for microbial ingress. The catheter tube 110 being a single catheter tube enables the dressing to be pinched more tightly around the catheter tube 110 than possible for the multiple extension legs of the existing CVCs or PICCs. For example, the dressing can be easily wrapped around an entirety of the catheter tube 110 and pinched together under the catheter tube 110 or between the catheter tube 110 and the patient. In contrast, even wrapping the dressing around the multiple extension legs of the existing CVCs

or PICCs leaves gaps between the extension tubes. Thus, the catheter tube 110 being a single catheter tube limits bacterial ingress between the dressing applied over the suture wing 140 and the skin of the patient.

[0061] The catheter tube 110 between the suture wing 140 and the hub 150, which section of the catheter tube 110 is also known as the catheter-tube extension herein, is also configured to mitigate patient discomfort from proximity of the number or extension legs 160 to a head or neck of the patient. As set forth above, the second section 214 or the third section 318 of the catheter tube 110 proximal of the suture wing 140 provides a thicker, more kink-resistant catheter-tube wall; however, the second section 214 or the third section 318 of the catheter tube 110 is flexible enough to enable the catheter tube 110 to be bent away from the head or neck of the patient and secured to the patient for his or her comfort.

[0062] FIG. 4 illustrates the distal portion of the catheter tube 110 of the RICC 100 in accordance with some embodiments. FIGS. 5A-5C illustrate different transverse cross sections of the catheter tube 110 of the RICC 100 in accordance with some embodiments.

[0063] The RICC 100 can be a monoluminal catheter or a multiluminal catheter such as a diluminal catheter, a triluminal catheter, a tetraluminal catheter, a pentaluminal catheter, or a hexaluminal catheter.

[0064] When the RICC 100 is configured as a triluminal catheter as shown in FIGS. 4 and 5A-5C, the RICC 100 includes a first lumen, a second lumen, and a third lumen. The first lumen extends from an opening in a tip or distal end of the first section 212 of the catheter tube 110 to an opening in a proximal end of a first Luer connector of the number of Luer connectors 170. The second lumen extends from an eyelet 420 in a distal-end portion of the second section 214 or 314 of the catheter tube 110 to an opening in a proximal end of a second Luer connector of the number of Luer connectors 170. The third lumen extends from an eyelet 422 in the distal-end portion of the second section 214 or 314 of the catheter tube 110 proximal of the eyelet 420 to an opening in a proximal end of a third Luer connector of the number of Luer connectors 170. Each lumen of the first lumen, the second lumen, and the third lumen is further described in a separate paragraph set forth below.

[0065] The first lumen of the RICC 100 includes fluidly connected luminal sections including a lumen 524 of the first section 212 of the catheter tube 110, a lumen 526 of the optional section 216 of the catheter tube 110, when the optional section 216 is present, and a

first lumen 528 of the second section 214 or 314 of the catheter tube 110. If the catheter tube 110 is that of the second embodiment of the catheter tube 110, the fluidly connected luminal sections of the first lumen of the RICC 100 further include a first fluid passageway or first cannula lumen of the suture wing 140 and a first lumen of the third section 318 of the catheter tube 110. (The first lumen of the third section 318 of the catheter tube 110 is not shown as it is akin to the first lumen 528 of the second section 314 of the catheter tube 110.) Whether the catheter tube 110 is that of the second or third embodiment of the catheter tube 110, the fluidly connected luminal sections of the first lumen of the RICC 100 further include a first fluid passageway or first cannula lumen of the hub 150, a first extension-leg lumen of a first extension leg (e.g., the extension leg labeled "distal" in FIGS. 1-3) of the number of extension legs 160, and a first Luer-connector lumen of the first Luer connector of the number of Luer connectors 170.

[0066] The second lumen of the RICC 100 includes fluidly connected luminal sections including a second lumen 530 of the second section 214 or 314 of the catheter tube 110, which extends from the eyelet 420 in the distal-end portion of the second section 214 or 314 of the catheter tube 110. If the catheter tube 110 is that of the second embodiment of the catheter tube 110, the fluidly connected luminal sections of the second lumen of the RICC 100 further include a second fluid passageway or second cannula lumen of the suture wing 140 and a second lumen of the third section 318 of the catheter tube 110. (The second lumen of the third section 318 of the catheter tube 110 is not shown as it is akin to the second lumen 530 of the second section 314 of the catheter tube 110.) Whether the catheter tube 110 is that of the second or third embodiment of the catheter tube 110, the fluidly connected luminal sections of the second lumen of the RICC 100 further include a second fluid passageway or second cannula lumen of the hub 150, a second extension-leg lumen of a second extension leg (e.g., the extension leg labeled "medial" in FIGS. 1-3) of the number of extension legs 160, and a second Luer-connector lumen of the second Luer connector of the number of Luer connectors 170.

[0067] The third lumen of the RICC 100 includes fluidly connected luminal sections including a third lumen 532 of the second section 214 or 314 of the catheter tube 110, which extends from the eyelet 422 in the distal-end portion of the second section 214 or 314 of the catheter tube 110. If the catheter tube 110 is that of the second embodiment of the catheter tube 110, the fluidly connected luminal sections of the third lumen of the RICC 100 further include a third fluid passageway or third cannula lumen of the suture wing 140 and a third lumen of

the third section 318 of the catheter tube 110. (The third lumen of the third section 318 of the catheter tube 110 is not shown as it is akin to the third lumen 532 of the second section 314 of the catheter tube 110.) Whether the catheter tube 110 is that of the second or third embodiment of the catheter tube 110, the fluidly connected luminal sections of the third lumen of the RICC 100 further include a third fluid passageway or third cannula lumen of the hub 150, a third extension-leg lumen of a third extension leg (e.g., the extension leg labeled "proximal" in FIGS. 1-3) of the number of extension legs 160, and a third Luer-connector lumen of the third Luer connector of the number of Luer connectors 170.

[0068] When the RICC 100 is configured as a diluminal catheter, the RICC 100 includes a first lumen and a second lumen. Like the RICC 100 when configured as the triluminal catheter, the first lumen extends from an opening in a tip or distal end of the first section 212 of the catheter tube 110 to an opening in a proximal end of a first Luer connector of the number of Luer connectors 170. The second lumen extends from an eyelet akin to the eyelet 420 in the distal-end portion of the second section 214 or 314 of the catheter tube 110 to an opening in a proximal end of a second Luer connector of the number of Luer connectors 170. Because the first lumen and the second lumen of the RICC 100 configured as the diluminal catheter are analogous to the first lumen and the second lumen of the RICC 100 configured as the triluminal catheter, additional detail for each lumen of the first lumen and the second lumen of the RICC 100 configured as the diluminal catheter can be discerned from the description set forth above for the first lumen and the second lumen of the RICC 100 configured as the triluminal catheter.

[0069] When the RICC 100 is configured as a monoluminal catheter, the RICC 100 includes a single lumen, which single lumen is also known as a first lumen herein for consistency with description set forth above. Like the RICC 100 when configured as the triluminal catheter, the first lumen extends from an opening in a tip or distal end of the first section 212 of the catheter tube 110 to an opening in a proximal end of a first Luer connector of the number of Luer connectors 170. Because the first lumen of the RICC 100 configured as the monoluminal catheter is analogous to the first lumen of the RICC 100 configured as the triluminal catheter, additional detail for the first lumen of the RICC 100 configured as the monoluminal catheter can be discerned from the description set forth above for the first lumen of the RICC 100 configured as the triluminal catheter.

Methods

[0070] A method for making the RICC 100 includes one or more extruding steps of extruding one or more extrudable components, one or more molding steps of molding one or more moldable components, and one or more assembling steps of assembling the RICC 100 or any portion thereof by coupling the extrudable and moldable components together.

[0071] The one or more extruding steps can include extruding any one or more sections of the catheter tube 110 selected from the first section 212 of the catheter tube 110, the second section 214 or 314 of the catheter tube 110, the optional section 216 of the catheter tube 110, and the third section 318 of the catheter tube 110 in accordance with description set forth above for the foregoing one or more sections of the catheter tube 110. The one or more extruding steps can further include extruding any one or more extension legs of the number of extension legs 160 in accordance with description set forth above for the one or more extension legs.

[0072] The one or more molding steps includes molding any one or more moldable components selected from the suture wing 140 and the hub 150 in accordance with description set forth above for the one or more moldable components. The one or more molding steps can further include molding any one or more Luer connectors of the number of Luer connectors 170 in accordance with description set forth above for the one or more Luer connectors.

[0073] The one or more assembling steps of assembling the RICC 100 or any portion thereof can include coupling the first section 212 of the catheter tube 110 to the second section 214 or 314 of the catheter tube 110 either directly or indirectly through the optional section 216 of the catheter tube 110 as described in U.S. Provisional Patent Application Nos. 62/923,320 and 62/898,408 filed, October 18, 2019, and September 6, 2019, respectively, each of which is incorporated herein in its entirety. The foregoing incorporation by reference includes any other steps desired in support of coupling the first section 212 of the catheter tube 110 to the second section 214 or 314 of the catheter tube 110.

[0074] A method of using the RICC 100 includes a creating step of creating an insertion site to access a vasculature of a patient with a needle disposed within a lumen of the RICC 100. The insertion site can be at a subclavian vein such as a right or left subclavian vein, an internal jugular vein such as a right or left internal jugular vein, or a femoral vein.

[0075] The method further includes an inserting step of inserting the distal-end portion of the catheter tube 110 into the insertion site.

[0076] The method further includes a withdrawing step of withdrawing the needle from the lumen of the RICC 100 after creating the insertion site and inserting at least some of the first section 212 of the catheter tube 110 into the insertion site.

[0077] The method further includes an advancing step of advancing the catheter tube 110 through the vasculature of the patient without having to use the Seldinger technique. For example, if the insertion site is at the right subclavian vein or the right internal jugular vein, the advancing step can further include inserting the catheter tube 110 farther into the insertion site such that the catheter tube 110 or at least the distal-end portion thereof is advanced through the right subclavian vein or the right internal jugular vein, a right brachiocephalic vein, and into a superior vena cava. Other insertions sites such as at the left subclavian vein or the left internal jugular vein require advancing the distal-end portion of the catheter tube 110 through corresponding vasculature. The Seldinger technique need not be used due to the catheter tube 110 having a column strength sufficient to prevent buckling of the catheter tube 110 when inserted into the insertion site and advanced through the vasculature of the patient.

[0078] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.

CLAIMS

What is claimed is:

1. A rapidly insertable central catheter ("RICC"), comprising:

a catheter tube including:

a first section in a distal portion of the catheter tube formed of a first polymeric material having a first durometer; and

a second section proximal of the first section of the catheter tube formed of a second polymeric material having a second durometer less than the first durometer, the catheter tube having a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and advanced through a vasculature of a patient;

a suture wing disposed over a medial portion of the catheter tube;

a hub coupled to a proximal-end portion of the catheter tube; and

a number of extension legs extending from the hub equal to a number of lumens extending through the RICC.

2. The RICC of claim 1, wherein the catheter tube between the suture wing and the hub is a single catheter tube configured to abate bacterial ingress between a dressing applied over the suture wing and skin of the patient by enabling the dressing to be pinched more tightly around the single catheter tube than possible for multiple extension legs extending from suture wing-hub combinations common to existing central venous catheters or peripherally inserted central catheters.

3. The RICC of either claim 1 or 2, wherein the catheter tube between the suture wing and the hub is configured to mitigate patient discomfort from proximity of the number or extension legs to a head or neck of the patient by being flexible enough to enable the catheter tube to be bent away from the head or neck of the patient and secured to the patient.

4. The RICC of any claim of claims 1-3, wherein the first section of the catheter tube is polytetrafluoroethylene, polypropylene, or polyurethane.

5. The RICC of any claim of claims 1-4, wherein the second section of the catheter tube is bump tubing, the suture wing disposed over a bump in the second section of the catheter

tube such that the catheter tube proximal of the suture wing has a larger outer diameter than the catheter tube distal of the suture wing.

6. The RICC of any claim of claims 1-4, wherein the catheter tube further includes a third section proximal of the second section of the catheter tube having a larger outer diameter than the second section of the catheter tube, the suture wing disposed over a proximal-end portion of the second section of the catheter tube and a distal-end portion of the third section of the catheter tube.

7. The RICC of claim 6, wherein the third section of the catheter tube is polyvinyl chloride, polyethylene, polyurethane, or silicone.

8. The RICC of any claim of claims 1-7, wherein the second section of the catheter tube is polyvinyl chloride, polyethylene, polyurethane, or silicone.

9. The RICC of any claim of claims 1-8, wherein the RICC is a triluminal catheter including a trifurcated hub having three extension legs extending therefrom, each extension leg of the three extension legs including a Luer connector coupled to a proximal-end portion of the extension leg.

10. The RICC of claim 9, wherein the RICC includes a first lumen extending from an opening in a proximal end of a first Luer connector to an opening in a distal end of the first section of the catheter tube, a second lumen extending from an opening in a proximal end of a second Luer connector to a first eyelet in the second section of the catheter tube, and a third lumen extending from an opening in a proximal end of a third Luer connector to a second eyelet in the second section of the catheter tube.

11. The RICC of any claim of claims 1-8, wherein the RICC is a diluminal catheter including a bifurcated hub having two extension legs extending therefrom, each extension leg of the two extension legs including a Luer connector coupled to a proximal-end portion of the extension leg.

12. The RICC of claim 11, wherein the RICC includes a first lumen extending from an opening in a proximal end of a first Luer connector to an opening in a distal end of the first section of the catheter tube and a second lumen extending from an opening in a proximal end of a second Luer connector to an eyelet in the second section of the catheter tube.

13. A rapidly insertable central catheter ("RICC"), comprising:

a catheter tube including:

a first section in a distal portion of the catheter tube formed of a first polymeric material having a first durometer; and

a second section proximal of the first section of the catheter tube formed of bump tubing of a second polymeric material having a second durometer less than the first durometer, the catheter tube having a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and advanced through a vasculature of a patient without use of a Seldinger technique;

a suture wing disposed over a medial portion of the catheter tube, the suture wing disposed over a bump in the second section of the catheter tube such that the catheter tube proximal of the suture wing has a larger outer diameter than the catheter tube distal of the suture wing;

a hub coupled to a proximal-end portion of the catheter tube; and

three extension legs extending from the hub, each extension leg of the three extension legs having a Luer connector coupled to a proximal-end portion of the extension leg.

14. The RICC of claim 13, wherein a first lumen extends from an opening in a proximal end of a first Luer connector to an opening in a distal end of the first section of the catheter tube, a second lumen extends from an opening in a proximal end of a second Luer connector to a first eyelet in the second section of the catheter tube, and a third lumen extends from an opening in a proximal end of a third Luer connector to a second eyelet in the second section of the catheter tube.

15. The RICC of either claim 13 or 14, wherein the catheter tube between the suture wing and the hub is configured to abate bacterial ingress between a dressing applied over the suture wing and skin of the patient by enabling the dressing to be pinched more tightly around the catheter tube than possible for multiple extension legs extending from suture wing-hub combinations common to existing central venous catheters or peripherally inserted central catheters.

16. The RICC of any claim of claims 13-15, wherein the catheter tube between the suture wing and the hub is configured to mitigate patient discomfort from proximity of the

number or extension legs to a head or neck of the patient by being flexible enough to enable the catheter tube to be bent away from the head or neck of the patient and secured to the patient.

17. A method of a rapidly inserted central catheter ("RICC"), comprising:

creating an insertion site to access a vasculature of a patient with a needle disposed within a lumen of the RICC, the RICC including a catheter tube comprising:

a first section in a distal portion of the catheter tube formed of a first polymeric material with a first durometer and

a second section proximal of the first section of the catheter tube formed of a second polymeric material with a second durometer less than the first durometer;

inserting a distal-end portion of the catheter tube into the insertion site; and

advancing the catheter tube through the vasculature of the patient, the advancing including further inserting the catheter tube into the insertion site without having to use a Seldinger technique due to the catheter tube having a column strength sufficient to prevent buckling of the catheter tube when inserted into the insertion site and advanced through the vasculature of the patient.

18. The method of claim 17, further comprising withdrawing the needle from the lumen of the RICC after creating the insertion site and inserting at least some of the first section of the catheter tube into the insertion site.

19. The method of either claim 17 or 18, wherein the insertion site is at a right subclavian vein or a right internal jugular vein.

20. The method of claim 19, wherein advancing the catheter tube through the vasculature of the patient includes advancing the first section of the catheter tube through the right subclavian vein or the right internal jugular vein, a right brachiocephalic vein, and into a superior vena cava.

21. A rapidly insertable central catheter ("RICC"), comprising:

a catheter tube including:

a first section in a distal portion of the catheter tube formed of a first polymeric material; and

a second section proximal of the first section of the catheter tube formed of a second polymeric material having a substantially equal durometer to the first polymeric material, the catheter tube having a column strength sufficient to prevent buckling of the catheter tube when inserted into an insertion site and advanced through a vasculature of a patient;

a suture wing disposed over a medial portion of the catheter tube;

a hub coupled to a proximal-end portion of the catheter tube; and

a number of extension legs extending from the hub equal to a number of lumens extending through the RICC.

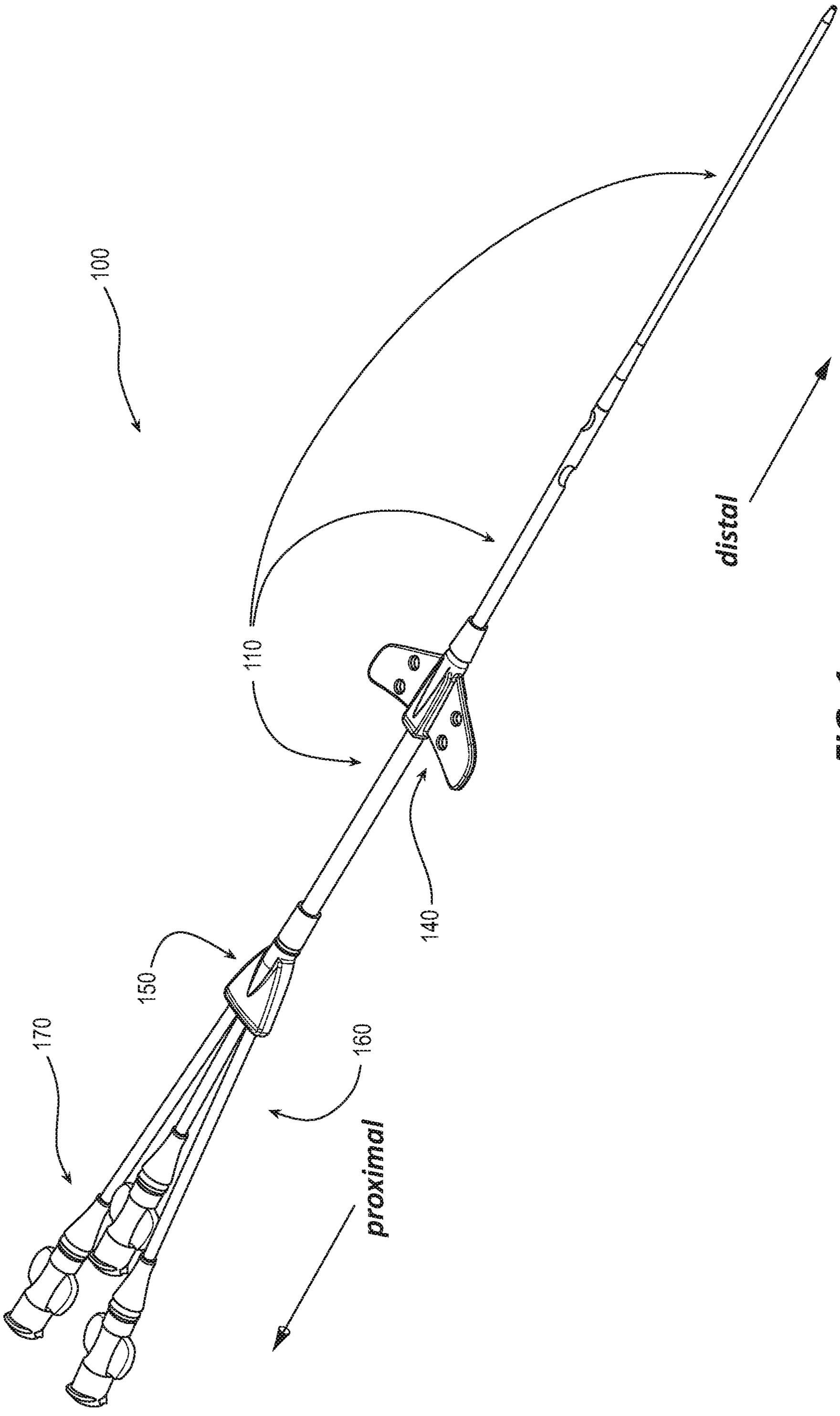


FIG. 1

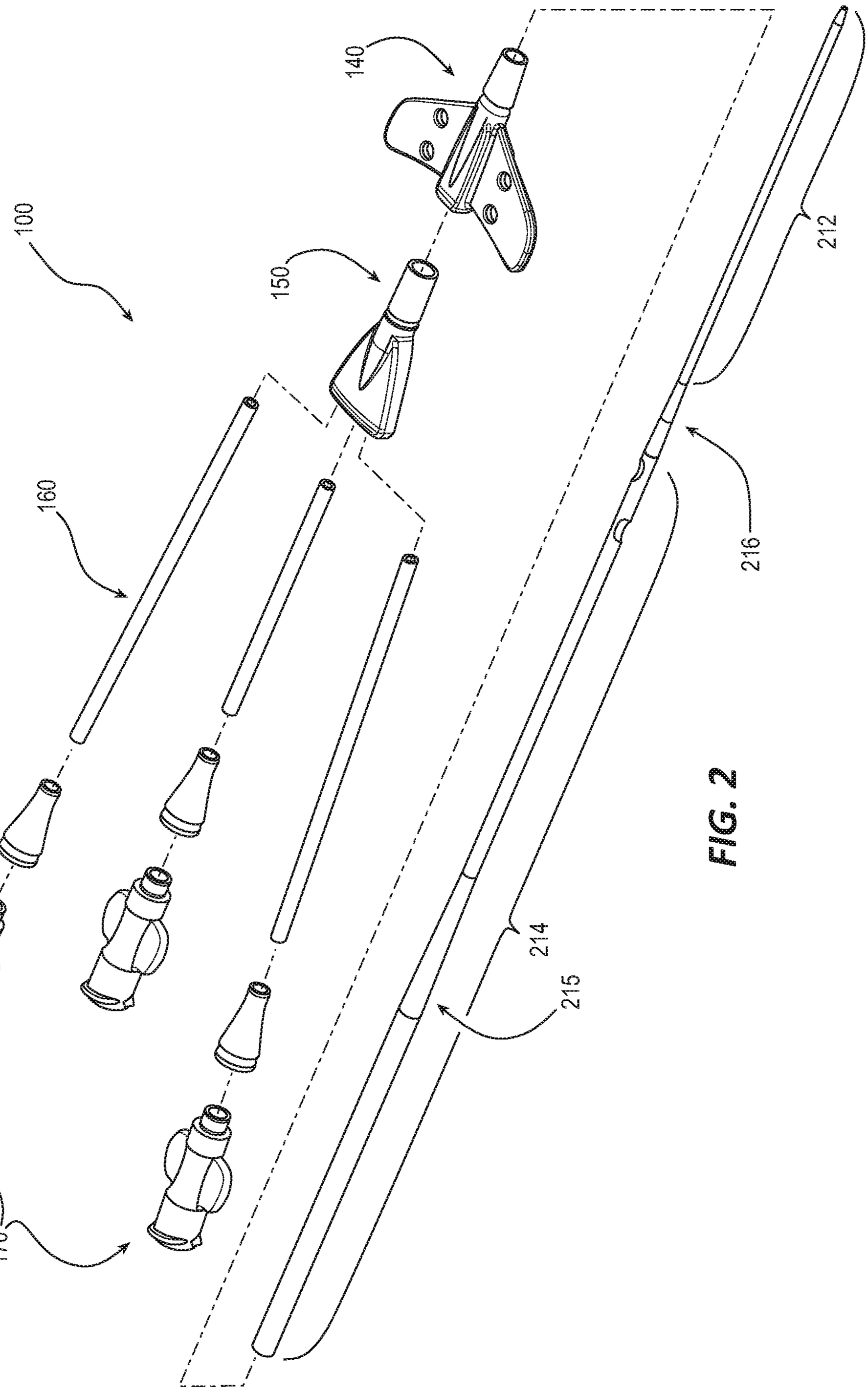


FIG. 2

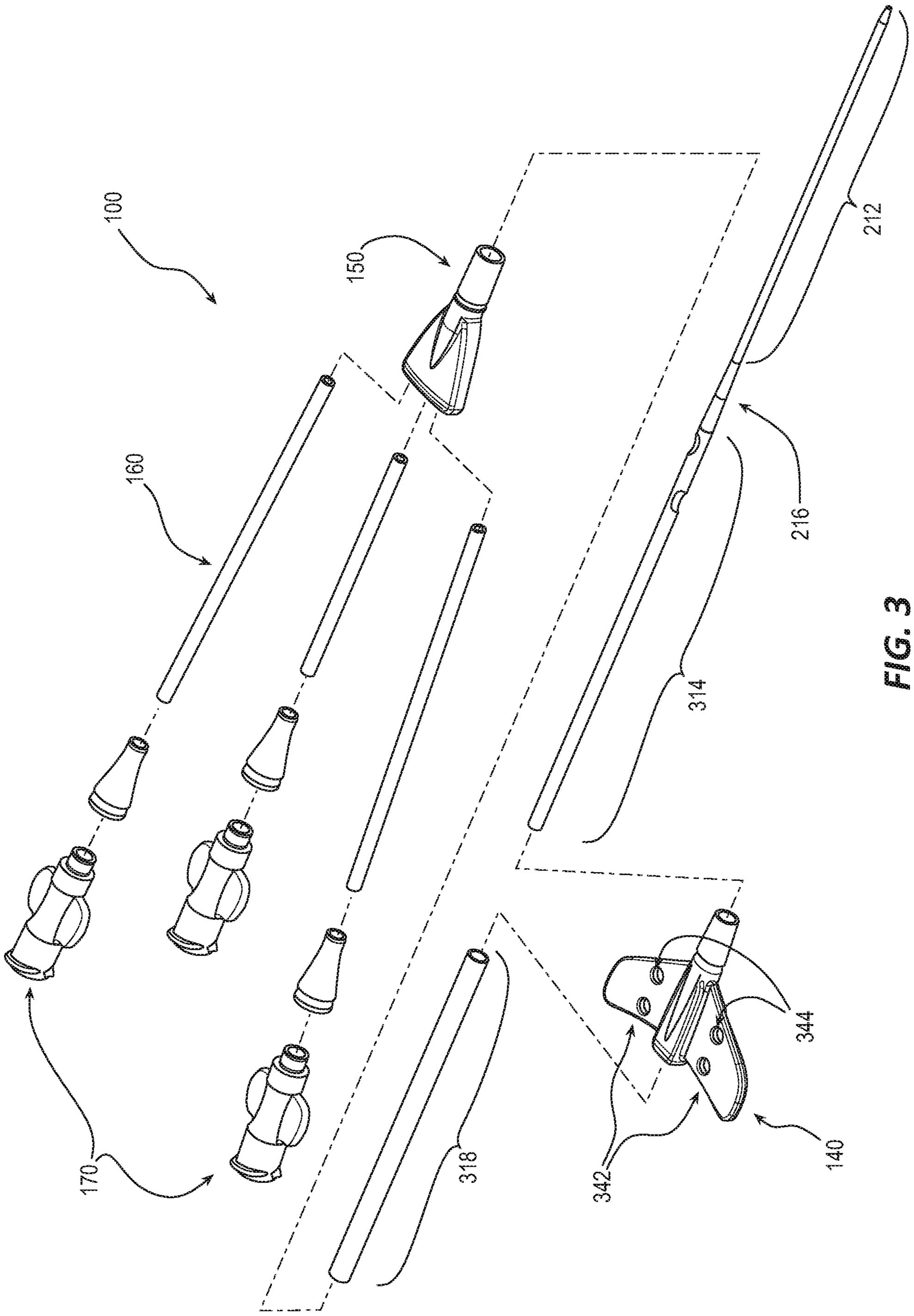


FIG. 3

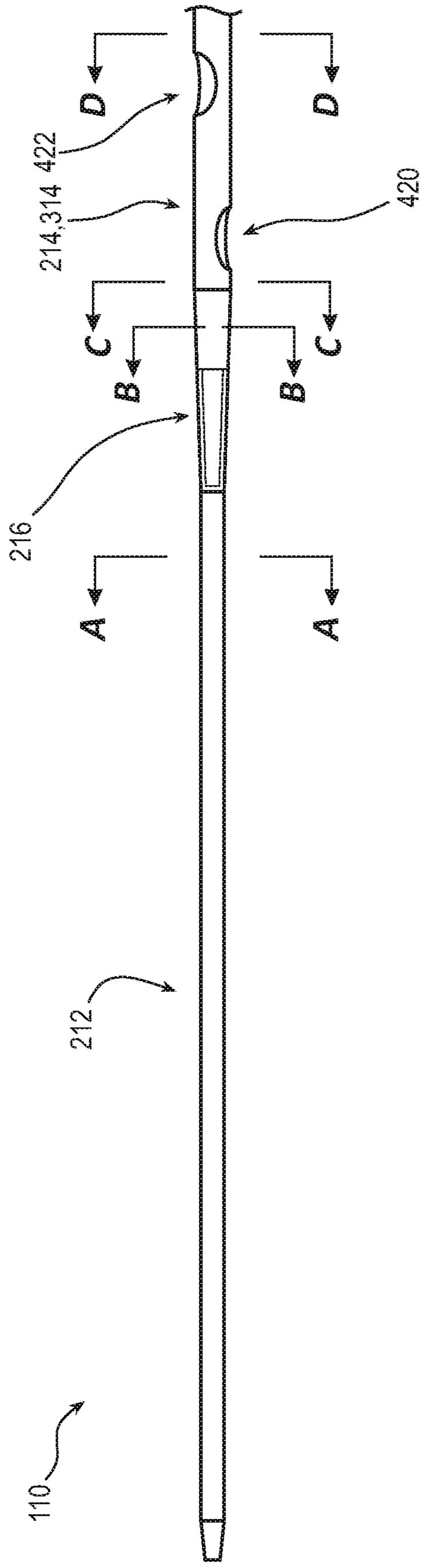


FIG. 4

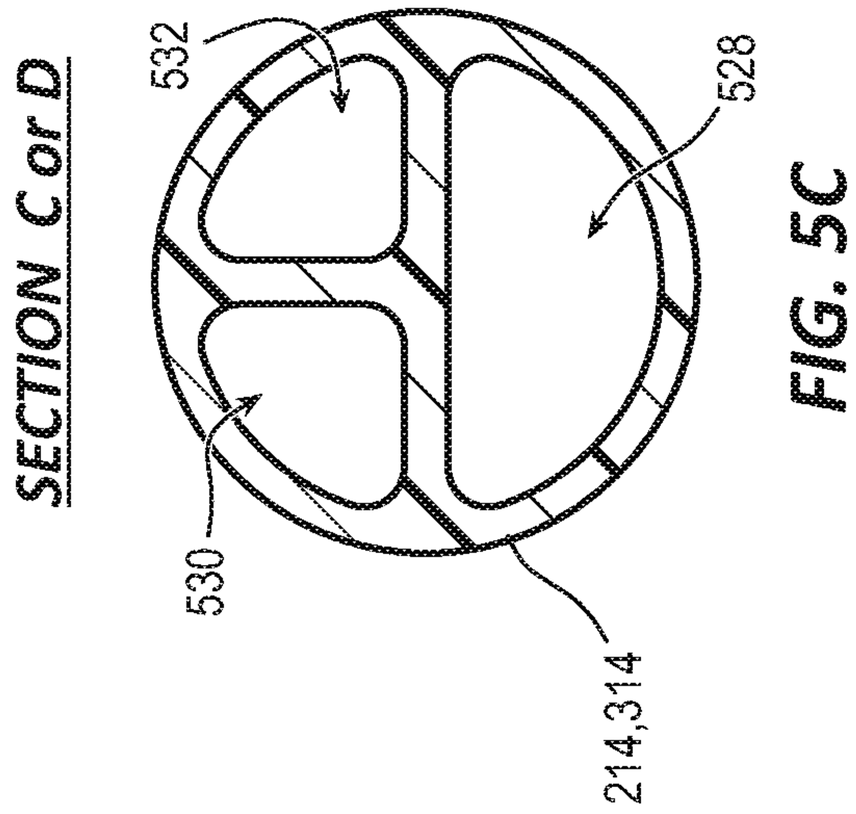


FIG. 5C

FIG. 5B

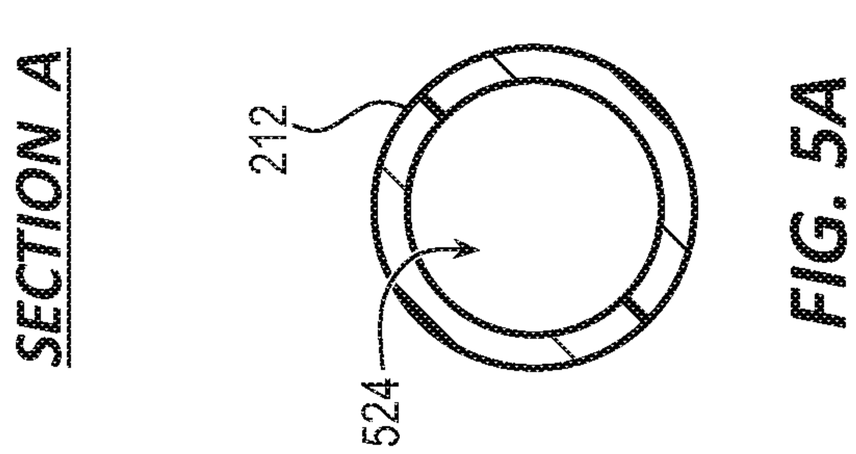


FIG. 5A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/056864

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/01; A61M 5/00; A61M 25/00; A61M 25/02; A61M 25/08; A61M 31/00 (2020.01)
CPC - A61M 25/01; A61M 5/00; A61M 25/00; A61M 25/02; A61M 31/00 (2020.08)

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)
see Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,112,312 A (LUTHER) 12 May 1992 (12.05.1992) entire document	17, 18 --- 1-3, 13-15, 19-21
Y	US 6,206,849 B1 (MARTIN et al) 27 March 2001 (27.03.2001) entire document	1-3, 13-15, 21
Y	US 2003/0060863 A1 (DOBAK III) 27 March 2003 (27.03.2003) entire document	19, 20
A	US 5,683,370 A (LUTHER et al) 04 November 1997 (04.11.1997) entire document	1-3, 13-15, 17-21

☐ 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
"D" document cited by the applicant in the international application
"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
10 December 2020	14 JAN 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300