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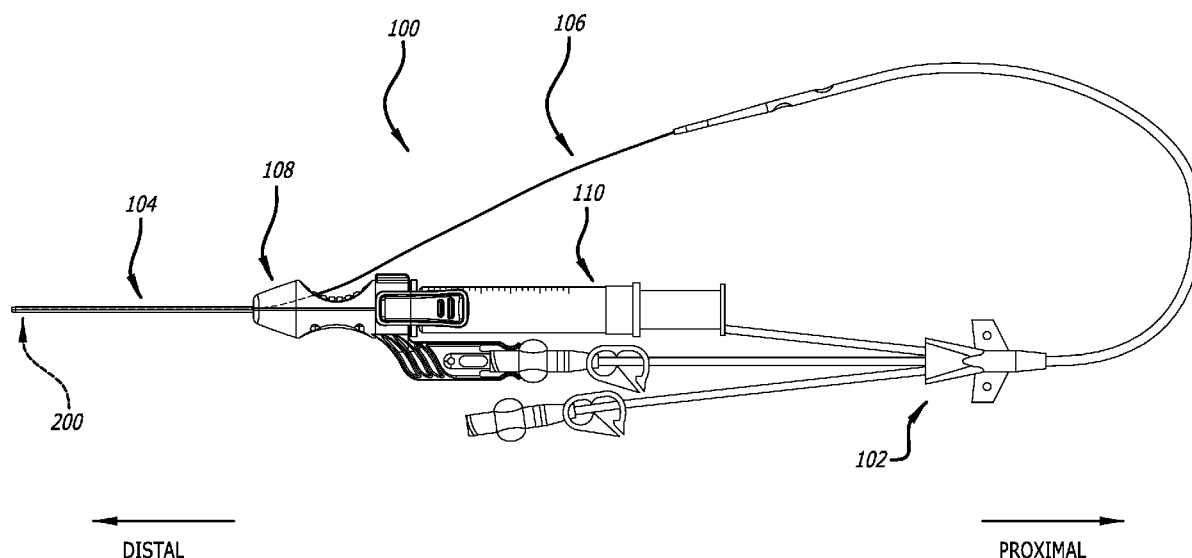


FIG. 1

(57) **Abstract:** Disclosed herein are couplers and assemblies thereof for rapidly insertable central catheters ("RICCs"). For example, a coupler assembly can include an introducer needle and a coupler coupled together. The introducer needle can include a needle hub over both a needle shaft and a sheath over the needle shaft. The needle shaft can include a longitudinal needle slot extending through a distal needle tip. The sheath can seal the needle slot thereunder except for the needle slot under a sheath opening in a proximal portion of the sheath. The needle hub can include a needle-hub clip. The coupler can include a coupler housing and an extension arm connected to the coupler housing. The needle-hub clip can be clipped onto the coupler housing in at least a ready -to-deploy state of the coupler assembly. The extension arm can be configured for attaching a proximal end of an access guidewire thereto.

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COUPLERS AND ASSEMBLIES THEREOF FOR RAPIDLY INSERTABLE CENTRAL CATHETERS

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 63/249,009, filed September 27, 2021; U.S. Provisional Application No. 63/271,043, filed October 22, 2021; and U.S. Provisional Application No. 63/318,945, filed March 11, 2022, each of which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] Central venous catheter (“CVCs”) are commonly introduced into patients and advanced through their vasculatures 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 Seldinger technique. As such, there is a need to reduce the number of steps and medical devices involved in introducing a catheter such as a CVC into a patient and advancing the catheter through a vasculature thereof.

[0003] Disclosed herein are couplers and assemblies thereof for rapidly insertable central catheters (“RICCs”) that address the foregoing.

SUMMARY

[0004] Disclosed herein is a RICC insertion assembly including, in some embodiments, a RICC, an introducer needle, an access guidewire, and a coupler coupling the RICC, the introducer needle, and the access guidewire together. The introducer needle includes a needle shaft, a sheath over the needle shaft, and a needle hub over both the needle shaft and the sheath. The needle shaft includes a longitudinal needle slot extending from a proximal portion of the needle shaft through a distal needle tip. The sheath is over the needle shaft sealing the needle slot thereunder except for the needle slot under a sheath opening in a proximal portion of the sheath. The needle hub is over the proximal portions of the needle shaft and the sheath. The access guidewire includes a proximal portion including a proximal end and a distal portion

including a distal end. The distal end of the access guidewire is disposed in the introducer needle just proximal of the needle tip in at least a ready-to-deploy state of the RICC insertion assembly. The coupler includes a coupler housing and an extension arm connected to the coupler housing. A securing means for securing the needle hub to the coupler housing secures the needle hub to the coupler housing in at least the ready-to-deploy state of the RICC insertion assembly. In addition, the proximal end of the access guidewire is attached to the extension arm in at least the ready-to-deploy state of the RICC insertion assembly. The proximal and distal ends of the access guidewire enforce a loop in the access guidewire over which the RICC is disposed in at least the ready-to-deploy state of the RICC insertion assembly.

[0005] In some embodiments, the securing means for securing the needle hub to the coupler housing is a needle-hub clip. The needle-hub clip is clipped onto the coupler housing in at least the ready-to-deploy state of the RICC insertion assembly.

[0006] In some embodiments, the needle-hub clip is integral with the needle hub.

[0007] In some embodiments, the needle-hub clip includes a single levered clip arm distally extending over the needle hub from a fulcrum connecting the clip arm to a remainder of the needle hub. The clip arm includes a protrusion extending from a distal portion thereof configured to engage with a recess in a corresponding side of coupler housing when the clip arm is clipped onto the coupler housing. The protrusion is also configured to disengage from the recess in the corresponding side of the coupler housing when a proximal portion of the clip arm is pressed in toward a centerline of the needle hub.

[0008] In some embodiments, the needle-hub clip includes a pair of levered clip arms distally extending over opposite sides of the needle hub from a corresponding pair of fulcrums connecting the clip arms to a remainder of the needle hub. Each clip arm of the pair of clip arms includes a protrusion extending from a distal portion thereof configured to engage with a recess in a corresponding side of the coupler housing to clip the needle hub onto the coupler housing. The protrusion is also configured to disengage from the recess in the corresponding side of the coupler housing when a proximal portion of the clip arm is pressed in toward a centerline of the needle hub.

[0009] In some embodiments, the coupler housing includes a longitudinal coupler-housing slot in a side of the coupler housing opposite the extension arm. The coupler-housing slot opens in a same direction as the needle slot of the needle shaft. The coupler-housing slot

is configured to allow the access guidewire to escape from the coupler housing during withdrawal of the introducer needle from the coupler by the needle hub.

[0010] In some embodiments, the coupler housing includes a thumb depression in the side of the coupler housing that includes the coupler-housing slot. The thumb depression is configured for pressing the access guidewire therein with a thumb to hold the access guidewire in place during at least a percutaneous puncture with the introducer needle or withdrawal of the introducer needle from the coupler by the needle hub.

[0011] In some embodiments, the coupler-housing slot partially extends into the thumb depression such that the distal portion of the access guidewire extends into the thumb depression in at least the ready-to-deploy state of the state of the RICC insertion assembly.

[0012] In some embodiments, a surface of the thumb depression is textured.

[0013] In some embodiments, the coupler housing includes a finger depression in a side of the coupler housing opposite the thumb depression. The finger depression is configured for cradling the RICC insertion assembly thereby with a finger while pressing the access guidewire into the thumb depression with the thumb during at least the percutaneous puncture with the introducer needle or withdrawal of the introducer needle from the coupler by the needle hub.

[0014] In some embodiments, the extension arm is integral with the coupler housing.

[0015] In some embodiments, the extension arm terminates with an extension-arm clip clipped onto a Luer connector of the RICC in at least the ready-to-deploy state of the RICC insertion assembly. The proximal portion of the access guidewire extends from the Luer connector, through a center of the extension-arm clip, and to a guidewire attachment point of the extension arm to which the proximal end of the access guidewire is attached.

[0016] In some embodiments, the extension-arm clip includes a socket into which a proximal end of the Luer connector is inserted when the extension-arm clip is clipped onto the Luer connector of the RICC.

[0017] In some embodiments, the extension arm includes an extension-arm opening through opposite sides of the extension arm between the extension-arm clip and a connecting portion of the extension arm that connects the extension arm to a remainder of the coupler housing. The extension-arm opening is configured to provide a window through which the

access guidewire is visualized for confirmation that the access guidewire is attached to the guidewire attachment point of the extension arm.

[0018] In some embodiments, the coupler housing includes a needle-hub receptacle in a proximal portion of the coupler housing into which needle-hub receptacle a distal portion of the needle hub is inserted in at least the ready-to-deploy state of the RICC insertion assembly.

[0019] In some embodiments, the coupler further includes a valve module disposed in a valve-module compartment of the coupler housing. The valve module seals around the proximal portion of the sheath and the distal portion of the access guidewire that extends through the sheath opening in at least the ready-to-deploy state of the RICC insertion assembly, thereby enabling leak-free aspiration through the introducer needle.

[0020] In some embodiments, the valve module includes an integrated blade disposed in the needle slot under a distal end of the sheath opening. The blade includes a distal-facing blade edge configured to cut the sheath off the needle shaft during withdrawal of the introducer needle from the coupler by the needle hub, thereby allowing the access guidewire to escape from the needle shaft by way of the needle slot thereof.

[0021] In some embodiments, the RICC insertion assembly further includes a syringe fluidly coupled to the introducer needle in at least the ready-to-deploy state of the RICC insertion assembly.

[0022] Also disclosed herein is a coupler assembly for a RICC insertion assembly including, in some embodiments, an introducer needle and a coupler coupled together. The introducer needle includes a needle shaft, a sheath over the needle shaft, and a needle hub over both the needle shaft and the sheath. The needle shaft includes a longitudinal needle slot extending from a proximal portion of the needle shaft through a distal needle tip. The sheath is over the needle shaft sealing the needle slot thereunder except for the needle slot under a sheath opening in a proximal portion of the sheath. The needle hub is over the proximal portions of the needle shaft and the sheath. The needle hub includes a needle-hub clip. The coupler includes a coupler housing and an extension arm connected to the coupler housing. The needle-hub clip is clipped onto the coupler housing in at least a ready-to-deploy state of the coupler assembly. The extension arm is configured for attaching a proximal end of an access guidewire thereto.

[0023] In some embodiments, the needle-hub clip includes a pair of levered clip arms distally extending over opposite sides of the needle hub from a corresponding pair of fulcrums connecting the clip arms to a remainder of the needle hub. Each clip arm of the pair of clip arms includes a protrusion extending from a distal portion thereof configured to engage with a recess in a corresponding side of the coupler housing to clip the needle hub onto the coupler housing. The protrusion is also configured to disengage from the recess in the corresponding side of the coupler housing when a proximal portion of the clip arm is pressed in toward a centerline of the needle hub.

[0024] In some embodiments, the coupler housing includes a longitudinal coupler-housing slot in a side of the coupler housing opposite the extension arm. The coupler-housing slot opens in a same direction as the needle slot of the needle shaft. The coupler-housing slot is configured to allow the access guidewire to escape from the coupler housing when the access guidewire is disposed therein.

[0025] In some embodiments, the coupler housing includes a thumb depression in the side of the coupler housing that includes the coupler-housing slot such that the coupler-housing slot partially extends into the thumb depression. The thumb depression is configured for pressing the access guidewire therein with a thumb to hold the access guidewire in place when the access guidewire is disposed in the coupler housing.

[0026] In some embodiments, the coupler housing includes a finger depression in a side of the coupler housing opposite the thumb depression. The finger depression is configured for cradling the coupler assembly thereby with a finger while pressing the access guidewire into the thumb depression with the thumb when the access guidewire is disposed in the coupler housing.

[0027] In some embodiments, the extension arm terminates with an extension-arm clip configured as a socket into which a proximal end of a Luer connector of a RICC is inserted to clip the extension-arm clip onto the Luer connector.

[0028] In some embodiments, the extension arm includes an extension-arm opening through opposite sides of the extension arm between the extension-arm clip and a connecting portion of the extension arm that connects the extension arm to a remainder of the coupler housing. The extension-arm opening is configured to provide a window through which the access guidewire is visualized for confirmation that the access guidewire is attached to a

guidewire attachment point of the extension arm when the access guidewire should be attached thereto.

[0029] In some embodiments, the coupler housing includes a needle-hub receptacle in a proximal portion of the coupler housing into which needle-hub receptacle a distal portion of the needle hub is inserted in at least the ready-to-deploy state of the coupler assembly.

[0030] In some embodiments, the coupler further includes a valve module disposed in a valve-module compartment of the coupler housing. The valve module seals around the proximal portion of the sheath and the access guidewire when the access guidewire extends through the sheath opening, thereby enabling leak-free aspiration through the introducer needle.

[0031] In some embodiments, the valve module includes an integrated blade disposed in the needle slot under a distal end of the sheath opening. The blade includes a distal-facing blade edge configured to cut the sheath off the needle shaft during withdrawal of the introducer needle from the coupler by the needle hub.

[0032] Also disclosed herein is a method for inserting a RICC into a blood-vessel lumen of a patient. The method includes, in some embodiments, a RICC insertion assembly-obtaining step, a needle tract-establishing step, an access guidewire-advancing step, a clip-opening step, an introducer needle-withdrawing step, and a RICC-advancing step. The RICC insertion assembly-obtaining step includes obtaining a RICC insertion assembly. The RICC insertion assembly includes the RICC, an introducer needle including a sheath over a needle shaft, and an access guidewire coupled together by a coupler. A proximal end of the access guidewire is coupled to an extension arm of the coupler. A distal end of the access guidewire is disposed in the introducer needle by way of a valve module of the coupler. The proximal and distal ends of the access guidewire enforce a loop in the access guidewire over which the RICC is disposed in at least a ready-to-deploy state of the RICC insertion assembly. The needle tract-establishing step includes establishing a needle tract from an area of skin to the blood-vessel lumen with the introducer needle. The access guidewire-advancing step includes advancing the distal end of the access guidewire from its initial location in the needle shaft just proximal of a needle tip of the needle shaft into the blood-vessel lumen. The clip-opening step includes pressing a pair of levered clip arms in toward a centerline of a needle hub of the introducer needle. The pressing of the pair of clip arms in toward the needle hub disengages each clip arm

of the pair of clip arms from a coupler housing of the coupler over which the clip arms distally extend. The introducer needle-withdrawing step includes withdrawing the introducer needle by the needle hub from the coupler leaving the access guidewire in place in the blood-vessel lumen. The introducer needle includes a longitudinal needle slot extending from a proximal portion of the needle shaft through the needle tip. The needle slot allows the access guidewire to escape therefrom with the withdrawing of the introducer needle from the coupler. The RICC-advancing step includes advancing a catheter tube of the RICC over the access guidewire for inserting the RICC into the blood-vessel lumen.

[0033] In some embodiments, the method further includes a blood-aspirating step. The blood-aspirating step includes aspirating blood with a syringe coupled to the needle hub for confirmation the needle tract extends into the blood-vessel lumen. The sheath is over the needle shaft sealing the needle slot thereunder for the aspirating of the blood with the syringe. The blood-aspirating step is performed before the introducer needle-withdrawing step.

[0034] In some embodiments, the introducer needle-withdrawing step includes simultaneously cutting the sheath off the needle shaft with an integrated blade of a valve module disposed in a valve-module compartment of the coupler housing. The cutting of the sheath off the needle shaft allows the access guidewire to escape from the needle shaft by way of the needle slot thereof.

[0035] In some embodiments, the coupler housing includes a longitudinal coupler-housing slot in a side of the coupler housing opposite the extension arm. The coupler-housing slot opens in a same direction as the needle slot of the needle shaft. The coupler-housing slot allows the access guidewire to escape from the coupler housing during the introducer needle-withdrawing step.

[0036] In some embodiments, the method further includes an access guidewire-securing step. The access guidewire-securing step includes pressing the access guidewire into a thumb depression in the side of the coupler housing including the coupler-housing slot with a thumb. Pressing the access guidewire into the thumb depression holds the access guidewire in place during the needle tract-establishing step or the introducer needle-withdrawing step.

[0037] In some embodiments, the method further includes an access guidewire-visualizing step. The access guidewire-visualizing step includes visualizing the access guidewire in an extension-arm opening. The extension-arm opening is through opposites sides

of the extension arm between a proximal end of the extension arm and a connecting portion of the extension arm that connects the extension arm to a remainder of the coupler housing. The visualizing of the access guidewire is for confirmation that the access guidewire is attached to a guidewire attachment point of the extension arm.

[0038] In some embodiments, the method further includes a RICC-decoupling step. The RICC-decoupling step includes removing a Luer connector of the RICC from an extension-arm clip of the extension arm during the RICC-advancing step, thereby decoupling the RICC from the coupler for a remainder of the RICC-advancing step. The coupler or the extension arm thereof becomes a handle for the access guidewire.

[0039] 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

[0040] FIG. 1 illustrates a side view of a RICC insertion assembly in accordance with some embodiments.

[0041] FIG. 2 illustrates a side view of a coupler assembly in accordance with some embodiments.

[0042] FIG. 3 illustrates a top view of the coupler assembly in accordance with some embodiments.

[0043] FIG. 4 illustrates a bottom view of the coupler assembly in accordance with some embodiments.

[0044] FIG. 5 illustrates a side view of the coupler assembly with an introducer needle being withdrawn from a coupler in accordance with some embodiments.

[0045] FIG. 6 illustrates a longitudinal cross section of the coupler assembly in accordance with some embodiments.

[0046] FIG. 7 illustrates a longitudinal cross section of the coupler of the coupler assembly in accordance with some embodiments.

[0047] FIG. 8 illustrates a longitudinal cross section of the introducer needle of the coupler assembly in accordance with some embodiments.

[0048] FIG. 9 illustrates a side view of the introducer needle in accordance with some embodiments.

[0049] FIG. 10 illustrates a top view of the introducer needle in accordance with some embodiments.

[0050] FIG. 11 illustrates a top view of a sheath over a needle shaft as in the introducer needle in accordance with some embodiments.

[0051] FIG. 12 illustrates a top view of the sheath in accordance with some embodiments.

[0052] FIG. 13 illustrates a top view of the needle shaft in accordance with some embodiments.

[0053] FIG. 14 illustrates a RICC of the RICC insertion assembly in accordance with some embodiments.

[0054] FIG. 15 illustrates a detailed view of a distal portion of a catheter tube of the RICC in accordance with some embodiments.

[0055] FIG. 16 illustrates a transverse cross section of the distal portion of the catheter tube in accordance with some embodiments.

[0056] FIG. 17 illustrates another transverse cross section of the distal portion of the catheter tube in accordance with some embodiments.

[0057] FIG. 18 illustrates a longitudinal cross section of the distal portion of the catheter tube in accordance with some embodiments.

DESCRIPTION

[0058] 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.

[0059] 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. In addition, any of the foregoing features or steps can, in turn, further include one or more features or steps unless indicated otherwise. 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.

[0060] With respect to “proximal,” a “proximal portion” or a “proximal-end portion” of, for example, a catheter 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.

[0061] With respect to “distal,” a “distal portion” or a “distal-end portion” of, for example, a catheter 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.

[0062] 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.

[0063] As set forth above with respect to the Seldinger technique, 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 Seldinger technique. As such, there is a need to reduce the number of steps and medical devices involved in introducing a catheter such as a CVC into a patient and advancing the catheter through a vasculature thereof.

[0064] Disclosed herein are couplers and assemblies thereof for rapidly insertable central catheters (“RICCs”). For example, a coupler assembly can include an introducer needle and a coupler coupled together. The introducer needle can include a needle hub over both a needle shaft and a sheath over the needle shaft. The needle shaft can include a longitudinal needle slot extending through a distal needle tip. The sheath can seal the needle slot thereunder except for the needle slot under a sheath opening in a proximal portion of the sheath. The needle hub can include a needle-hub clip. The coupler can include a coupler housing and an extension arm connected to the coupler housing. The needle-hub clip can be clipped onto the coupler housing in at least a ready-to-deploy state of the coupler assembly. The extension arm can be configured for attaching a proximal end of an access guidewire thereto.

[0065] The foregoing features as well as other features of the couplers and assemblies thereof for the RICCs 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 the foregoing in the context of RICC insertion assemblies. Notably, the RICC insertion assemblies are but one type of catheter that can be incorporated into catheter insertion assemblies like the RICC insertion assemblies provided herein. Indeed, peripherally inserted

central catheters (“PICCs”), dialysis catheters, or the like can also be incorporated into catheter insertion assemblies.

RICC insertion assemblies

[0066] FIG. 1 illustrates a RICC insertion assembly 100 in accordance with some embodiments.

[0067] As shown, the RICC insertion assembly 100 includes a RICC 102, an introducer needle 104, an access guidewire 106, and a coupler 108 coupling the RICC 102, the introducer needle 104, and the access guidewire 106 together in at least a ready-to-deploy state of the RICC insertion assembly 100. Notably, the proximal end of the access guidewire 106 is attached to the extension arm 178 of the coupler 108 and the distal end of the access guidewire 106 is disposed in the needle lumen 156 of the introducer needle 104 as set forth below. This enforces a loop in the access guidewire 106. The RICC 102 is disposed over the loop in the ready-to-deploy state of the RICC insertion assembly 100 keeping the RICC insertion assembly 100 in a relatively compact form.

[0068] The RICC insertion assembly 100 can further include a syringe 110 fluidly coupled to the introducer needle 104 in at least the ready-to-deploy state of the RICC insertion assembly 100. As set forth below, the sheath 144 seals the needle slot 150 of the needle shaft 142. In particular, the sheath 144 seals the needle slot 150 outside of the valve module 176. The valve module 176, in turn, seals over the sheath opening 160 of the sheath 144 that opens to the needle slot 150. The valve module 176 also seals around the access guidewire 106. Such seals enable the syringe 110 to aspirate blood in accordance with the blood-aspirating step of the method set forth below.

[0069] Lastly, any component of the RICC insertion assembly 100 selected from at least the RICC 102, the introducer needle 104, the access guidewire 106, the coupler 108, and the syringe 110, or any portion of the component selected from the foregoing components, can include an antimicrobial thereon or therein. In an example, the catheter tube 112 of the RICC 102 can include an antimicrobial coating on an abluminal surface of the catheter tube 112, a luminal surface of the catheter tube 112, or both. In another example, a pre-extrusion material of the catheter tube 112 can include the antimicrobial admixed therein such that the antimicrobial is incorporated into the catheter tube 112 when extruded, the antimicrobial

protecting both the abluminal surface of the catheter tube 112 and the luminal surface of the catheter tube 112 from microbial contamination.

[0070] FIG. 14 illustrates the RICC 102 of the RICC insertion assembly 100 in accordance with some embodiments.

[0071] As shown, the RICC 102 includes a catheter tube 112, a catheter hub 114, one or more extension legs 116, and one or more extension-leg connectors 118.

[0072] FIGS. 15-18 illustrate various views of the catheter tube 112 of the RICC 102 in accordance with some embodiments.

[0073] The catheter tube 112 includes a first section 120 in a distal portion of the catheter tube 112, a second section 122 in the distal portion of the catheter tube 112 proximal of the first section 120, and a tapered junction 124 between the first and second sections 120 and 122 of the catheter tube 112.

[0074] The first section 120 of the catheter tube 112 includes a catheter tip 126 having a relatively short taper from an outer diameter of a distal portion of the first section 120 distal of the junction 124 to an outer diameter of a distal end of the first section 120. The taper of the catheter tip 126 is configured for immediate dilation of tissue about a needle tract established with the introducer needle 104 up to the outer diameter of the distal portion of the first section 120 of the catheter tube 112. As best shown in FIG. 18, the first section 120 of the catheter tube 112 also includes a proximal portion disposed in a bore of a distal portion of the junction 124 and fixedly coupled thereto such as by a solvent bond, an adhesive bond, or a heat weld.

[0075] The second section 122 of the catheter tube 112 includes a consistent outer diameter over its length from a distal end of the second section 122 to a proximal end of the second section 122. The consistent diameter of the second section 122 of the catheter tube 112 is configured for smooth insertion into the needle tract and targeted vasculature subsequent to any dilation by the first section 120 of the catheter tube 112 and the junction 124. The distal end of the second section 122 of the catheter tube 112 has a flat face flush with the flat-faced proximal end of the junction 124 and fixedly coupled thereto such as by a solvent bond, an adhesive bond, or a heat weld.

[0076] The junction 124 includes a taper over its length from a proximal end of the junction 124 to a distal end of the junction 124. The taper of the junction 124 is configured for immediate dilation of the tissue about the needle tract from the outer diameter of the proximal portion of the first section 120 of the catheter tube 112 to the outer diameter of the second section 122 of the catheter tube 112. An abluminal surface of the junction 124 smoothly transitions from an abluminal surface of the first section 120 of the catheter tube 112 to an abluminal surface of the second section 122 of the catheter tube 112 without edges that catch on skin when the catheter tube 112 is inserted into the needle tract. In addition to the edges being minimal to negligible, the edges can include solvent-interdiffused polymeric material of the polymeric materials from which the catheter tube 112 is formed, which smoothens the transitions from the first section 120 of the catheter tube 112 to the junction 124 and from the junction 124 to the second section 122 of the catheter tube 112. Notably, the junction 124 has a length approximately commensurate with a length of an exposed portion of the first section 120 of the catheter tube 112 or between lengths of exposed portions of the first and second sections 120 and 122 of the catheter tube 112. As such, the length of the exposed portion of the first section 120 of the catheter tube 112 is less than the length of the junction 124 up to approximately commensurate with the length of the junction 124.

[0077] The first section 120 of the catheter tube 112 is formed of a first polymeric material (e.g., a polytetrafluoroethylene, a polypropylene, or a polyurethane) having a first durometer. The second section 122 of the catheter tube 112 is formed of a second polymeric material (e.g., a polyvinyl chloride, a polyethylene, another polyurethane, or a silicone) having a second durometer less than the first durometer. For example, the first section 120 of the catheter tube 112 can be formed of a first polyurethane having the first durometer while the second section 122 of the catheter tube 112 can be formed of a second, different polyurethane (e.g., a same or different diisocyanate or triisocyanate reacted with a different diol or triol, a different diisocyanate or triisocyanate reacted with a same or different diol or triol, a same diisocyanate or triisocyanate reacted with a same diol or triol under different conditions or with different additives, etc.) having the second durometer less than the first durometer. Indeed, polyurethanes are advantageous for the catheter tube 112 in that polyurethanes can be relatively rigid at room-temperature but become more flexible *in vivo* at body temperature, which reduces irritation to vessel walls as well as phlebitis. Polyurethanes are also advantageous in that they can be less thrombogenic than some other polymers. The junction 124 is formed of the second polymeric material or a third polymeric material (e.g., yet another polyurethane) having a third

durometer less than the first durometer and greater than, approximately equal to, or less than the second durometer.

[0078] It should be understood the first durometer of the first polymeric material, the second durometer of the second polymeric material, and the third durometer of the third polymeric material can be on different scales (e.g., Type A or Type D). With this understanding, the second durometer of the second polymeric material or the third durometer of the third polymeric material might not be numerically less than the first durometer of the first polymeric material when the second durometer or the third durometer is less than the first durometer. Indeed, the hardness of the second polymeric material or the third 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.

[0079] In accordance with the first section 120 of the catheter tube 112, the second section 122 of the catheter tube 112, and the junction 124 between the first and second sections 120 and 122 of the catheter tube 112 set forth above, the catheter tube 112 possesses a column strength sufficient to prevent buckling of the catheter tube 112 when inserted into a needle tract established by with the introducer needle 104. The column strength of the catheter tube 112 is also sufficient to prevent buckling of the catheter tube 112 when advanced through a vasculature of a patient without dilation of tissue about the needle tract or any blood vessels of the vasculature beforehand with a separate dilator.

[0080] The catheter tube 112 includes one or more catheter-tube lumens extending through the catheter tube 112; however, only one catheter-tube lumen typically extends from a proximal end of the catheter tube 112 to a distal end of the catheter tube 112 in a multiluminal RICC (e.g., a diluminal RICC, a triluminal RICC, a tetraluminal RICC, a pentaluminal RICC, a hexaluminal RICC, etc.). (*See* FIGS. 13-16.) Indeed, the first section 120 of the catheter tube 112 typically includes a single lumen therethrough as shown in FIGS. 15-18.

[0081] The catheter hub 114 is coupled to a proximal portion of the catheter tube 112. The catheter hub 114 includes one or more catheter-hub lumens corresponding in number to the one-or-more catheter-tube lumens. The one-or-more catheter-hub lumens extends through an entirety of the catheter hub 114 from a proximal end of the catheter hub 114 to a distal end of the catheter hub 114.

[0082] Each extension leg of the one-or-more extension legs 116 is coupled to the catheter hub 114 by a distal portion thereof. The one-or-more extension legs 116 respectively include one or more extension-leg lumens, which, in turn, correspond in number to the one-or-more catheter-hub lumens. Each extension-leg lumen of the one-or-more extension-leg lumens extends through an entirety of the extension leg from a proximal end of the extension leg to a distal end of the extension leg.

[0083] Each extension-leg connector of the one-or-more extension-leg connectors 118 is over a proximal portion of an extension leg of the one-or-more extension legs 116. For example, each extension-leg connector of the one-or-more extension-leg connectors 118 can be a Luer connector over a proximal portion of an extension leg of the one-or-more extension legs 116. Through such an extension-leg connector, a corresponding extension leg and the extension-leg lumen thereof can be connected to another medical device and a lumen thereof. However, in at least the ready-to-deploy state of the RICC insertion assembly 100 at least one extension-leg connector (e.g., the extension-leg connector including part of the primary lumen 128 of the RICC 102) is connected to the extension-arm clip 194 of the extension arm 178 of the coupler 108 to enforce the loop in the access guidewire 106 and the RICC 102 thereover.

[0084] As shown, the RICC 102 is a triluminal RICC including a set of three lumens; however, the RICC 102 is not limited to the set of the three lumens as set forth above. The set of three lumens includes a primary lumen 128, a secondary lumen 130, and a tertiary lumen 132 formed of fluidly connected portions of three catheter-tube lumens, three catheter-hub lumens, and three extension-leg lumens. The primary lumen 128 has a primary-lumen aperture 134 in the distal end of the first section 120 of the catheter tube 112, which corresponds to the distal end of the catheter tube 112 and a distal end of the RICC 102. The secondary lumen 130 has a secondary-lumen aperture 136 in a side of the distal portion of the catheter tube 112. The tertiary lumen 132 has a tertiary-lumen aperture 138 in the side of the distal portion of the catheter tube 112 proximal of the secondary-lumen aperture 136.

[0085] FIGS. 2-6 illustrate various views of a coupler assembly 140 in accordance with some embodiments.

[0086] As shown, the coupler assembly 140 is a subassembly of the RICC insertion assembly 100. Indeed, the coupler assembly 140 includes the introducer needle 104 and the coupler 108 coupled together.

[0087] FIGS. 8-13 illustrate various views of the introducer needle 104 or components thereof in accordance with some embodiments. FIGS. 2-6 illustrate the introducer needle 104 as part of the coupler assembly 140 in accordance with some embodiments.

[0088] As shown, the introducer needle 104 includes a needle shaft 142, a sheath 144 over the needle shaft 142, and a needle hub 146 over both a proximal portion of the needle shaft 142 and a proximal portion of the sheath 144. In at least the ready-to-deploy state of the RICC insertion assembly 100, the needle shaft 142 and the sheath 144 extend from the needle hub 146, through the valve module 176, and out a distal end of the coupler housing 174.

[0089] The needle shaft 142 includes a needle tip 148 in a distal portion of the needle shaft 142 and a longitudinal needle slot 150 extending from the proximal portion of the needle shaft 142 through the needle tip 148.

[0090] The needle tip 148 includes a bevel 152 having a tip bevel and a primary bevel proximal of the tip bevel. While not shown, a tip-bevel angle of the tip bevel is greater than a primary-bevel angle of the primary bevel such that the bevel 152 provides a smooth transition over the needle tip 148. Such a needle tip is thusly configured for establishing a needle tract from an area of skin into a blood-vessel lumen of a patient in accordance with the needle tract-establishing step of the method set forth below.

[0091] The needle slot 150 extends from the proximal portion of the needle shaft 142 through the needle tip 148, thereby forming a needle channel 154 along a majority of a length of the needle shaft 142 as opposed to a needle lumen therethrough. The needle slot 150 has a width sized in accordance with an outer diameter of the access guidewire 106, which allows the access guidewire 106 to pass from the proximal portion of the needle shaft 142 through the needle tip 148 when the introducer needle-withdrawing step of the method set forth below is performed.

[0092] While the needle shaft 142 includes the needle slot 150, it should be understood the introducer needle 104 includes a needle lumen 156; however, the needle lumen 156 results from the combination of the needle shaft 142 and the sheath 144 over the needle shaft 142. Indeed, the sheath 144 over the needle shaft 142 seals the needle slot 150 thereunder forming the needle lumen 156 of the introducer needle 104 and enabling the syringe 110 to aspirate blood in accordance with the blood-aspirating step of the method set forth below.

[0093] The sheath 144 includes a sheath tip 158 in a distal portion of the sheath 144 and a sheath opening 160 in a side of the proximal portion of the sheath 144.

[0094] The sheath tip 158 includes a relatively short taper from an outer diameter of the distal portion of the sheath 144 to an outer diameter of a distal end of the sheath 144, the latter of which is commensurate with an outer diameter of the distal portion of the needle shaft 142. The taper has a taper angle less than the primary-bevel angle of the primary bevel of the needle tip 148, which, in turn, is less than the tip-bevel angle of the tip bevel of the needle tip 148. The sheath tip 158 having such a taper is configured to provide a smooth transition from the needle tip 148 to the sheath 144 body for the needle tract-establishing step of the method set forth below.

[0095] The sheath opening 160 opens to the needle slot 150 of the needle shaft 142 allowing the access guidewire 106 to pass through the sheath opening 160 and into the needle channel 154 or the needle lumen 156 formed therefrom in at least the ready-to-deploy state of the RICC insertion assembly 100. Thus, the sheath opening 160 has a width approximately commensurate with a width of the needle slot 150, which, in turn, is sized in accordance with the diameter of the access guidewire 106. The sheath opening 160 also has a length sufficient to allow the access guidewire 106 to pass through the sheath opening 160 and into the needle slot 150 or the needle lumen 156 formed therefrom while also accommodating the blade 192 of the valve module 176 under a distal end of the sheath opening 160. Notably, the sheath 144 over the needle shaft 142 seals the needle slot 150 thereunder except for that under the sheath opening 160. However, the valve module 176 seals over the needle slot 150 exposed by the sheath opening 160 by sealing the proximal portions of the needle shaft 142 and the sheath 144 therein, thereby enabling the syringe 110 to aspirate blood in accordance with the blood-aspirating step of the method set forth below.

[0096] The sheath 144, or a sheath body thereof, is formed of a polymeric material configured to facilitate a smooth, consistent insertion of the introducer needle 104 from an area of skin to a blood-vessel lumen of a patient in accordance with the needle tract-establishing step of the method set forth below. In addition, the polymeric material has mechanical properties at a thickness of the sheath 144 sufficient to resist collapse of the sheath 144 into the needle slot 150 of the needle shaft 142 when the blood-aspirating step of the method set forth below is performed, notably, while also facilitating the cutting of the sheath 144 off the needle shaft 142 in accordance with the introducer needle-withdrawing step of the method set forth

below. Such a polymeric material can include, but is not limited to, polyethylene, polypropylene, or polytetrafluoroethylene.

[0097] The needle hub 146 includes a needle-hub clip 162 and a needle-hub connector 164 in a proximal portion of the needle hub 146. However, it should be understood that other securing means for securing the needle hub 146 to the coupler housing 174 are possible. For example, one or more removable pins through the needle hub 146 and the coupler housing 174, one or more removable bands around the needle hub 146 and the coupler housing 174, one or more buttons, one or more lever arms, locking threads, a spin collar, or a needle-housing clip that engages the needle hub 146 can be used as a securing means for securing the needle hub 146 to the coupler housing 174.

[0098] The needle-hub clip 162 includes at least a single levered clip arm 166 distally extending over the needle hub 146. For example, the needle-hub clip 162 can include a pair of such clip arms 166 distally extending over opposite sides of the needle hub 146 as shown in FIGS. 3, 4, and 10. When integral with the needle hub 146 such as when the needle-hub clip 162 is molded with the needle hub 146, the single clip arm 166 distally extends over the needle hub 146 from a fulcrum 168 connecting the clip arm 166 to a remainder of the needle hub 146. Likewise, the pair of clip arms 166 distally extend over opposite sides of the needle hub 146 from a corresponding pair of fulcrums 168 connecting the clip arms 166 to a remainder of the needle hub 146 when the pair of clip arms 166 are molded with the needle hub 146. Alternatively, it should be understood each clip arm 166 of the foregoing clip arms 166 can be molded separately from the remainder of the needle hub 146 and mounted thereto such as on an axle with a tensioned spring between the clip arm 166 and the needle hub 146. Each clip arm 166 of the foregoing clip arms 166 includes a protrusion 170 extending from a distal portion thereof configured to engage with a recess 169 in the corresponding side of the coupler housing 174 to clip the needle hub 146 onto the coupler housing 174 such as in the ready-to-deploy state of the RICC insertion assembly 100. (*See* FIG. 1, wherein the needle-hub clip 162 is clipped onto the coupler housing 174 in the ready-to-deploy state of the RICC insertion assembly 100 or the coupler assembly 140 thereof.) The protrusion 170 is also configured to disengage from the recess 169 in the corresponding side of the coupler housing 174 when a proximal portion of the clip arm 166 is pressed in toward a centerline of the needle hub 146.

[0099] The needle-hub connector 164 includes a needle-hub bore 171 and an optional needle-hub flange 172 about the needle-hub bore 171.

[0100] The needle-hub bore 171 of the needle-hub connector 164 is configured to accept a syringe tip (not shown) of the syringe 110 therein for fluidly connecting the introducer needle 104 to the syringe 110. (*See* FIG. 1 for the fluidly connected introducer needle 104 and syringe 110.) Indeed, the needle-hub bore 171 can have a Luer taper (e.g., a 6% taper) configured to accept the syringe tip therein, which syringe tip can be complementarily configured with a Luer taper.

[0101] When present, the needle-hub flange 172 about the needle-hub bore 171 is configured to screw together with internal threads of a threaded collar around the syringe tip of the syringe 110. While the threaded collar of the syringe 110 is also optional, the needle-hub flange 172 advantageously provides a so-called Luer lock-style connection with the internal threads of the threaded collar when both are present. This provides added security against inadvertent disconnection of the introducer needle 104 and the syringe 110 over that provided by an otherwise Luer slip-style connection.

[0102] FIG. 6 illustrates a longitudinal cross section of the coupler 108 in accordance with some embodiments. FIGS. 2-6 illustrate the coupler 108 as part of the coupler assembly 140 in accordance with some embodiments.

[0103] As shown, the coupler 108 includes a coupler housing 174, a valve module 176 disposed in the coupler housing 174, and an extension arm 178 connected to the coupler housing 174.

[0104] The coupler housing 174 includes two molded pieces coupled together (e.g., coupled together with compression pins or heat-staked pins, fastened or screwed together with screws or bolts, welded together with an ultrasonic weld or a hot-plate weld, etc.) to form a bullet-shaped body configured to be comfortably held underhand (e.g., cradled) in either a left hand for a left-handed venipuncture or a right hand for a right-handed venipuncture with the RICC insertion assembly 100. An inside of each piece of the two molded pieces includes depressions that form a valve-module compartment 180 and a needle-hub receptacle 182 when the two molded pieces are coupled together as shown. (*See* FIGS. 6 and 7, which include the valve module 176 disposed in the valve-module compartment 180 in a distal portion of the coupler housing 174. FIG. 6 also includes a distal portion of the needle hub 146 of the introducer needle 104 inserted or disposed in the needle-hub receptacle 182 in a proximal portion of the coupler housing 174 as in at least the ready-to-deploy state of the RICC insertion

assembly 100.) An outside of each piece of the two molded pieces can also include depressions such as a thumb depression 184 and a finger depression 186 configured for at least cradling the RICC insertion assembly 100 or the coupler assembly 140 thereof thereby. The coupler housing 174 can also include a coupler-housing slot 188 partially extending into the thumb depression 184.

[0105] Beginning with the coupler-housing slot 188, the coupler-housing slot 188 is formed in a piece of the two molded pieces not including the extension arm 178 connected thereto. As such, the coupler-housing slot 188 is in a side of the coupler housing 174 not including the extension arm 178 such as the side of the coupler housing 174 opposite the extension arm 178. The coupler-housing slot 188 opens in a same direction as the needle slot 150 of the needle shaft 142, thereby configuring the coupler-housing slot 188 to allow the access guidewire 106 to escape from the coupler housing 174 as the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0106] Notwithstanding the foregoing, it should be understood the coupler-housing slot 188 can be alternatively located in another location than that illustrated in, for example, FIG. 3 and set forth above. For example, the coupler-housing slot 188 can be alternatively located opposite or orthogonal to that illustrated in FIG. 3 and set forth above.

[0107] Adverting to the thumb depression 184, the thumb depression 184 is in the side of the coupler housing 174 that includes the coupler-housing slot 188. Indeed, the coupler-housing slot 188 partially extends into the thumb depression 184 such that the distal portion of the access guidewire 106 extends into the thumb depression 184 in at least the ready-to-deploy state of the state of the RICC insertion assembly 100. The thumb depression 184 is configured for pressing the access guidewire 106 into the thumb depression 184 with a thumb to hold the access guidewire 106 in place during at least a percutaneous puncture with the introducer needle 104 or withdrawal of the introducer needle 104 from the coupler 108 by the needle hub 146. Advantageously, a surface of the thumb depression 184 can be textured, for example, with ridges as shown in FIG. 3, bumps, or, inversely, dimples, which textured surface facilitates holding the access guidewire 106 in place even in an environment in which stray fluids can make holding the access guidewire 106 in place difficult.

[0108] As to the finger depression 186, the finger depression 186 is in the side of the coupler housing 174 opposite the thumb depression 184. The finger depression 186 is configured for cradling the RICC insertion assembly 100 or the coupler assembly 140 thereof thereby with a finger while resting the thumb in the thumb depression 184 or pressing the access guidewire 106 into the thumb depression 184 with the thumb during at least the percutaneous puncture with the introducer needle 104 or withdrawal of the introducer needle 104 from the coupler 108 by the needle hub 146. While not shown, a surface of the finger depression 186 can be textured, for example, with ridges, bumps, or dimples, which textured surface can facilitate cradling the RICC insertion assembly 100 or the coupler assembly 140 thereof even in an environment in which stray fluids can make such cradling difficult.

[0109] Notwithstanding the foregoing, it should be understood the thumb depression 184 and the finger depression 186 can be alternatively located in other locations than those illustrated in, for example, FIG. 2 and set forth above. For example, the thumb depression 184 and the finger depression 186 can be alternatively located orthogonal to those illustrated in FIG. 2 and set forth above, thereby providing a handedness to the RICC insertion assembly 100 or the coupler assembly 140 thereof depending upon how the thumb depression 184 and the finger depression 186 are distributed between sides of the coupler housing 174. Notably, the handedness of the RICC insertion assembly 100 or the coupler assembly 140 thereof further depends upon how a clinician chooses to hold such a RICC insertion assembly or coupler assembly. In an example, a left-handed clinician might find the RICC insertion assembly 100 with the thumb depression 184 on a sinistral side of the coupler housing 174 and the finger depression 186 on a dextral side of the coupler housing 174 suitable for a left-handed venipuncture while holding the RICC insertion assembly 100 underhand. However, a right-handed clinician might find the foregoing RICC insertion assembly 100 suitable for a right-handed venipuncture while holding the RICC insertion assembly 100 overhand. In another example, a right-handed clinician might find the RICC insertion assembly 100 with the thumb depression 184 on a dextral side of the coupler housing 174 and the finger depression 186 on a sinistral side of the coupler housing 174 suitable for a right-handed venipuncture while holding the RICC insertion assembly 100 underhand. However, a left-handed clinician might find the foregoing RICC insertion assembly 100 suitable for a left-handed venipuncture while holding the RICC insertion assembly 100 overhand.

[0110] Adverting to the needle-hub receptacle 182, the needle-hub receptacle 182 is configured to hold the needle hub 146 of the introducer needle 104 therein. Indeed, the needle-hub receptacle 182 includes the needle hub 146 inserted therein in at least the ready-to-deploy state of the RICC insertion assembly 100 or the coupler assembly 140 thereof. Notably, the needle-hub clip 162 is configured to lock the needle hub 146 in the needle-hub receptacle 182. The needle-hub clip 162 is also configured to unlock the needle hub 146 when, for example, the pair of clip arms 166 are pressed in toward the needle hub 146 for withdrawal of the introducer needle 104 from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0111] Lastly, the valve-module compartment 180 is configured to hold the valve module 176 therein. (Again, *see* FIGS. 6 and 7, which include the valve module 176 disposed in the valve-module compartment 180 in the distal portion of the coupler housing 174.) Notably, the valve-module compartment 180 is further configured with sufficient space to allow the valve module 176 to separate for the escape of the access guidewire 106 therefrom when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0112] The valve module 176 includes an access-guidewire conduit 190 and an integrated blade 192.

[0113] The access-guidewire conduit 190 is configured to direct the access guidewire 106 from the coupler-housing slot 188 of the coupler housing 174 into both the sheath opening 160 of the sheath 144 and the needle channel 154 of the needle shaft 142 or the needle lumen 156 of the introducer needle 104. Indeed, the access-guidewire conduit 190 includes the access guidewire 106 disposed therein in at least the ready-to-deploy state of the RICC insertion assembly 100. Notably, the valve module 176 seals around both a proximal portion of the sheath 144 and the distal portion of the access guidewire 106 that extends through the sheath opening 160 in at least the ready-to-deploy state of the RICC insertion assembly 100, thereby enabling leak-free aspiration through the introducer needle 104 in accordance with the blood-aspirating step of the method set forth below.

[0114] The blade 192 extends from an attachment point in the valve module 176 into the needle slot 150 of the needle shaft 142 such that the blade 192 is disposed in the needle slot 150 under the distal end of the sheath opening 160 of the sheath 144. The blade 192 includes a

distal facing blade edge configured to cut the sheath 144 off the needle shaft 142 as the introducer needle 104 is withdrawn by the needle hub 146 in a proximal direction from the coupler 108 in the introducer needle-withdrawing step of the method set forth below. Cutting the sheath 144 off the needle shaft 142 allows the access guidewire 106 to escape from both the needle shaft 142 by way of the needle slot 150 thereof and the coupler 108 by way of the coupler-housing slot 188 of the coupler housing 174.

[0115] The extension arm 178 includes an extension-arm clip 194, an extension-arm opening 196 (aka extension-arm window), and a guidewire attachment point 198. The extension arm 178 terminates with the extension-arm clip 194, which is configured to clip onto a Luer connector of the RICC 102. Indeed, as shown in FIG. 1, the extension-arm clip 194 is clipped onto a Luer connector of the RICC 102 in at least the ready-to-deploy state of the RICC insertion assembly 100. Notably, the extension-arm clip 194 includes a socket formed by two or more clip arms of the extension-arm clip 194 into which socket a proximal end of a Luer connector of the RICC 102 is inserted when the extension-arm clip 194 is clipped onto the Luer connector. The extension-arm opening 196 is through opposite sides of the extension arm 178 between the extension-arm clip 194 and a connecting portion of the extension arm 178 that connects the extension arm 178 to a remainder of the coupler housing 174. The extension-arm opening 196 is configured to provide a window through which the access guidewire 106 is visualized for confirmation the access guidewire 106 is attached to the guidewire attachment point 198 of the extension arm 178 when it should be, for example, in at least the ready-to-deploy state of the RICC insertion assembly 100. The guidewire attachment point 198 can be a tie point between a through hole distal of the extension-arm opening 196 and the extension-arm opening 196 to which tie point the access guidewire 106 can be tied or adhered with an adhesive. Alternatively, the guidewire attachment point 198 can be the foregoing through hole. In such embodiments, the access guidewire 106 can include a stop (e.g., a hub, a ball, a stopper knot, etc.) at its proximal end configured to stop the access guidewire 106 from passing through the through hole in a distal direction. Further alternatively, the proximal end of the access guidewire 106 is overmolded into the extension arm 178 distal of the extension-arm opening 196 such as to the guidewire attachment point 198.

[0116] The extension arm 178 can be molded in a piece of the two molded pieces of the coupler housing 174 not including the coupler-housing slot 188 such that the extension arm 178 is integral therewith. Alternatively, the extension arm 178 is separately molded and

connected to the molded piece of the coupler housing 174 not including the coupler-housing slot 188. Regardless, the extension arm 178 is fixedly and preferably immovably connected to the side of the coupler housing 174 not including the coupler-housing slot 188 such as the side of the coupler housing 174 opposite the coupler-housing slot 188. In view of the extension arm 178 being part of the side of the coupler housing 174 opposite the coupler-housing slot 188, the RICC insertion assembly 100 or the coupler assembly 140 thereof advantageously has an immediately recognizable orientation.

[0117] FIG. 1 illustrates the access guidewire 106 as part of the RICC insertion assembly 100 in accordance with some embodiments.

[0118] The access guidewire 106 includes a proximal portion including a proximal end and a distal portion including a distal end. In at least the ready-to-deploy state of the RICC insertion assembly 100, the proximal end of the access guidewire 106 is attached to the extension arm 178, particularly the guidewire attachment point 198 of the extension arm 178. Indeed, the proximal portion of the access guidewire 106 extends from the guidewire attachment point 198 of the extension arm 178, through a center of the extension-arm clip 194 into the Luer connector, and along the primary lumen 128 of the RICC 102. The distal portion of the access guidewire 106 also extends along the primary lumen 128 of the RICC 102, but the distal portion of the access guidewire 106 further extends out the distal end of the RICC 102, into the valve module 176 by way of the coupler-housing slot 188, into the needle shaft 142 through both the sheath opening 160 of the sheath 144 and the needle slot 150 of the needle shaft 142, and along the needle channel 154 of the needle shaft 142 or the needle lumen 156 of the introducer needle 104 in the ready-to-deploy state of the RICC insertion assembly 100. As alluded to in FIG. 1, the distal end of the access guidewire 106 is disposed in the needle lumen 156 of the introducer needle 104 just proximal of the needle tip 148 in at least the ready-to-deploy state of the RICC insertion assembly 100. Again, the proximal and distal ends of the access guidewire 106 enforce the loop in the access guidewire 106 in at least the ready-to-deploy state of the RICC insertion assembly 100, which loop the RICC 102 is disposed over, thereby keeping the RICC insertion assembly 100 in a relatively compact form.

[0119] The access guidewire 106 can include a guidewire tip 200 in the distal portion of the access guidewire 106, which adopts a 'J' shape configured to prevent puncturing a back wall of a blood vessel. Such a guidewire tip assumes a straightened state in at least the ready-to-deploy state of the RICC insertion assembly 100 and a curved state when the guidewire tip

200 is advanced beyond the needle tip 148 (e.g., advanced into a blood-vessel lumen) in a deployed state of the RICC insertion assembly 100.

[0120] The access guidewire 106 can further include a bare-wire portion and a wound-wire portion proximal of the bare-wire portion. While not shown, the bare-wire portion, when present, distally extends through the access-guidewire conduit 190 of the valve module 176 in at least the ready-to-deploy state of the RICC insertion assembly 100 such that the valve module 176 forms a fluid-tight seal around the bare-wire portion of the access guidewire 106. Notably, the foregoing bare-wire portion can instead be a flat-wound or ground-wound portion of the access guidewire 106, wherein the flat-wound portion includes windings of a tape instead of a round wire, and wherein the ground-wound portion includes windings of a round wire ground down to flatten the windings.

Methods

[0121] Methods include a method for inserting the RICC 102 into a blood-vessel lumen of a patient. Such a method includes one or more steps selected from a RICC insertion assembly-obtaining step, a needle tract-establishing step, a blood-aspirating step, an access guidewire-advancing step, a clip-opening step, an access guidewire-securing step, an access guidewire-visualizing step, an introducer needle-withdrawing step, a RICC-advancing step, a RICC-decoupling step, an access guidewire-withdrawing step, a maneuver guidewire-advancing step, another RICC-advancing step, and a maneuver guidewire-withdrawing step.

[0122] The insertion assembly-obtaining step includes obtaining the RICC insertion assembly 100. As set forth above, the RICC insertion assembly 100 includes the RICC 102, the introducer needle 104 including the sheath 144 over the needle shaft 142, and the access guidewire 106 coupled together by the coupler 108. The proximal end of the access guidewire 106 is coupled to the extension arm 178 of the coupler 108. The distal end of the access guidewire 106 is disposed in the introducer needle 104 by way of the valve module 176 of the coupler 108. The proximal and distal ends of the access guidewire 106 enforce the loop in the access guidewire 106 over which the RICC 102 is disposed in at least the ready-to-deploy state of the RICC insertion assembly 100. The RICC 102 disposed over the loop in the ready-to-deploy state of the RICC insertion assembly 100 keeps the RICC insertion assembly 100 in a relatively compact form.

[0123] The needle tract-establishing step includes establishing a needle tract from an area of skin to the blood-vessel lumen with the introducer needle 104. The needle tract-establishing step can also include ensuring blood flashback while establishing the needle tract. Ensuring blood flashback while establishing the needle tract includes ensuring blood flashes back into the needle hub 146 of the introducer needle 104, particularly when the needle hub 146 is clear and colorless, the syringe tip of the syringe 110 fluidly connected to the introducer needle 104, a barrel of the syringe 110, or a combination thereof. A slight vacuum can be drawn with the syringe 110 while establishing the needle tract such that the blood flashes back into at least the needle hub 146 of the introducer needle 104 upon establishing the needle tract. Ensuring the blood flashes back in accordance with the foregoing confirms the needle tract extends into the blood-vessel lumen.

[0124] The blood-aspirating step includes aspirating blood with the syringe 110 coupled to the needle hub 146 for confirmation the needle tract extends into the blood-vessel lumen, notably before withdrawing the introducer needle 104 from the coupler 108 in the introducer needle-withdrawing step. Again, the sheath 144 over the needle shaft 142 seals the needle slot 150 of the needle shaft 142 thereunder. In particular, the sheath 144 seals the needle slot 150 outside of the valve module 176. The valve module 176, in turn, seals over the sheath opening 160 of the sheath 144, which sheath opening 160 allows the access guidewire 106 to pass into the needle shaft 142 by way of the needle slot 150 in the ready-to-deploy state of the RICC insertion assembly 100. The valve module 176 also seals around the distal portion of the access guidewire 106. Such seals enable the syringe 110 to aspirate blood in the blood-aspirating step.

[0125] The access guidewire-advancing step includes advancing the distal end of the access guidewire 106 from its initial location in the needle shaft 142 just proximal of the needle tip 148 of the needle shaft 142 into the blood-vessel lumen, thereby securing blood-vessel access for the RICC 102 in the RICC-advancing step.

[0126] The clip-opening step includes pressing, for example, the pair of clip arms 166 in toward the centerline of the needle hub 146 of the introducer needle 104. The pressing of the pair of clip arms 166 in toward the needle hub 146 disengages each clip arm 166 of the pair of clip arms 166 from the coupler housing 174 of the coupler 108 over which they extend for subsequently performing the introducer needle-withdrawing step.

[0127] The access guidewire-securing step includes pressing the access guidewire 106 into the thumb depression 184 in the side of the coupler housing 174 including the coupler-housing slot 188 with a thumb. Pressing the access guidewire 106 into the thumb depression 184 holds the access guidewire 106 in place during the needle tract-establishing step or the introducer needle-withdrawing step.

[0128] The access guidewire-visualizing step includes visualizing the access guidewire 106 in the extension-arm opening 196. As set forth above, the extension-arm opening 196 is through opposites sides of the extension arm 178 between the proximal end of the extension arm 178 and the connecting portion of the extension arm 178 that connects the extension arm 178 to the remainder of the coupler housing 174. The visualizing of the access guidewire 106 is for confirmation the access guidewire 106 is attached to the guidewire attachment point 198 of the extension arm 178.

[0129] The introducer needle-withdrawing step includes withdrawing the introducer needle 104 by the needle hub 146 from the coupler 108 leaving the access guidewire 106 in place in the blood-vessel lumen. The introducer needle-withdrawing step includes simultaneously cutting the sheath 144 off the needle shaft 142 with the blade 192 of the valve module 176 disposed in the valve-module compartment 180 of the coupler housing 174 when the introducer needle 104 is withdrawn from the coupler 108. The cutting of the sheath 144 off the needle shaft 142 allows the access guidewire 106 to escape from the needle shaft 142 by way of the needle slot 150 thereof. Again, the introducer needle 104 includes the needle slot 150 extending from the proximal portion of the needle shaft 142 through the needle tip 148, which allows the access guidewire 106 to escape from the introducer needle 104 with the cutting of the sheath 144 off the needle shaft 142. Notably, the valve module 176 around the needle shaft 142 and the sheath 144 separates to allow the access guidewire 106 to further escape from the valve module 176 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step. In addition, the coupler housing 174 includes the coupler-housing slot 188 in the side of the coupler housing 174 opposite the extension arm 178, which coupler-housing slot 188 opens in the same direction as the needle slot 150 of the needle shaft 142. The coupler-housing slot 188 is configured to allow the access guidewire 106 to yet further escape from the coupler housing 174 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step.

[0130] The RICC-advancing step includes advancing the catheter tube 112 of the RICC 102 over the access guidewire 106 and into the blood-vessel lumen, thereby inserting the RICC 102 into the blood-vessel lumen.

[0131] The RICC-decoupling step includes removing the Luer connector of the RICC 102 from the extension-arm clip 194 of the extension arm 178 during the RICC-advancing step, thereby decoupling the RICC 102 from the coupler 108 for a remainder of the RICC-advancing step. Notably, the coupler 108 or the extension arm 178 thereof becomes a handle for the access guidewire 106.

[0132] The access guidewire-withdrawing step includes withdrawing the access guidewire 106 leaving the catheter tube 112 in place in the blood-vessel lumen.

[0133] The maneuver guidewire-advancing step includes advancing a maneuver guidewire into the blood-vessel lumen by way of the primary lumen 128 of the RICC 102 and to a lower $\frac{1}{3}$ of an SVC of a heart of the patient.

[0134] The other RICC-advancing step includes advancing the distal portion of the catheter tube 112 farther into the blood-vessel lumen over the maneuver guidewire to the lower $\frac{1}{3}$ of the SVC of the heart of the patient.

[0135] The maneuver guidewire-withdrawing step includes withdrawing the maneuver guidewire leaving the catheter tube 112 in place in the lower $\frac{1}{3}$ of the SVC.

[0136] 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 or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations 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”) insertion assembly, comprising:
 - a RICC;
 - an introducer needle including:
 - a needle shaft including a longitudinal needle slot extending from a proximal portion of the needle shaft through a distal needle tip;
 - a sheath over the needle shaft sealing the needle slot thereunder except for that under a sheath opening in a proximal portion of the sheath; and
 - a needle hub over the proximal portions of the needle shaft and the sheath;
 - an access guidewire including:
 - a proximal portion including a proximal end; and
 - a distal portion including a distal end disposed in the introducer needle just proximal of the needle tip in at least a ready-to-deploy state of the RICC insertion assembly; and
 - a coupler coupling the RICC, the introducer needle, and the access guidewire together, the coupler including:
 - a coupler housing onto which a securing means for securing the needle hub to the coupler housing secures the needle hub to the coupler housing in at least the ready-to-deploy state of the RICC insertion assembly; and
 - an extension arm connected to the coupler housing to which extension arm the proximal end of the access guidewire is attached, the proximal and distal ends of the access guidewire enforcing a loop in the access guidewire over which the RICC is disposed in at least the ready-to-deploy state of the RICC insertion assembly.
2. The RICC insertion assembly according to claim 1, wherein the securing means for securing the needle hub to the coupler housing is a needle-hub clip, the needle-hub clip clipped onto the coupler housing in at least the ready-to-deploy state of the RICC insertion assembly.
3. The RICC insertion assembly according to claim 2, wherein the needle-hub clip is integral with the needle hub.

4. The RICC insertion assembly according to claim 2 or claim 3, wherein the needle-hub clip includes a single levered clip arm distally extending over the needle hub from a fulcrum connecting the clip arm to a remainder of the needle hub, the clip arm including a protrusion extending from a distal portion thereof configured to engage with a recess in a corresponding side of coupler housing when the clip arm is clipped onto the coupler housing and disengage from the recess when a proximal portion of the clip arm is pressed in toward a centerline of the needle hub.

5. The RICC insertion assembly according to claim 2 or claim 3, wherein the needle-hub clip includes a pair of levered clip arms distally extending over opposite sides of the needle hub from a corresponding pair of fulcrums connecting the clip arms to a remainder of the needle hub, each clip arm of the pair of clip arms including a protrusion extending from a distal portion thereof configured to engage with a recess in a corresponding side of the coupler housing to clip the needle hub onto the coupler housing and disengage from the recess when a proximal portion of the clip arm is pressed in toward a centerline of the needle hub.

6. The RICC insertion assembly according to any of claims 2-5, wherein the coupler housing includes a longitudinal coupler-housing slot in a side of the coupler housing opposite the extension arm opening in a same direction as the needle slot of the needle shaft, the coupler-housing slot configured to allow the access guidewire to escape from the coupler housing during withdrawal of the introducer needle from the coupler by the needle hub.

7. The RICC insertion assembly according to claim 6, wherein the coupler housing includes a thumb depression in the side of the coupler housing including the coupler-housing slot, the thumb depression configured for pressing the access guidewire therein with a thumb to hold the access guidewire in place during at least a percutaneous puncture with the introducer needle or withdrawal of the introducer needle from the coupler by the needle hub.

8. The RICC insertion assembly according to claim 7, wherein the coupler-housing slot partially extends into the thumb depression such that the distal portion of the access guidewire extends into the thumb depression in at least the ready-to-deploy state of the state of the RICC insertion assembly.

9. The RICC insertion assembly according to claim 7 or claim 8, wherein a surface of the thumb depression is textured.

10. The RICC insertion assembly according to any of claims 7-9, wherein the coupler housing includes a finger depression in a side of the coupler housing opposite the thumb depression, the finger depression configured for cradling the RICC insertion assembly thereby with a finger while pressing the access guidewire into the thumb depression with the thumb during at least the percutaneous puncture with the introducer needle or withdrawal of the introducer needle from the coupler by the needle hub.

11. The RICC insertion assembly according to any of claims 2-10, wherein the extension arm is integral with the coupler housing.

12. The RICC insertion assembly according to any of claims 2-11, wherein the extension arm terminates with an extension-arm clip clipped onto a Luer connector of the RICC in at least the ready-to-deploy state of the RICC insertion assembly, the proximal portion of the access guidewire extending from the Luer connector, through a center of the extension-arm clip, and to a guidewire attachment point of the extension arm to which the proximal end of the access guidewire is attached.

13. The RICC insertion assembly according to claim 12, wherein the extension-arm clip includes a socket into which a proximal end of the Luer connector is inserted when the extension-arm clip is clipped onto the Luer connector of the RICC.

14. The RICC insertion assembly according to claim 12 or claim 13, wherein the extension arm includes an extension-arm opening through opposite sides of the extension arm between the extension-arm clip and a connecting portion of the extension arm connecting the extension arm to a remainder of the coupler housing, the extension-arm opening configured to provide a window through which the access guidewire is visualized for confirmation that the access guidewire is attached to the guidewire attachment point of the extension arm.

15. The RICC insertion assembly according to any of claims 2-14, wherein the coupler housing includes a needle-hub receptacle in a proximal portion of the coupler housing into which needle-hub receptacle a distal portion of the needle hub is inserted in at least the ready-to-deploy state of the RICC insertion assembly.

16. The RICC insertion assembly according to any of claims 2-15, the coupler further including a valve module disposed in a valve-module compartment of the coupler housing sealing around the proximal portion of the sheath and the distal portion of the access

guidewire that extends through the sheath opening in at least the ready-to-deploy state of the RICC insertion assembly, thereby enabling leak-free aspiration through the introducer needle.

17. The RICC insertion assembly according to claim 16, wherein the valve module includes an integrated blade disposed in the needle slot under a distal end of the sheath opening, the blade including a distal-facing blade edge configured to cut the sheath off the needle shaft during withdrawal of the introducer needle from the coupler by the needle hub, thereby allowing the access guidewire to escape from the needle shaft by way of the needle slot thereof.

18. The RICC insertion assembly according to any of claims 2-17, further comprising a syringe fluidly coupled to the introducer needle in at least the ready-to-deploy state of the RICC insertion assembly.

19. A coupler assembly for a rapidly insertable central catheter (“RICC”) insertion assembly, comprising:

an introducer needle including:

a needle shaft including a longitudinal needle slot extending from a proximal portion of the needle shaft through a distal needle tip;

a sheath over the needle shaft sealing the needle slot thereunder except for that under a sheath opening in a proximal portion of the sheath; and

a needle hub over the proximal portions of the needle shaft and the sheath, the needle hub including a needle-hub clip; and

a coupler coupled together with the introducer needle, the coupler including:

a coupler housing onto which the needle-hub clip is clipped in at least the ready-to-deploy state of the coupler assembly; and

an extension arm connected to the coupler housing, which extension arm is configured for attaching a proximal end of an access guidewire thereto.

20. The coupler assembly according to claim 19, wherein the needle-hub clip includes a pair of levered clip arms distally extending over opposite sides of the needle hub from a corresponding pair of fulcrums connecting the clip arms to a remainder of the needle hub, each clip arm of the pair of clip arms including a protrusion extending from a distal portion thereof configured to engage with a recess in a corresponding side of the coupler housing to clip the needle hub onto the coupler housing and disengage from the recess when a proximal portion of the clip arm is pressed in toward a centerline of the needle hub.

21. The coupler assembly according to claim 19 or claim 20, wherein the coupler housing includes a longitudinal coupler-housing slot in a side of the coupler housing opposite the extension arm opening in a same direction as the needle slot of the needle shaft, the coupler-housing slot configured to allow the access guidewire to escape from the coupler housing when the access guidewire is disposed therein.

22. The coupler assembly according to claim 21, wherein the coupler housing includes a thumb depression in the side of the coupler housing including the coupler-housing slot such that the coupler-housing slot partially extends into the thumb depression, the thumb depression configured for pressing the access guidewire therein with a thumb to hold the access guidewire in place when the access guidewire is disposed in the coupler housing.

23. The coupler assembly according to claim 22, wherein the coupler housing includes a finger depression in a side of the coupler housing opposite the thumb depression, the finger depression configured for cradling the coupler assembly thereby with a finger while pressing the access guidewire into the thumb depression with the thumb when the access guidewire is disposed in the coupler housing.

24. The coupler assembly according to any of claims 19-23, wherein the extension arm terminates with an extension-arm clip configured as a socket into which a proximal end of a Luer connector of a RICC is inserted to clip the extension-arm clip onto the Luer connector.

25. The coupler assembly according to claim 24, wherein the extension arm includes an extension-arm opening through opposite sides of the extension arm between the extension-arm clip and a connecting portion of the extension arm connecting the extension arm to a remainder of the coupler housing, the extension-arm opening configured to provide a window through which the access guidewire is visualized for confirmation that the access guidewire is attached to a guidewire attachment point of the extension arm when the access guidewire should be attached thereto.

26. The coupler assembly according to any of claims 19-25, wherein the coupler housing includes a needle-hub receptacle in a proximal portion of the coupler housing into which a distal portion of the needle hub is inserted in at least the ready-to-deploy state of the coupler assembly.

27. The coupler assembly according to any of claims 19-26, the coupler further including a valve module disposed in a valve-module compartment of the coupler housing sealing around the proximal portion of the sheath and the access guidewire when the access guidewire extends through the sheath opening, thereby enabling leak-free aspiration through the introducer needle.

28. The coupler assembly according to claim 27, wherein the valve module includes an integrated blade disposed in the needle slot under a distal end of the sheath opening, the blade including a distal-facing blade edge configured to cut the sheath off the needle shaft during withdrawal of the introducer needle from the coupler by the needle hub.

29. A method for inserting a rapidly insertable central catheter (“RICC”) into a blood-vessel lumen of a patient, comprising:

obtaining a RICC insertion assembly including the RICC, an introducer needle including a sheath over a needle shaft, and an access guidewire coupled together by a coupler, a proximal end of the access guidewire coupled to an extension arm of the coupler and a distal end of the access guidewire disposed in the introducer needle by way of a valve module of the coupler such that the proximal and distal ends of the access guidewire enforce a loop in the access guidewire, over which the RICC is disposed in at least a ready-to-deploy state of the RICC insertion assembly;

establishing a needle tract from an area of skin to the blood-vessel lumen with the introducer needle;

advancing the distal end of the access guidewire from its initial location in the needle shaft just proximal of a needle tip of the needle shaft into the blood-vessel lumen;

pressing a pair of levered clip arms in toward a centerline of a needle hub of the introducer needle, thereby disengaging each clip arm of the pair of clip arms from a coupler housing of the coupler over which the clip arms distally extend;

withdrawing the introducer needle by the needle hub from the coupler housing leaving the access guidewire in place in the blood-vessel lumen, the introducer needle including a longitudinal needle slot extending from a proximal portion of the needle shaft through the needle tip allowing the

access guidewire to escape therefrom with the withdrawing of the introducer needle from the coupler; and
advancing a catheter tube of the RICC over the access guidewire for inserting the RICC into the blood-vessel lumen.

30. The method according to claim 29, further comprising aspirating blood with a syringe coupled to the needle hub for confirmation the needle tract extends into the blood-vessel lumen before the withdrawing of the introducer needle from the coupler, the sheath over the needle shaft sealing the needle slot thereunder for the aspirating of the blood with the syringe.

31. The method according to claim 29 or claim 30, wherein the withdrawing of the introducer needle from the coupler includes simultaneously cutting the sheath off the needle shaft with an integrated blade of a valve module disposed in a valve-module compartment of the coupler housing, the cutting of the sheath off the needle shaft allowing the access guidewire to escape from the needle shaft by way of the needle slot thereof.

32. The method according to any of claims 29-31, wherein the coupler housing includes a longitudinal coupler-housing slot in a side of the coupler housing opposite the extension arm opening in a same direction as the needle slot of the needle shaft allowing the access guidewire to escape from the coupler housing during the withdrawing of the introducer needle from the coupler.

33. The method according to claim 32, further comprising pressing the access guidewire into a thumb depression in the side of the coupler housing including the coupler-housing slot with a thumb, thereby holding the access guidewire in place during the establishing of the needle tract or the withdrawing of the introducer needle from the coupler.

34. The method according to any of claims 29-33, further comprising visualizing the access guidewire in an extension-arm opening through opposites sides of the extension arm between a proximal end of the extension arm and a connecting portion of the extension arm connecting the extension arm to a remainder of the coupler housing, the visualizing of the access guidewire for confirmation that the access guidewire is attached to a guidewire attachment point of the extension arm.

35. The method according to any of claims 29-34, further comprising removing a Luer connector of the RICC from an extension-arm clip of the extension arm during the advancing of the catheter tube of the RICC over the access guidewire, thereby decoupling the RICC from the coupler for a remainder of the advancing of the catheter tube of the RICC over the access guidewire, the coupler or the extension arm thereof becoming a handle for the access guidewire.

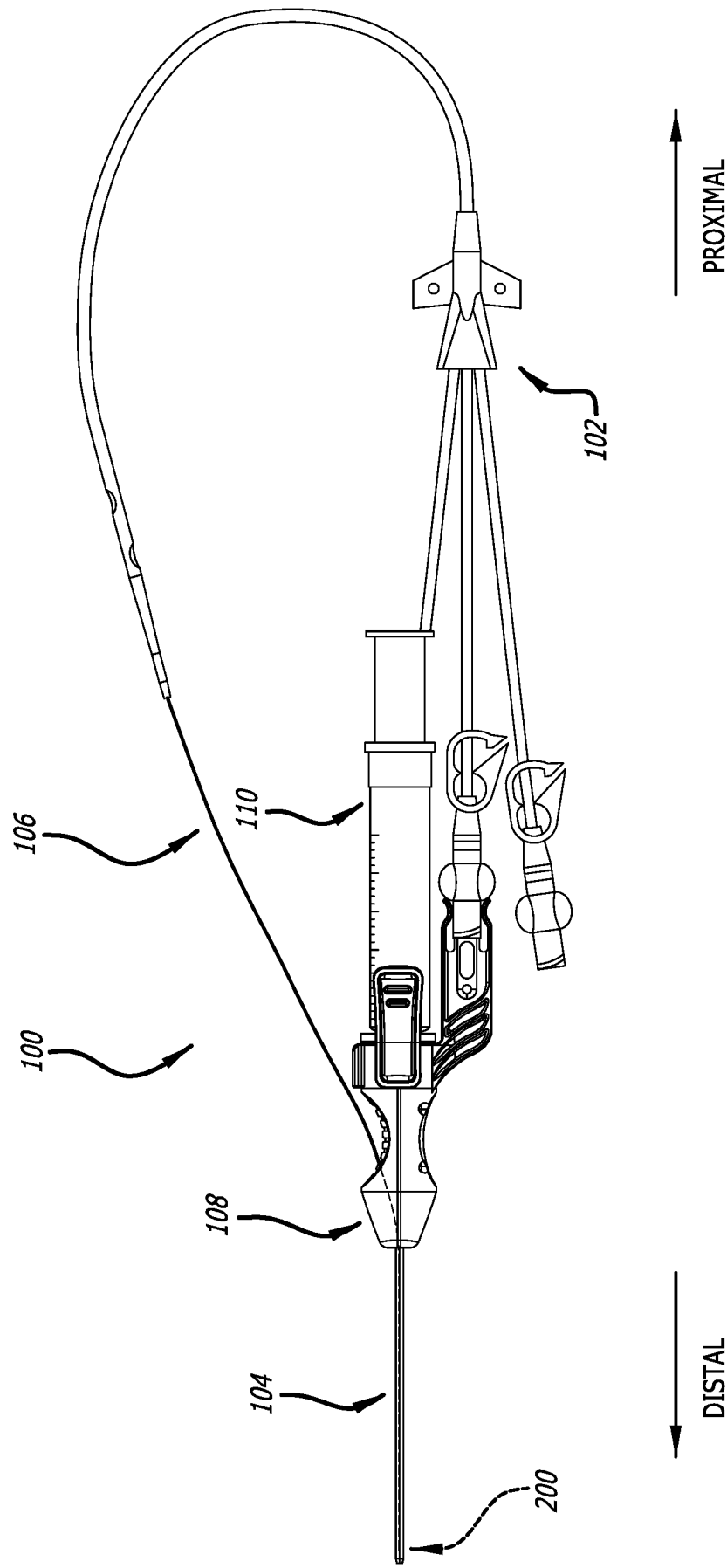
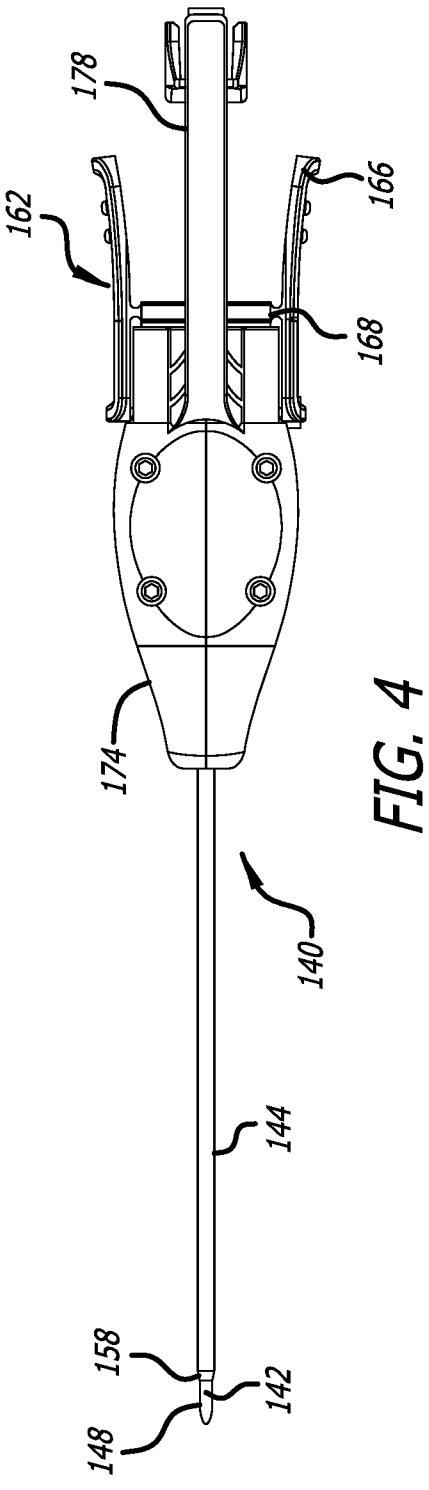
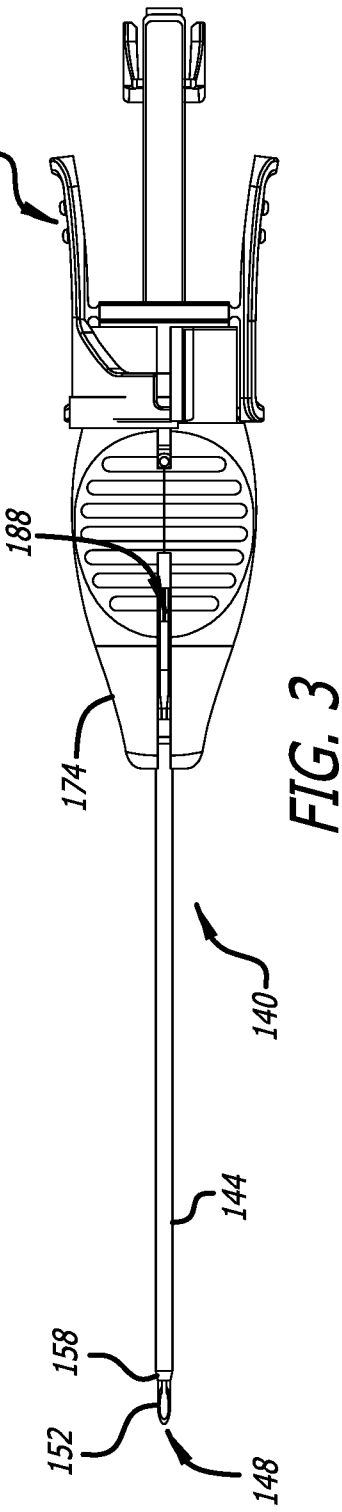
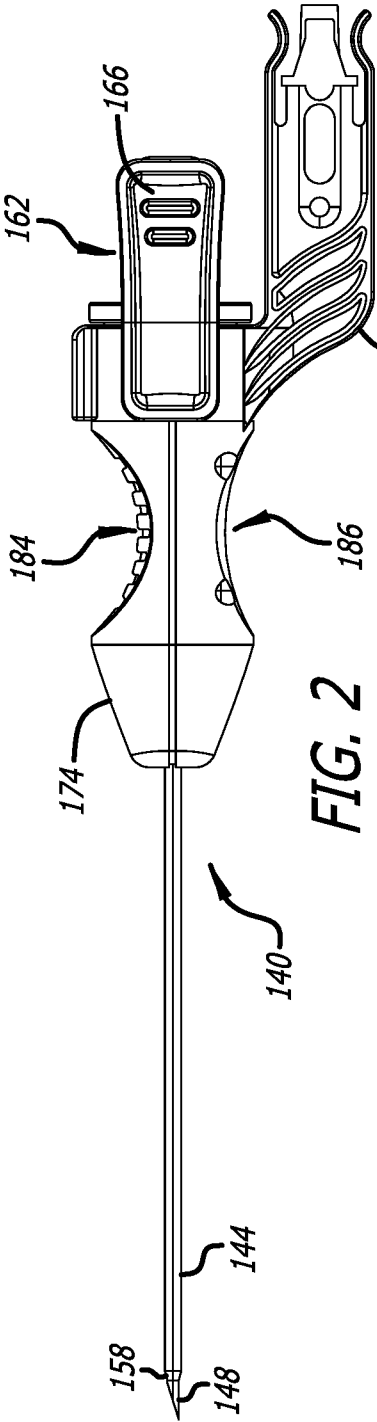


FIG. 1



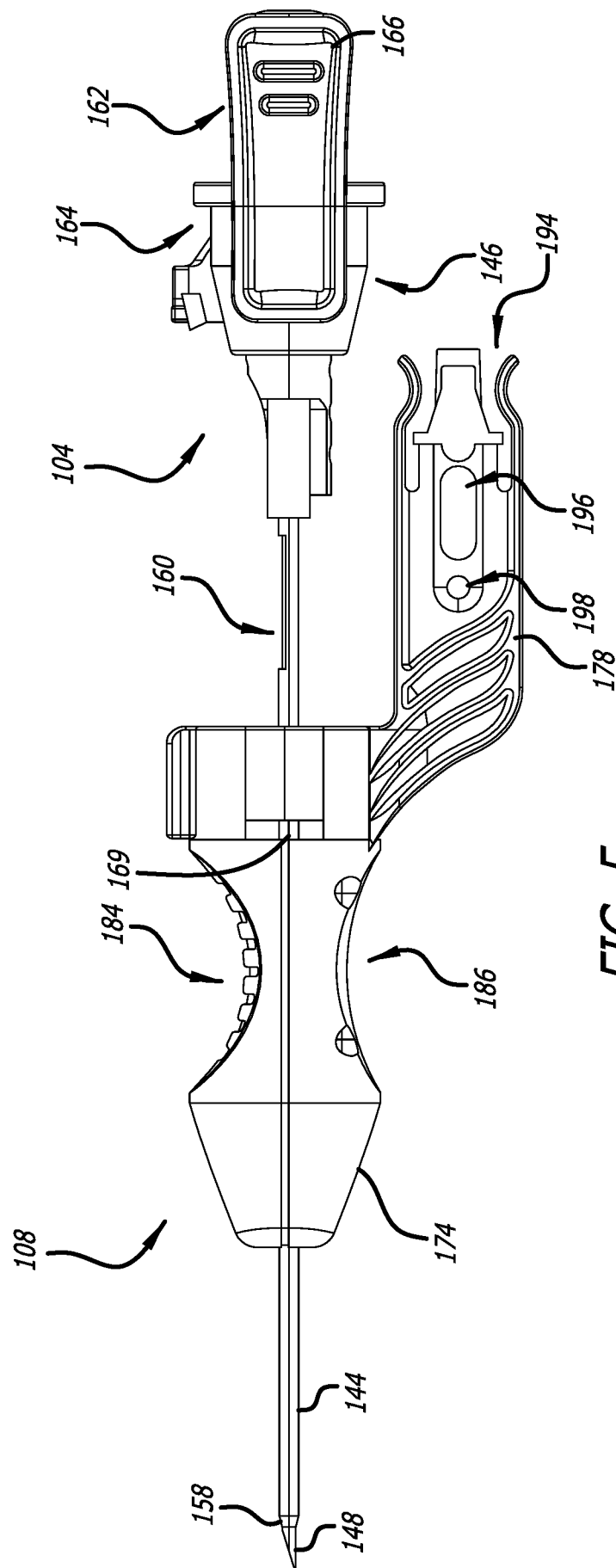


FIG. 5

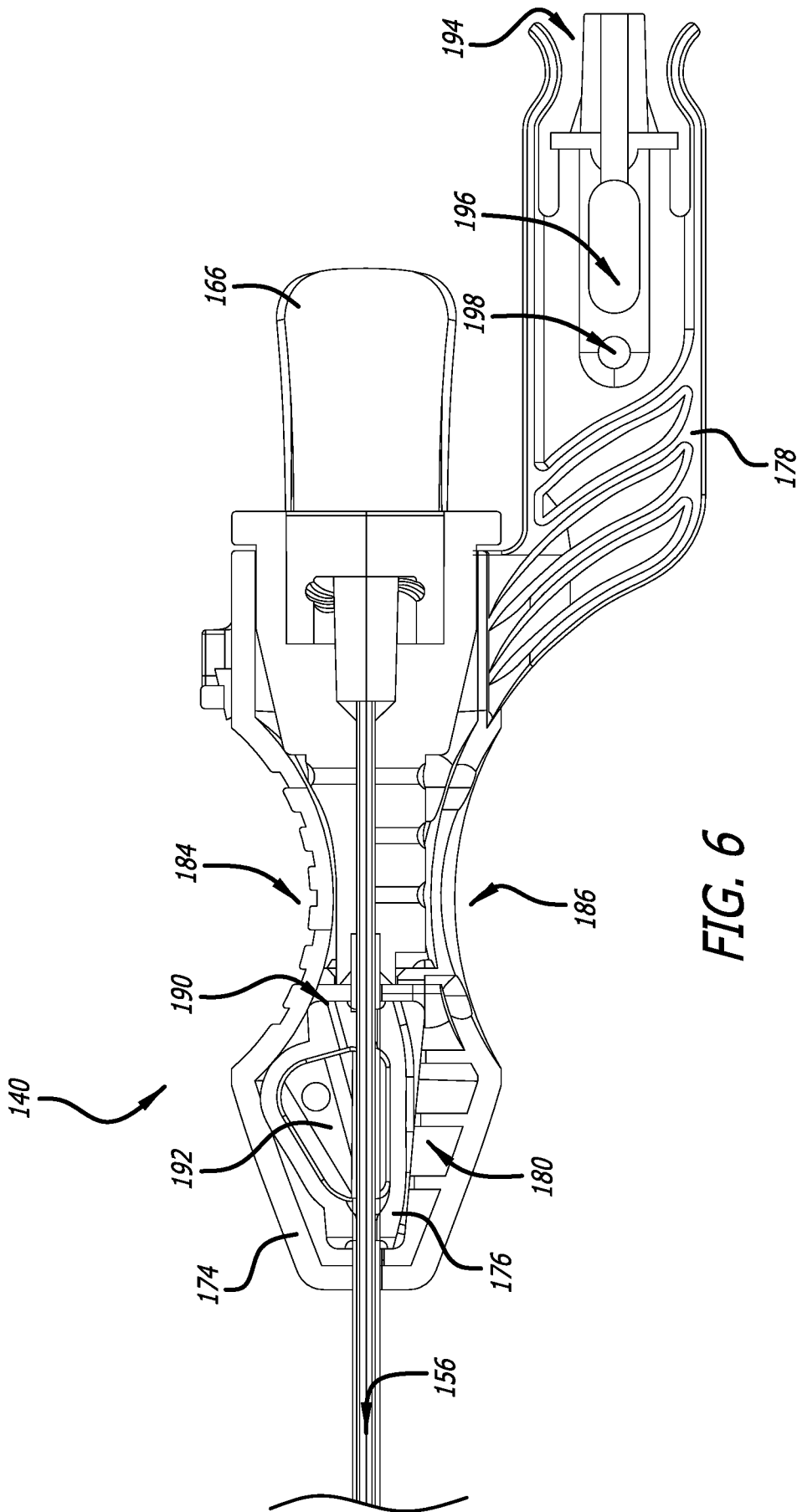
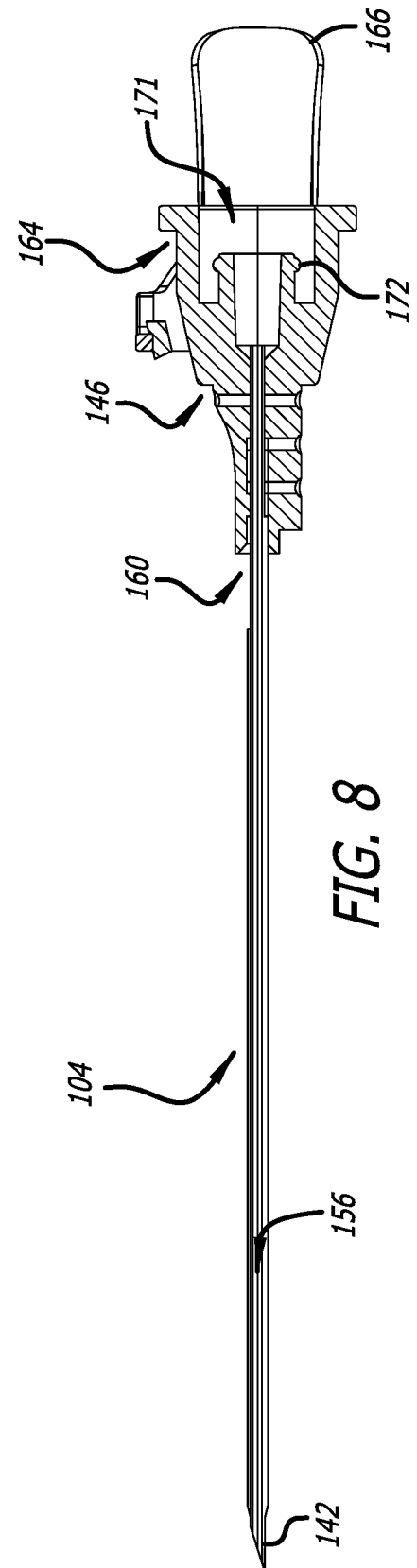
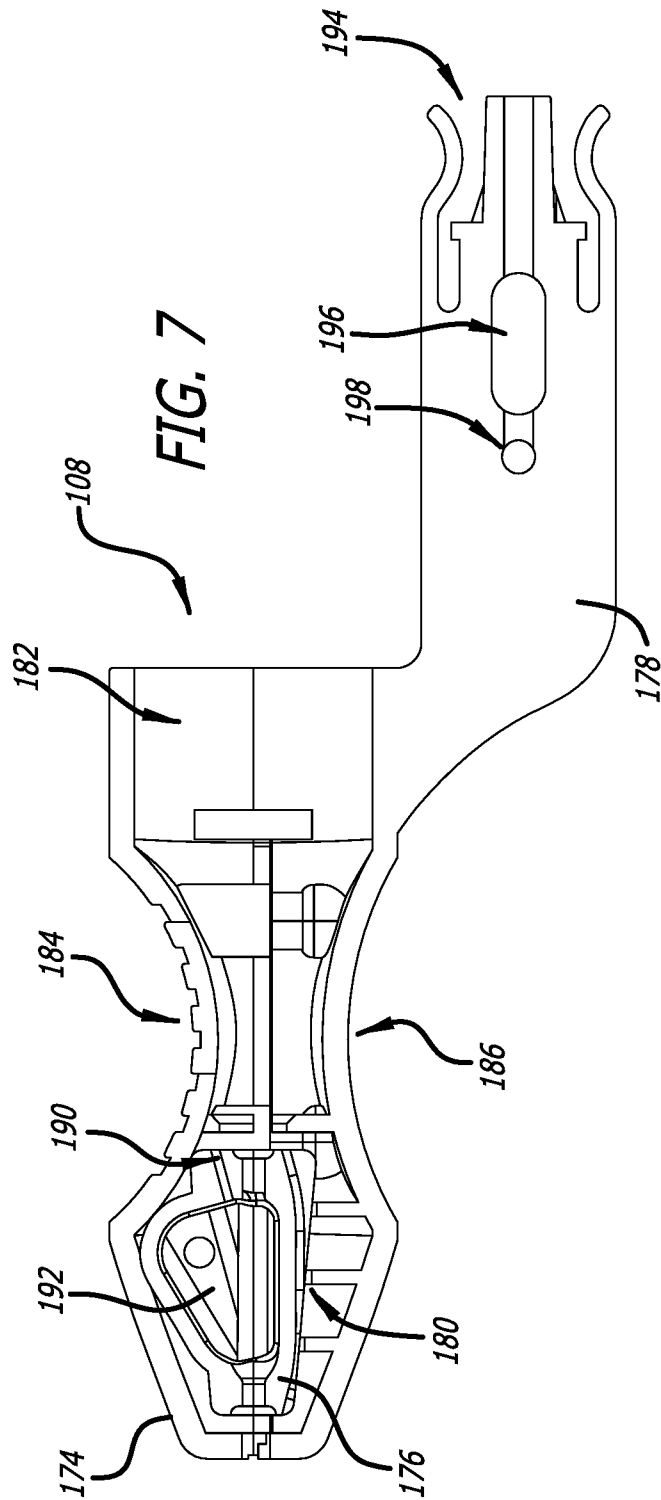
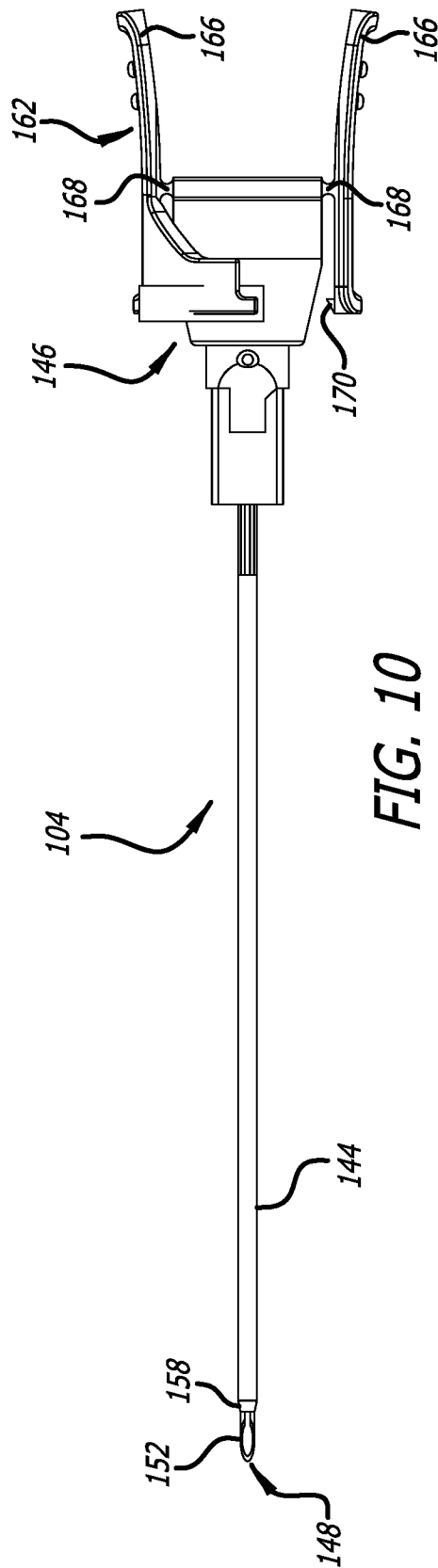
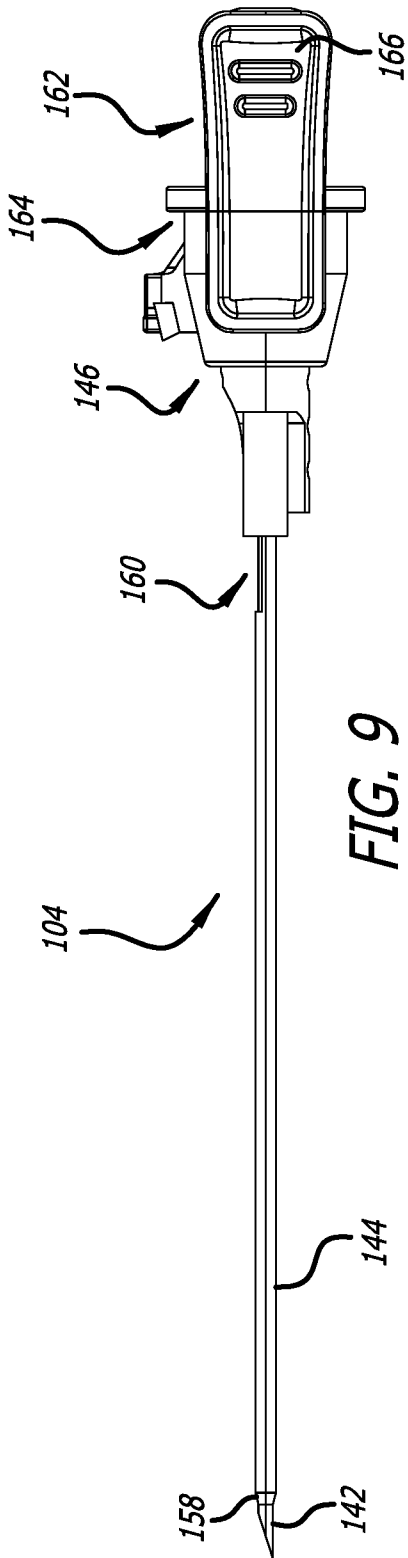
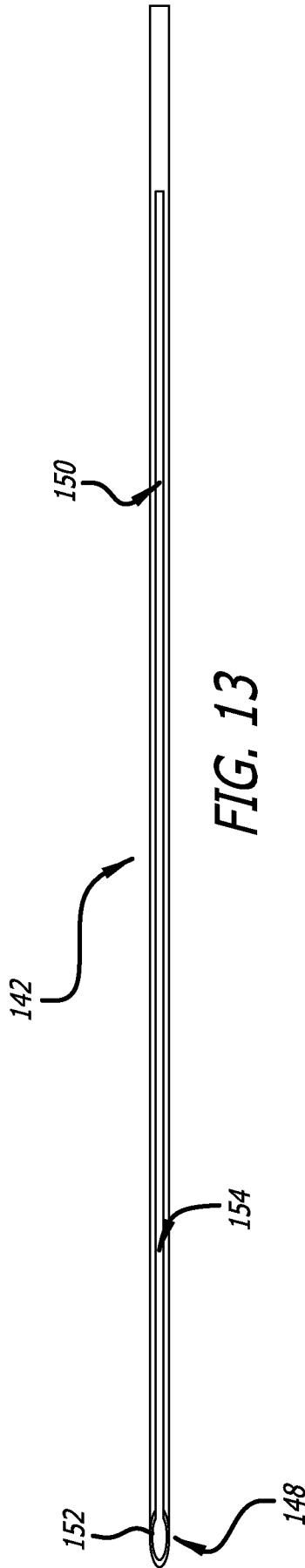
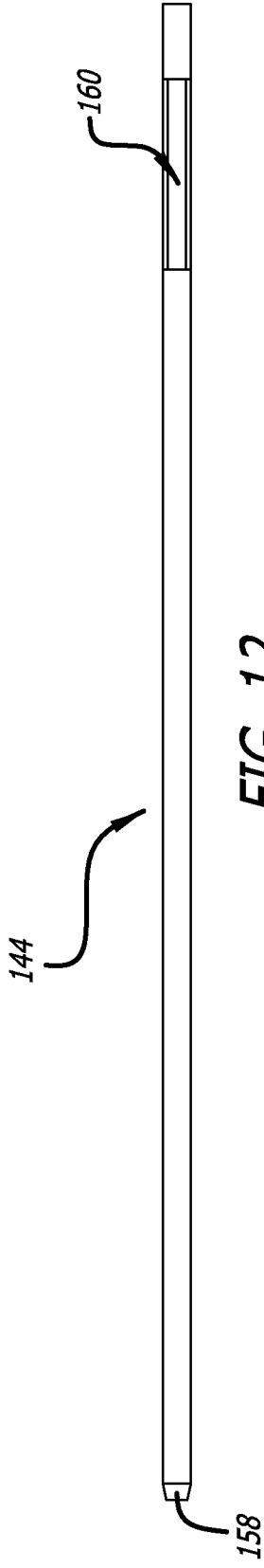
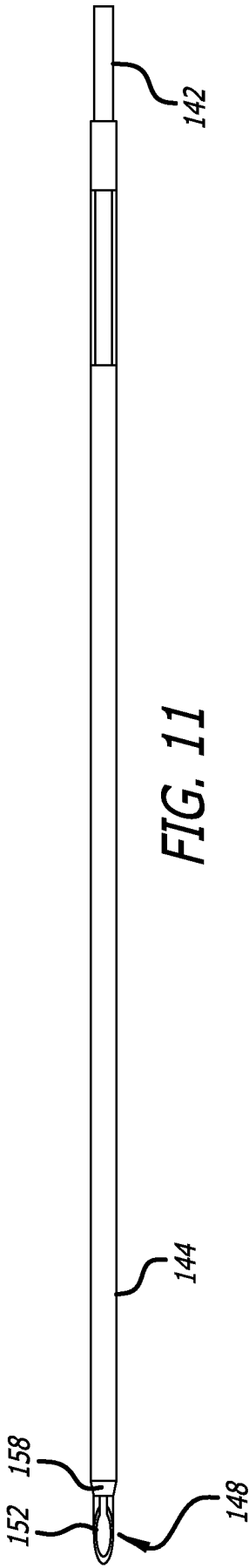
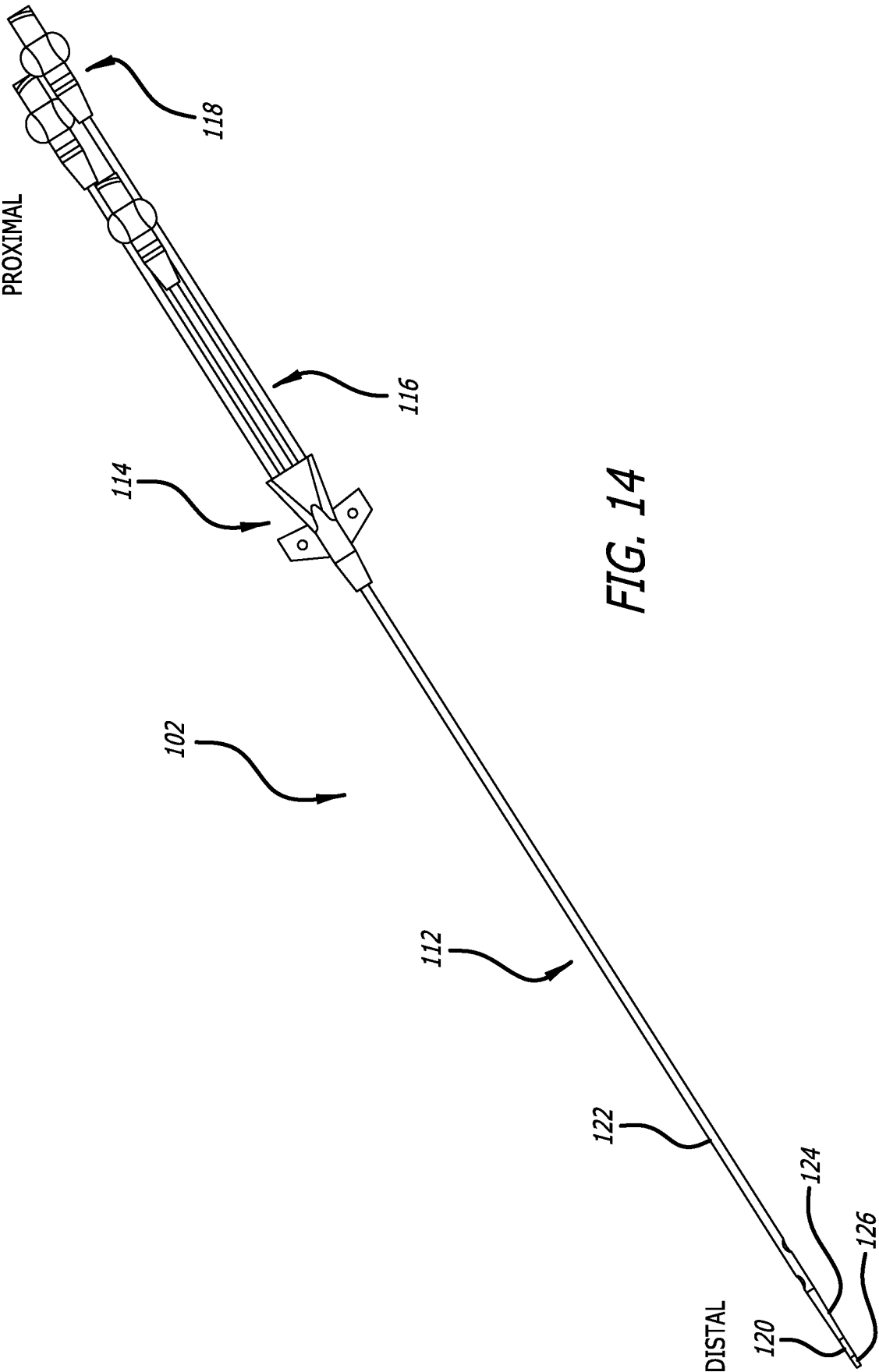


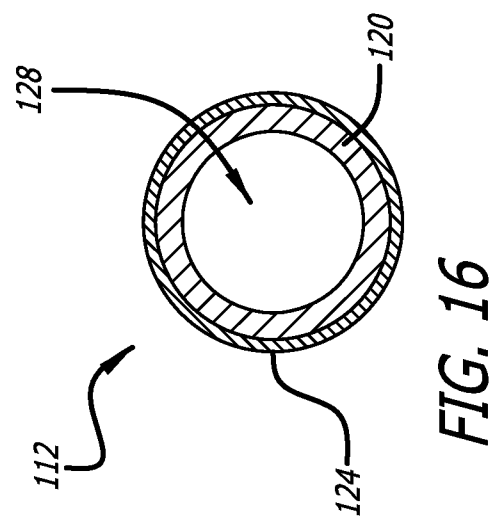
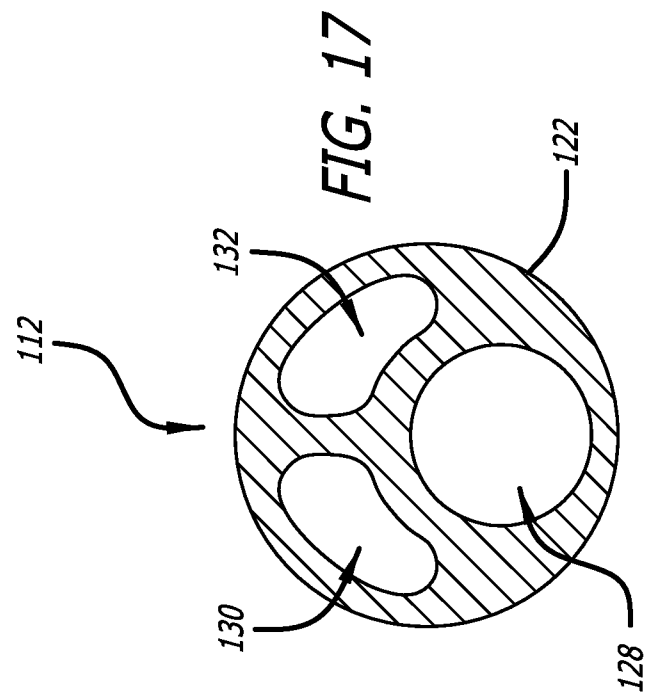
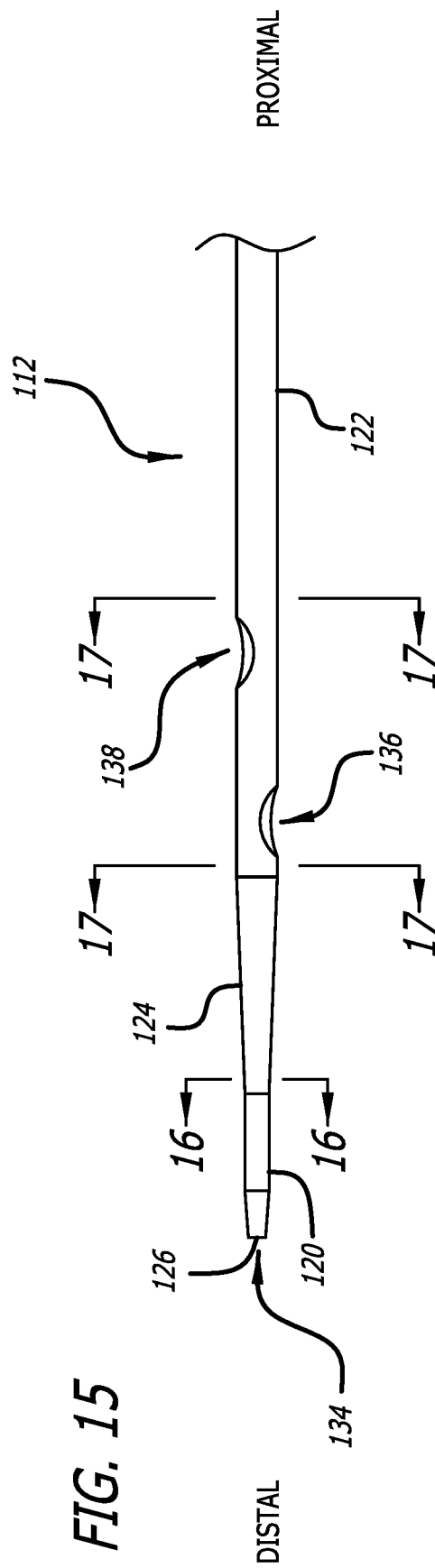
FIG. 6











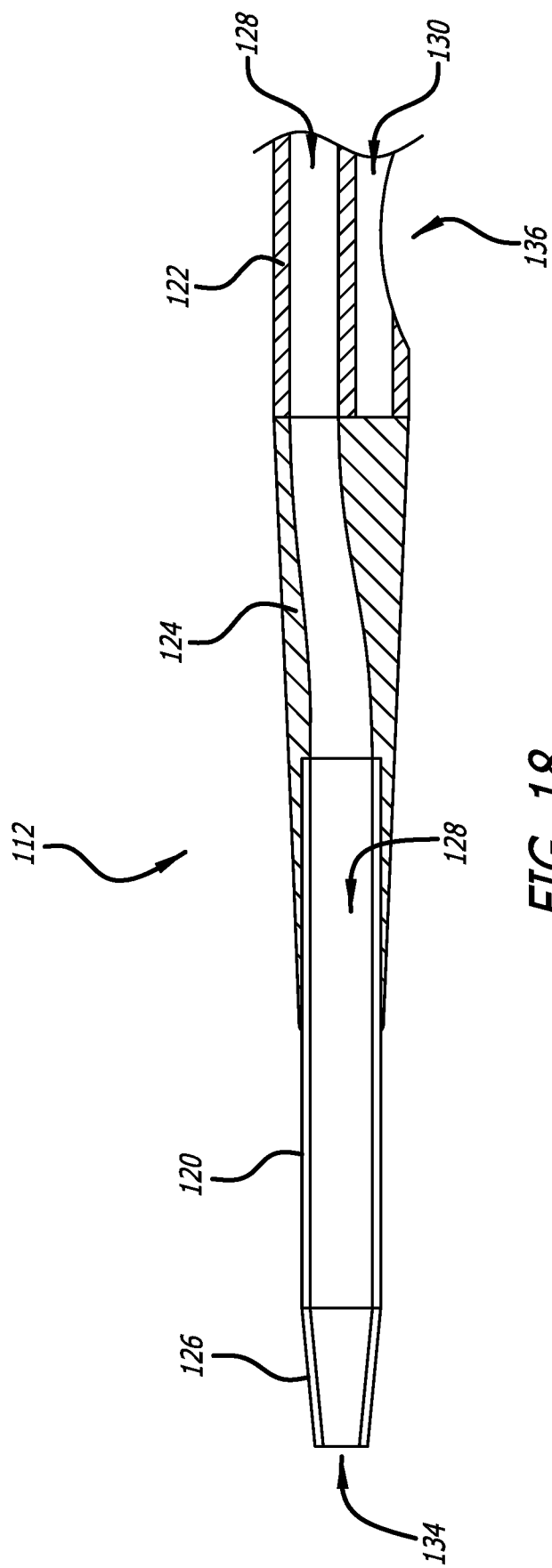


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/044918

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M25/06 ADD.		
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		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2021/085927 A1 (HOWELL GLADE H [US]) 25 March 2021 (2021-03-25) paragraphs [0004], [0006], [0008], [0021] - [0025], [0032] - [0033], [0036], [0042]; figures 1-4 -----	1-28
A	US 5 380 290 A (MAKOWER JOSHUA [US] ET AL) 10 January 1995 (1995-01-10) column 3, line 51 - line 64; figures 1-2, 9 column 5, line 11 - line 14 column 6, line 40 - column 7, line 24 -----	1-28
A	EP 3 473 291 A1 (BARD INC C R [US]) 24 April 2019 (2019-04-24) paragraphs [0002] - [0004], [0043], [0062]; figures 17A-17C ----- -/--	1-28
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 14 February 2023		Date of mailing of the international search report 21/02/2023
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Berndorfer, Urs

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/044918

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.: **29–35**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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 fees, this Authority did not invite payment of additional fees.
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

International application No

PCT/US2022/044918

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/187147 A1 (KURTH PAUL A [US] ET AL) 23 July 2009 (2009-07-23) paragraphs [0016] - [0016], [0053]; figures 3-4 -----	1-28

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2022/044918

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 29-35

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery: Claim 29: "... establishing a needle tract from an area of skin to the blood-vessel lumen with the introducer needle; advancing the distal end of the access guidewire from its initial location in the needle shaft just proximal of a needle tip of the needle shaft into the blood-vessel lumen; ... and advancing a catheter tube of the RICC over the access guidewire for inserting the RICC into the blood-vessel lumen"). This claim implies the use (e.g. catheter introduction) of such a device within the body. The claimed method therefore clearly impacts the result of the described treatment carried out by a physician.