

RAPIDLY INSERTABLE CENTRAL CATHETER INSERTION ASSEMBLIES AND METHODS

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 63/229,862, filed August 5, 2021, 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 rapidly insertable central catheter (“RICC”) insertion assemblies and methods that address the foregoing.

SUMMARY

[0004] Disclosed herein is a RICC insertion assembly including, in some embodiments, a RICC, an access guidewire disposed in the RICC, an introducer needle, and a coupler coupling the RICC and the introducer needle together. The introducer needle includes a needle shaft and a sheath over the needle shaft. The needle shaft includes a longitudinal needle slot extending from a proximal portion of the needle shaft through a distal needle tip. The sheath seals the needle slot thereunder except for a portion of the needle slot under a sheath opening in a proximal portion of the sheath. The coupler includes a coupler housing and a valve module disposed in the coupler housing. The valve module seals the proximal portions of the needle shaft and the sheath therein. The access guidewire includes a proximal end coupled to a swivel arm of the coupler and a distal end disposed in the introducer needle. The proximal and distal

ends of the access guidewire enforce a loop in the access guidewire. The RICC is disposed over the loop of the access guidewire in a ready-to-deploy state of the RICC insertion assembly.

[0005] In some embodiments, the RICC insertion assembly further includes a syringe fluidly coupled to the introducer needle in the ready-to-deploy state of the RICC insertion assembly. The sheath seals the needle slot of the needle shaft thereunder outside of the valve module. The valve module seals the sheath opening of the sheath therein. In addition, the valve module seals around the access guidewire enabling the syringe to aspirate blood.

[0006] 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 as the introducer needle is withdrawn from the coupler. Cutting the sheath off the needle shaft allows the access guidewire to escape from the needle shaft by way of the needle slot thereof.

[0007] In some embodiments, the coupler housing includes a longitudinal coupler-housing slot configured to allow the access guidewire to escape from the coupler housing when the introducer needle is withdrawn from the coupler.

[0008] In some embodiments, the valve module includes separable pieces around the needle shaft and the sheath. The separable pieces are configured to separate and allow the access guidewire to escape from the valve module when the introducer needle is withdrawn from the coupler.

[0009] Also disclosed herein is a RICC insertion assembly including, in some embodiments, a RICC, an access guidewire disposed in the RICC, an introducer needle, and a coupler coupling the RICC and the introducer needle together in a ready-to-deploy state of the RICC insertion assembly. The RICC includes a catheter tube, a catheter hub, one or more extension legs, and one or more extension-leg connectors. The catheter hub is coupled to a proximal portion of the catheter tube. Each extension leg of the one-or-more extension legs is coupled to the catheter hub by a distal portion thereof. Each extension-leg connector of the one-or-more extension-leg connectors is over a proximal portion of an extension leg of the one-or-more extension legs. The introducer needle includes a needle shaft, a sheath over the needle shaft, and a needle hub over a proximal portion of the needle shaft and a proximal portion of the sheath. The needle shaft includes a longitudinal needle slot extending from the proximal portion of the needle shaft through a needle tip in a distal portion of the needle shaft. The sheath

includes a sheath opening in the proximal portion of the sheath. The coupler includes a coupler housing, a valve module disposed in the coupler housing, and a swivel arm swivelably coupled to the coupler housing. The coupler housing includes a needle-hub receptacle with the needle hub inserted into the needle-hub receptacle. The needle shaft and the sheath extend from the needle hub, through the valve module, and out a distal end of the coupler housing. The swivel arm includes a swivel-arm connector connected to an extension-leg connector of the one-or-more extension-leg connectors. The access guidewire includes a proximal portion including a proximal end and a distal portion including a distal end. The proximal end of the access guidewire is coupled to the swivel-arm connector. The proximal portion of the access guidewire extends along a primary lumen of the RICC. The distal portion of the access guidewire extends along the primary lumen of the RICC, out a distal end of the RICC, into the valve module over the needle hub, into the needle shaft through both the sheath opening and the needle slot, and along a needle lumen of the introducer needle. The distal end of the access guidewire is disposed in the needle lumen just proximal of the needle tip.

[0010] In some embodiments, the RICC insertion assembly further includes a syringe fluidly coupled to the introducer needle in the ready-to-deploy state of the RICC insertion assembly. The sheath seals the needle slot of the needle shaft thereunder outside of the valve module. The valve module seals the sheath opening of the sheath therein. And the valve module seals around the access guidewire enabling the syringe to aspirate blood.

[0011] In some embodiments, the proximal end of the access guidewire is coupled to the swivel-arm connector and the distal end of the access guidewire is disposed in the needle lumen, thereby enforcing a loop in the access guidewire. The RICC is disposed over the loop of the access guidewire in the ready-to-deploy state of the RICC insertion assembly.

[0012] In some embodiments, the swivel arm is configured to flip the loop between a sinistral side of the RICC insertion assembly and a dextral side of the RICC insertion assembly to accommodate both left-handed and right-handed venipunctures with the RICC insertion assembly.

[0013] In some embodiments, the coupler includes a needle-hub lock configured to lock the needle hub in the needle-hub receptacle. A pair of lock buttons of the needle-hub lock is distributed between opposing sides of the coupler. The lock buttons are configured to unlock

the needle hub when the lock buttons are pressed into the coupler for withdrawal of the introducer needle from the coupler.

[0014] 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 as the introducer needle is withdrawn from the coupler. Cutting the sheath off the needle shaft allows the access guidewire to escape from the needle shaft by way of the needle slot thereof.

[0015] In some embodiments, the coupler housing includes a longitudinal coupler-housing slot configured to allow the access guidewire to escape from the coupler housing when the introducer needle is withdrawn from the coupler.

[0016] In some embodiments, the valve module includes separable pieces around the needle shaft and the sheath. The separable pieces are configured to separate and allow the access guidewire to escape from the valve module when the introducer needle is withdrawn from the coupler.

[0017] In some embodiments, the catheter tube includes a first section in a distal portion of the catheter tube, a second section in the distal portion of the catheter tube proximal of the first section of the catheter tube, and a tapered junction between the first and second sections of the catheter tube. The first section is formed of a first polymeric material having a first durometer. The second section is formed of a second polymeric material having a second durometer less than the first durometer. The junction has a length between that of exposed portions of the first and second sections of the catheter tube.

[0018] In some embodiments, a proximal portion of the first section of the catheter tube is disposed in a bore in a distal portion of the junction and bonded thereto.

[0019] In some embodiments, a distal end of the second section of the catheter tube is flush with a proximal end of the junction and bonded thereto.

[0020] In some embodiments, the catheter tube possess a column strength sufficient to prevent buckling of the catheter tube when inserted into a needle tract established by a percutaneous puncture with the introducer needle. The column strength is also sufficient to prevent buckling of the catheter tube 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.

[0021] In some embodiments, the RICC includes a set of three lumens including the primary lumen, a secondary lumen, and a tertiary lumen formed of fluidly connected portions of three catheter-tube lumens, three catheter-hub lumens, and three extension-leg lumens.

[0022] In some embodiments, the primary lumen has a primary-lumen aperture in a distal end of the catheter tube, the secondary lumen has a secondary-lumen aperture in a side of the distal portion of catheter tube, and the tertiary lumen has a tertiary-lumen aperture in the side of the distal portion of the catheter tube proximal of the secondary-lumen aperture.

[0023] Also disclosed herein is a method for inserting a RICC into a blood-vessel lumen of a patient. The method includes, in some embodiments, insertion assembly-obtaining step, a needle tract-establishing step, an access guidewire-advancing step, an introducer needle-withdrawing step, and a RICC-advancing step. The 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 a swivel arm of the coupler while 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 as a result. The RICC is disposed over the loop of the access guidewire in 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 introducer needle-withdrawing step includes withdrawing the introducer needle 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, which allows the access guidewire to escape from the introducer needle with the introducer needle-withdrawing step. The RICC-advancing step includes advancing a catheter tube of the RICC over the access guidewire and into the blood-vessel lumen, thereby inserting the RICC into the blood-vessel lumen.

[0024] In some embodiments, the needle tract-establishing step includes flipping the swivel arm and, thus, the loop between a sinistral side of the RICC insertion assembly for a left-handed venipuncture and a dextral side of the RICC insertion assembly for a right-handed venipuncture with the RICC insertion assembly.

[0025] In some embodiments, the needle tract-establishing step includes ensuring blood flashes back into a needle hub of the introducer needle, a syringe tip of a syringe fluidly connected to the introducer needle, a barrel of the syringe, or a combination thereof. Ensuring the blood flashes back in accordance with the foregoing confirms the needle tract extends into the blood-vessel lumen.

[0026] In some embodiments, the needle tract-establishing step includes drawing a slight vacuum with the syringe while establishing the needle tract such that the blood flashes back into at least the needle hub of the introducer needle upon establishing the needle tract.

[0027] In some embodiments, the method further includes a blood-aspirating step. The blood-aspirating step includes aspirating blood with the syringe for confirmation the needle tract extends into the blood-vessel lumen before withdrawing the introducer needle from the coupler in the introducer needle-withdrawing step. The sheath over the needle shaft seals the needle slot thereunder for the blood-aspirating step.

[0028] In some embodiments, the valve module is sealed around a distal portion of the access guidewire as well as a sheath opening of the sheath. The sheath opening allows the access guidewire to pass into the needle shaft by way of the needle slot in the ready-to-deploy state of the RICC insertion assembly.

[0029] In some embodiments, the introducer needle-withdrawing step includes simultaneously cutting the sheath off the needle shaft with an integrated blade of the valve module while the introducer needle is withdrawn from the coupler. 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.

[0030] In some embodiments, separable pieces of the valve module around the needle shaft and the sheath in the ready-to-deploy state of the RICC insertion assembly separate to allow the access guidewire to escape from the valve module when the introducer needle is withdrawn from the coupler in the introducer needle-withdrawing step.

[0031] In some embodiments, the coupler housing includes a longitudinal coupler-housing slot allowing the access guidewire to escape from the coupler housing when the introducer needle is withdrawn from the coupler in the introducer needle-withdrawing step.

[0032] In some embodiments, the method further includes an access guidewire-withdrawing step. The access guidewire-withdrawing step includes withdrawing the access guidewire leaving the catheter tube in place in the blood-vessel lumen.

[0033] In some embodiments, the method further includes a maneuver guidewire-advancing step, another RICC-advancing step, and a maneuver guidewire-withdrawing step. The maneuver guidewire-advancing step includes advancing a maneuver guidewire into the blood-vessel lumen by way of a primary lumen of the RICC. The other RICC-advancing step includes advancing a distal portion of the catheter tube farther into the blood-vessel lumen over the maneuver guidewire to a lower $\frac{1}{3}$ of a superior vena cava ("SVC") of a heart of the patient. The maneuver guidewire-withdrawing step includes withdrawing the maneuver guidewire leaving the catheter tube in place in the lower $\frac{1}{3}$ of the SVC.

[0034] 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

[0035] FIG. 1 illustrates a top view of a RICC insertion assembly in accordance with some embodiments.

[0036] FIG. 2 illustrates a perspective view of the RICC insertion assembly in accordance with some embodiments.

[0037] FIG. 3 illustrates a bottom view of the RICC insertion assembly in accordance with some embodiments.

[0038] FIG. 4 illustrates a cutaway view of a coupler of the RICC insertion assembly in accordance with some embodiments.

[0039] FIG. 5 illustrates another cutaway view of the coupler in accordance with some embodiments.

[0040] FIG. 6 illustrates yet another cutaway view of the coupler in accordance with some embodiments.

[0041] FIG. 7 illustrates a longitudinal cross section of the coupler and an introducer needle of the RICC insertion assembly in accordance with some embodiments.

[0042] FIG. 8 illustrates a longitudinal cross section of the coupler, the introducer needle, and an access guidewire of the RICC insertion assembly in accordance with some embodiments.

[0043] FIG. 9 illustrates a top view of the introducer needle in accordance with some embodiments.

[0044] FIG. 10 illustrates a sheath of the introducer needle in accordance with some embodiments.

[0045] FIG. 11 illustrates a needle shaft of the introducer needle in accordance with some embodiments.

[0046] FIG. 12 illustrates a RICC of the RICC insertion assembly in accordance with some embodiments.

[0047] FIG. 13 illustrates a detailed view of a distal portion of a catheter tube of the RICC in accordance with some embodiments.

[0048] FIG. 14 illustrates a transverse cross section of the distal portion of the catheter tube in accordance with some embodiments.

[0049] FIG. 15 illustrates another transverse cross section of the distal portion of the catheter tube in accordance with some embodiments.

[0050] FIG. 16 illustrates a longitudinal cross section of the distal portion of the catheter tube in accordance with some embodiments.

[0051] FIG. 17 illustrates a needle tract-establishing step of a method of using the RICC insertion assembly in accordance with some embodiments.

[0052] FIG. 18 illustrates a blood-aspirating step of the method in accordance with some embodiments.

[0053] FIG. 19 illustrates an access guidewire-advancing step of the method in accordance with some embodiments.

[0054] FIG. 20 illustrates an introducer needle-withdrawing step of the method in accordance with some embodiments.

[0055] FIG. 21 illustrates a RICC-advancing step of the method in accordance with some embodiments.

DESCRIPTION

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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.

[0062] Disclosed herein are RICC insertion assemblies and methods that address the foregoing need. For example, a RICC insertion assembly can include a RICC, an access guidewire, an introducer needle, and a coupler coupling the foregoing components together. The introducer needle can include a needle shaft and a sheath. The needle shaft can include a

longitudinal needle slot. The sheath can seal the needle slot thereunder except for a sheath opening thereto in a proximal portion of the sheath. The coupler can include a coupler housing and a valve module disposed in the coupler housing. The valve module can seal the needle shaft and the sheath therein. The access guidewire can include a proximal end coupled to the coupler and a distal end disposed in the needle shaft, thereby enforcing a loop in the access guidewire. The RICC can be disposed over the loop in a ready-to-deploy state of the RICC insertion assembly.

[0063] The foregoing features as well as other features of the RICC insertion assemblies and methods 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 the RICC insertion assemblies and methods in greater detail. However, it should be understood the RICCs of the RICC insertion assemblies are but one type of catheter that can be incorporated into catheter insertion assemblies like those provided herein. Indeed, peripherally inserted central catheters (“PICCs”), dialysis catheters, or the like can also be incorporated into catheter insertion assemblies and methods.

RICC insertion assemblies

[0064] FIGS. 1-3 illustrate various views of a RICC insertion assembly 100 in accordance with some embodiments.

[0065] 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 a ready-to-deploy state of the RICC insertion assembly 100. Notably, the proximal end of the access guidewire 106 is coupled to the coupler 108 and the distal end of the access guidewire 106 is disposed in the needle lumen 158 of the introducer needle 104 as set forth below. This enforces a loop in the access guidewire 106, which loop the RICC 102 is disposed over in the ready-to-deploy state of the RICC insertion assembly 100 keeping the RICC insertion assembly 100 in a relatively compact form.

[0066] The RICC insertion assembly 100 can further include a syringe 110 fluidly coupled to the introducer needle 104 in the ready-to-deploy state of the RICC insertion assembly 100. As set forth below, the sheath 142 seals the needle slot 148 of the needle shaft 140. In particular, the sheath 142 seals the needle slot 148 outside of the valve module 180. The valve module 180, in turn, seals over the sheath opening 162 of the sheath 142 that opens

to the needle slot 148. The valve module 180 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.

[0067] FIG. 12 illustrates the RICC 102 of the RICC insertion assembly 100 in accordance with some embodiments.

[0068] 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.

[0069] FIGS. 13-16 illustrate various views of the catheter tube 112 of the RICC 102 in accordance with some embodiments.

[0070] 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.

[0071] 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. 16, 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.

[0072] 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.

[0073] 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.

[0074] 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.

[0075] 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.

[0076] 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.

[0077] 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. 14 and 16.

[0078] 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.

[0079] 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.

[0080] 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 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 swivel-arm connector 194 of the swivel arm 182 of the coupler 108 to enforce the loop in the access guidewire 106 and the RICC 102 thereover.

[0081] 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.

[0082] FIGS. 7-11 illustrate various views of the introducer needle 104 of the RICC insertion assembly 100 in accordance with some embodiments.

[0083] As shown, the introducer needle 104 includes a needle shaft 140, a sheath 142 over the needle shaft 140, and a needle hub 144 over both a proximal portion of the needle shaft 140 and a proximal portion of the sheath 142. In at least the ready-to-deploy state of the

RICC insertion assembly 100, the needle shaft 140 and the sheath 142 extend from the needle hub 144, through the valve module 180, and out a distal end of the coupler housing 178.

[0084] The needle shaft 140 includes a needle tip 146 in a distal portion of the needle shaft 140 and a longitudinal needle slot 148 extending from the proximal portion of the needle shaft 140 through the needle tip 146.

[0085] The needle tip 146 includes a bevel having a tip bevel 152 and a primary bevel 154 proximal of the tip bevel 152. A tip-bevel angle of the tip bevel 152 is greater than a primary-bevel angle of the primary bevel 154 such that the bevel provides a smooth transition over the needle tip 146. 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.

[0086] The needle slot 148 extends from the proximal portion of the needle shaft 140 through the needle tip 146, thereby forming a needle channel 156 along a majority of a length of the needle shaft 140 as opposed to a needle lumen therethrough. The needle slot 148 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 140 through the needle tip 146 when the introducer needle-withdrawing step of the method set forth below is performed.

[0087] While the needle shaft 140 includes the foregoing needle slot 148, it should be understood the introducer needle 104 includes a needle lumen 158; however, the needle lumen 158 results from the combination of the needle shaft 140 and the sheath 142 over the needle shaft 140. Indeed, the sheath 142 over the needle shaft 140 seals the needle slot 148 thereunder forming the needle lumen 158 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.

[0088] The sheath 142 includes a sheath tip 160 in a distal portion of the sheath 142 and a sheath opening 162 in a side of the proximal portion of the sheath 142.

[0089] The sheath tip 160 includes a relatively short taper from an outer diameter of the distal portion of the sheath 142 to an outer diameter of a distal end of the sheath 142, the latter of which is commensurate with an outer diameter of the distal portion of the needle shaft 140. The taper has a taper angle less than the primary-bevel angle of the primary bevel 154 of

the needle tip 146, which, in turn, is less than the tip-bevel angle of the tip bevel 152 of the needle tip 146. The sheath tip 160 including such a taper is configured to provide a smooth transition from the needle tip 146 to the sheath body for the needle tract-establishing step of the method set forth below.

[0090] The sheath opening 162 opens to the needle slot 148 of the needle shaft 140 allowing the access guidewire 106 to pass through the sheath opening 162 and into the needle slot 148 in the ready-to-deploy state of the RICC insertion assembly 100. Thus, the sheath opening 162 has a width approximately commensurate with a width of the needle slot 148, which, in turn, is sized in accordance with the diameter of the access guidewire 106. The sheath opening 162 also has a length sufficient to allow the access guidewire 106 to pass through the sheath opening 162 and into the needle slot 148 while also accommodating the blade 192 of the valve module 180 under a distal end of the sheath opening 162. Notably, the sheath 142 over the needle shaft 140 seals the needle slot 148 thereunder except for that under the sheath opening 162. However, the valve module 180 seals over the needle slot 148 exposed by the sheath opening 162 by sealing the proximal portions of the needle shaft 140 and the sheath 142 therein, thereby enabling the syringe 110 to aspirate blood in accordance with the blood-aspirating step of the method set forth below.

[0091] The sheath 142, 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 142 sufficient to withstand collapse of the sheath 142 into the needle slot 148 of the needle shaft 140 when the blood-aspirating step of the method set forth below is performed, notably, while also facilitating the cutting of the sheath 142 off the needle shaft 140 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.

[0092] The needle hub 144 includes an access-guidewire channel 164 in a distal portion of the needle hub 144 and a needle-hub connector 166 in a proximal portion of the needle hub 144.

[0093] The access-guidewire channel 164 of the needle hub 144 is configured to allow the access guidewire 106 to pass over the needle hub 144 and direct the access guidewire 106 into the access-guidewire conduit 190 of the valve module 180. The access-guidewire channel 164 is open such that the access guidewire 106 lies in the access-guidewire channel 164 in at least the ready-to-deploy state of the RICC insertion assembly 100. Advantageously, the open access-guidewire channel 164 allows the access guidewire 106 to remain in place when the introducer needle 104 is withdrawn from the RICC insertion assembly 100 in accordance with the introducer needle-withdrawing step of the method set forth below.

[0094] The needle-hub connector 166 includes a needle-hub bore 168 and an optional needle-hub flange 170 about the needle-hub connector 166.

[0095] The needle-hub bore 168 of the needle-hub connector 166 is configured to accept a syringe tip 172 of the syringe 110 therein for fluidly connecting the introducer needle 104 to the syringe 110. Indeed, the needle-hub bore 168 can have a Luer taper (e.g., a 6% taper) configured to accept the syringe tip 172 therein, which syringe tip 172 can be complementarily configured with a Luer taper.

[0096] The needle-hub flange 170 of the needle-hub connector 166 is configured to screw together with internal threads 174 of a threaded collar 176 around the syringe tip 172 of the syringe 110. While the threaded collar 176 of the syringe 110 is optional, the needle-hub flange 170 advantageously provides a so-called Luer lock-style connection with the internal threads 174 of the threaded collar 176 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.

[0097] FIGS. 4-8 illustrate various view of the coupler 108 of the RICC insertion assembly 100 in accordance with some embodiments.

[0098] As shown, the coupler 108 includes a coupler housing 178, a valve module 180 disposed in the coupler housing 178, and a swivel arm 182 swivelably coupled to the coupler housing 178.

[0099] The coupler housing 178 includes two molded halves coupled together to form an ovoid body configured to be comfortably held underhand (e.g., cradled) or overhand 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. To further facilitate such venipunctures, an outside of each half of the two molded halves can be textured as shown with grip-enhancing arcuate ridges 184 or the like. An inside of each half of the two molded halves includes depressions that form a valve-module compartment and a needle-hub receptacle when the two molded halves are coupled together as shown. (See FIGS. 4-8, which include the valve module 180 disposed in a depression of a molded half of the two molded halves that form the valve-module compartment. FIGS. 4-8 also include the needle hub 144 of the introducer needle 104 disposed in a depression of the molded half of the two molded halves that form the needle-hub receptacle.) In addition, each half of the two molded halves includes a lock-button through hole for a corresponding lock button of the pair of lock buttons 188 of the needle-hub lock. (See FIG. 3 for the lock buttons 188 extending through the corresponding pair of lock-button through holes.) Notably, the coupler housing 178 includes a longitudinal coupler-housing slot 186 formed between the two molded halves. The couple-housing slot is configured to allow the access guidewire 106 to escape from the coupler housing 178 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0100] The valve-module compartment is configured to hold the valve module 180 therein. Indeed, the valve-module compartment includes the valve module 180 disposed therein in the ready-to-deploy state of the RICC insertion assembly 100. Notably, the valve-module compartment is further configured with sufficient space to allow the separable pieces of the valve module 180 set forth below to separate for the escape of the access guidewire 106 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0101] The needle-hub receptacle is configured to hold the needle hub 144 of the introducer needle 104 therein. Indeed, the needle-hub receptacle includes the needle hub 144 inserted therein in the ready-to-deploy state of the RICC insertion assembly 100. Notably, a needle-hub lock configured to lock the needle hub 144 in the needle-hub receptacle is positioned about the needle-hub receptacle. A pair of lock buttons 188 (e.g., spring-loaded lock buttons) of the needle-hub lock is distributed between opposing sides of the coupler 108, particularly in the lock-button through holes of the two molded halves of the coupler housing 178 such that each lock button of the lock buttons 188 extends through the coupler housing 178 on its respective side of the coupler 108. The lock buttons 188 are configured to unlock the needle hub 144 when the lock buttons 188 are pressed into the coupler 108 for withdrawal of

the introducer needle 104 from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0102] The valve module 180 includes an access-guidewire conduit 190, an integrated blade 192, and a number of separable pieces.

[0103] The access-guidewire conduit 190 is configured to direct the access guidewire 106 from the access-guidewire channel 164 of the needle hub 144 into both the sheath opening 162 of the sheath 142 and the needle slot 148 of the needle shaft 140 thereunder. Indeed, the access-guidewire conduit 190 includes the access guidewire 106 disposed therein in the ready-to-deploy state of the RICC insertion assembly 100. Notably, the valve module 180 seals around the access guidewire 106 in the access-guidewire conduit 190 such that the syringe 110 is able to aspirate blood in accordance with the blood-aspirating step of the method set forth below.

[0104] The blade 192 extends from an attachment point in the valve module 180 into the needle slot 148 of the needle shaft 140 such that the blade 192 is disposed in the needle slot 148 under the distal end of the sheath opening 162 of the sheath 142. The blade 192 includes a distal facing blade edge configured to cut the sheath 142 off the needle shaft 140 as the introducer needle 104 is withdrawn in a proximal direction from the coupler 108 in the introducer needle-withdrawing step of the method set forth below. Cutting the sheath 142 off the needle shaft 140 allows the access guidewire 106 to escape from the needle shaft 140 by way of the needle slot 148.

[0105] The separable pieces of the valve module 180 are disposed around the needle shaft 140 and the sheath 142 in the ready-to-deploy state of the RICC insertion assembly 100. For example, the separable pieces of the valve module 180 can be separable halves of the valve module 180 disposed around the needle shaft 140 and the sheath 142. The separable pieces of the valve module 180 are configured to separate and allow the access guidewire 106 to escape from the valve module 180 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step of the method set forth below.

[0106] The swivel arm 182 includes a swivel-arm connector 194 connected to an extension-leg connector of the one-or-more extension-leg connectors 118 in the ready-to-deploy state of the RICC insertion assembly 100. While not shown, the swivel-arm connector 194 includes an access-guidewire attachment point within the swivel-arm connector 194 to

which the proximal end of the access guidewire 106 is attached in the ready-to-deploy state of the RICC insertion assembly 100. In combination with the distal end of the access guidewire 106 being disposed in the needle lumen 158 of the introducer needle 104, the loop in the access guidewire 106 set forth above is enforced. Advantageously, the swivel arm 182 is configured to flip the loop—or at least the one-or-more extension legs 116 of the RICC 102 thereof—between a sinistral side of the RICC insertion assembly 100 and a dextral side of the RICC insertion assembly 100 to accommodate both left-handed and right-handed venipunctures with the RICC insertion assembly 100. Indeed, the swivel arm 182 is configured to flip the loop from the sinistral side of the RICC insertion assembly 100 as shown in FIG. 1 to the dextral side of the RICC insertion assembly 100 to accommodate a left-handed venipuncture with the RICC insertion assembly 100. Likewise, the swivel arm 182 is configured to flip the loop from the dextral side of the RICC insertion assembly 100 to the sinistral side of the RICC insertion assembly 100 to accommodate a right-handed venipuncture with the RICC insertion assembly 100.

[0107] FIGS. 1, 2, and 8 illustrate various view of the access guidewire 106 of the RICC insertion assembly 100 in accordance with some embodiments.

[0108] The access guidewire 106 includes a proximal portion including a proximal end and a distal portion including a distal end. In the ready-to-deploy state of the RICC insertion assembly 100, the proximal end of the access guidewire 106 is coupled to the swivel arm 182, particularly the access-guidewire attachment point within the swivel-arm connector 194 of the swivel arm 182. In addition, the proximal portion of the access guidewire 106 extends 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 180 over the needle hub 144 by way of the access-guidewire channel 164, into the needle shaft 140 through both the sheath opening 162 of the sheath 142 and the needle slot 148 of the needle shaft 140, and along the needle lumen 158 of the introducer needle 104 in the ready-to-deploy state of the RICC insertion assembly 100. As shown in FIG. 8, the distal end of the access guidewire 106 is disposed in the needle lumen 158 just proximal of the needle tip 146 in 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 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.

[0109] The access guidewire 106 can include a guidewire tip 196 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 the ready-to-deploy state of the RICC insertion assembly 100 and a curved state when the guidewire tip 196 is advanced beyond the needle tip 146 (e.g., advanced into a blood-vessel lumen) in a deployed state of the RICC insertion assembly 100.

[0110] The access guidewire 106 can further include a bare-wire portion and a wound-wire portion distal of the bare-wire portion, proximal of the bare-wire portion, or both. While not shown, the bare-wire portion, when present, distally extends through the access-guidewire conduit 190 of the valve module 180 in at least the ready-to-deploy state of the RICC insertion assembly 100 such that the valve module 180 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

[0111] FIGS. 17-21 illustrate various steps a method of using the RICC insertion assembly 100 in accordance with some embodiments.

[0112] As shown, methods of the RICC insertion assembly 100 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 an insertion assembly-obtaining step, a needle tract-establishing step, a blood-aspirating step, an access guidewire-advancing step, an introducer needle-withdrawing step, a RICC-advancing step, an access guidewire-withdrawing step, a maneuver guidewire-advancing step, another RICC-advancing step, and a maneuver guidewire-withdrawing step.

[0113] 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 142 over the needle shaft 140, and the access guidewire 106 coupled together by the coupler 108. The proximal end of the access guidewire

106 is coupled to the swivel arm 182 of the coupler 108 while the distal end of the access guidewire 106 is disposed in the introducer needle 104 by way of the valve module 180 of the coupler 108. Again, the proximal and distal ends of the access guidewire 106 enforce a loop in the access guidewire 106 as a result. The RICC 102 is disposed over the loop of the access guidewire 106 in the ready-to-deploy state of the RICC insertion assembly 100.

[0114] FIG. 17 illustrates a needle tract-establishing step of the method in accordance with some embodiments.

[0115] 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. Such a needle tract-establishing step can include flipping the swivel arm 182, and, thus, the loop between two sides of the RICC insertion assembly 100 before puncturing the area of skin with the introducer needle 104. The needle tract-establishing step can also include ensuring blood flashback while establishing the needle tract.

[0116] Flipping the swivel arm 182 and, thus, the loop between the two sides of the RICC insertion assembly 100 include flipping the loop between a sinistral side of the RICC insertion assembly 100 for a left-handed venipuncture and a dextral side of the RICC insertion assembly 100 for a right-handed venipuncture with the RICC insertion assembly 100. Indeed, flipping the loop from the sinistral side of the RICC insertion assembly 100 to the dextral side of the RICC insertion assembly 100 accommodates a left-handed venipuncture with the RICC insertion assembly 100. Likewise, flipping the loop from the dextral side of the RICC insertion assembly 100 to the sinistral side of the RICC insertion assembly 100 accommodates a right-handed venipuncture with the RICC insertion assembly 100.

[0117] Ensuring blood flashback while establishing the needle tract includes ensuring blood flashes back into the needle hub 144 of the introducer needle 104, the syringe tip 172 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 144 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.

[0118] FIG. 18 illustrates a blood-aspirating step of the method in accordance with some embodiments.

[0119] The blood-aspirating step includes aspirating blood with the syringe 110 for confirmation the needle tract extends into the blood-vessel lumen before withdrawing the introducer needle 104 from the coupler 108 in the introducer needle-withdrawing step. Again, the sheath 142 over the needle shaft 140 seals the needle slot 148 of the needle shaft 140 thereunder. In particular, the sheath 142 seals the needle slot 148 outside of the valve module 180. The valve module 180, in turn, seals over the sheath opening 162 of the sheath 142, which sheath opening 162 allows the access guidewire 106 to pass into the needle shaft 140 by way of the needle slot 148 in the ready-to-deploy state of the RICC insertion assembly 100. The valve module 180 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.

[0120] FIG. 19 illustrates an access guidewire-advancing step of the method in accordance with some embodiments.

[0121] The access guidewire-advancing step includes advancing the distal end of the access guidewire 106 from its initial location in the needle shaft 140 just proximal of the needle tip 146 into the blood-vessel lumen, thereby securing blood-vessel access for the RICC 102 in the RICC-advancing step.

[0122] FIG. 20 illustrates an introducer needle-withdrawing step of the method in accordance with some embodiments.

[0123] The introducer needle-withdrawing step includes withdrawing the introducer needle 104 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 142 off the needle shaft 140 with the blade 192 of the valve module 180 when the introducer needle 104 is withdrawn from the coupler 108. The cutting of the sheath 142 off the needle shaft 140 allows the access guidewire 106 to escape from the needle shaft 140 by way of the needle slot 148 thereof. Again, the introducer needle 104 includes the needle slot 148 extending from the proximal portion of the needle shaft 140 through the needle tip 146, which allows the access guidewire 106 to escape from the introducer needle 104 with the cutting of the sheath 142 off the needle shaft 140. Notably, the separable pieces of the valve module 180 around the needle shaft 140 and the sheath 142 in the ready-to-deploy state of the RICC insertion assembly 100 separate to allow the access guidewire 106 to further escape from the valve module 180 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-

withdrawing step. In addition, the coupler housing 178 includes the coupler-housing slot 186 configured to allow the access guidewire 106 to yet further escape from the coupler housing 178 when the introducer needle 104 is withdrawn from the coupler 108 in the introducer needle-withdrawing step. (See, for example, FIG. 21, wherein the distal portion of the access guidewire 106 has completely escaped from the coupler 108 and the proximal end of the access guidewire 106 remains attached to the access-guidewire attachment point within the swivel-arm connector 194.)

[0124] FIG. 21 illustrates a RICC-advancing step of the method in accordance with some embodiments.

[0125] 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.

[0126] The access guidewire-withdrawing step includes withdrawing the access guidewire 106 leaving the catheter tube 112 in place in the blood-vessel lumen.

[0127] 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.

[0128] 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.

[0129] 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.

[0130] 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; and
 - a sheath over the needle shaft sealing the needle slot thereunder except for a portion of the needle slot under a sheath opening in a proximal portion of the sheath;
 - a coupler coupling the RICC and the introducer needle together, the coupler including:
 - a coupler housing; and
 - a valve module disposed in the coupler housing sealing the proximal portions of the needle shaft and the sheath therein; and
 - an access guidewire including:
 - a proximal end coupled to a swivel arm of the coupler; and
 - a distal end disposed in the introducer needle, the proximal and distal ends of the access guidewire enforcing a loop in the access guidewire over which the RICC is disposed in a ready-to-deploy state of the RICC insertion assembly.
2. The RICC insertion assembly of claim 1, further comprising a syringe fluidly coupled to the introducer needle in the ready-to-deploy state of the RICC insertion assembly, the sheath sealing the needle slot of the needle shaft thereunder outside of the valve module, the valve module sealing the sheath opening of the sheath therein, and the valve module sealing around the access guidewire enabling the syringe to aspirate blood.
3. The RICC insertion assembly of either claim 1 or 2, 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 as the introducer needle is withdrawn from the coupler, thereby allowing the access guidewire to escape from the needle shaft by way of the needle slot thereof.

4. The RICC insertion assembly of any claim of claims 1-3, wherein the coupler housing includes a longitudinal coupler-housing slot configured to allow the access guidewire to escape from the coupler housing when the introducer needle is withdrawn from the coupler.

5. The RICC insertion assembly of any claim of claims 1-4, wherein the valve module includes separable pieces around the needle shaft and the sheath configured to separate and allow the access guidewire to escape from the valve module when the introducer needle is withdrawn from the coupler.

6. A rapidly insertable central catheter ("RICC") insertion assembly, comprising:
- a RICC including:
 - a catheter tube;
 - a catheter hub coupled to a proximal portion of the catheter tube;
 - one or more extension legs, each extension leg of the one-or-more extension legs coupled to the catheter hub by a distal portion thereof; and
 - one or more extension-leg connectors, each extension-leg connector of the one-or-more extension-leg connectors over a proximal portion of an extension leg of the one-or-more extension legs;
 - an introducer needle including:
 - a needle shaft including a longitudinal needle slot extending from a proximal portion of the needle shaft through a needle tip in a distal portion of the needle shaft;
 - a sheath over the needle shaft, the sheath including a sheath opening in a proximal portion of the sheath; and
 - a needle hub over the proximal portion of the needle shaft and the proximal portion of the sheath;
 - a coupler coupling the RICC and the introducer needle together in a ready-to-deploy state of the RICC insertion assembly, the coupler including:
 - a coupler housing including a needle-hub receptacle, the needle hub inserted into the needle-hub receptacle;
 - a valve module disposed in the coupler housing, the needle shaft and the sheath extending from the needle hub, through the valve module, and out a distal end of the coupler housing; and

a swivel arm swivelably coupled to the coupler housing, the swivel arm including a swivel-arm connector connected to an extension-leg connector of the one-or-more extension-leg connectors; and
an access guidewire including:
a proximal end coupled to the swivel-arm connector;
a proximal portion extending along a primary lumen of the RICC;
a distal portion extending along the primary lumen of the RICC, out a distal end of the RICC, into the valve module over the needle hub, into the needle shaft through both the sheath opening and the needle slot, and along a needle lumen of the introducer needle; and
a distal end disposed in the needle lumen just proximal of the needle tip.

7. The RICC insertion assembly of claim 6, further comprising a syringe fluidly coupled to the introducer needle in the ready-to-deploy state of the RICC insertion assembly, the sheath sealing the needle slot of the needle shaft thereunder outside of the valve module, the valve module sealing the sheath opening of the sheath therein, and the valve module sealing around the access guidewire enabling the syringe to aspirate blood.

8. The RICC insertion assembly of either claim 6 or 7, wherein the proximal end of the access guidewire coupled to the swivel-arm connector and the distal end of the access guidewire disposed in the needle lumen enforces a loop in the access guidewire over which the RICC is disposed in the ready-to-deploy state of the RICC insertion assembly.

9. The RICC insertion assembly of claim 8, wherein the swivel arm is configured to flip the loop between a sinistral side of the RICC insertion assembly and a dextral side of the RICC insertion assembly to accommodate both left-handed and right-handed venipunctures with the RICC insertion assembly.

10. The RICC insertion assembly of any claim of claims 6-9, wherein the coupler includes a needle-hub lock configured to lock the needle hub in the needle-hub receptacle, a pair of lock buttons of the needle-hub lock distributed between opposing sides of the coupler configured to unlock the needle hub when the lock buttons are pressed into the coupler for withdrawal of the introducer needle from the coupler.

11. The RICC insertion assembly of any claim of claims 6-10, 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 as the introducer needle is withdrawn from the coupler, thereby allowing the access guidewire to escape from the needle shaft by way of the needle slot thereof.

12. The RICC insertion assembly of any claim of claims 6-11, wherein the coupler housing includes a longitudinal coupler-housing slot configured to allow the access guidewire to escape from the coupler housing when the introducer needle is withdrawn from the coupler.

13. The RICC insertion assembly of any claim of claims 6-12, wherein the valve module includes separable pieces around the needle shaft and the sheath configured to separate and allow the access guidewire to escape from the valve module when the introducer needle is withdrawn from the coupler.

14. The RICC insertion assembly of any claim of claims 6-13, the catheter tube including:

- a first section formed of a first polymeric material having a first durometer, the first section in a distal portion of the catheter tube;
- a second section formed of a second polymeric material having a second durometer less than the first durometer, the second section in the distal portion of the catheter tube proximal of the first section of the catheter tube;
- and
- a tapered junction between the first and second sections of the catheter tube, the junction having a length between that of exposed portions of the first and second sections of the catheter tube.

15. The RICC insertion assembly of claim 14, wherein a proximal portion of the first section of the catheter tube is disposed in a bore in a distal portion of the junction and bonded thereto.

16. The RICC insertion assembly of either claim 14 or 15, wherein a distal end of the second section of the catheter tube is flush with a proximal end of the junction and bonded thereto.

17. The RICC insertion assembly of any claim of claims 14-16, wherein the catheter tube possess a column strength sufficient to prevent buckling of the catheter tube when inserted into a needle tract established by a percutaneous puncture with the introducer needle and

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.

18. The RICC insertion assembly of any claim of claims 14-17, wherein the RICC includes a set of three lumens including the primary lumen, a secondary lumen, and a tertiary lumen formed of fluidly connected portions of three catheter-tube lumens, three catheter-hub lumens, and three extension-leg lumens.

19. The RICC insertion assembly of claim 18, wherein the primary lumen has a primary-lumen aperture in a distal end of the catheter tube, the secondary lumen has a secondary-lumen aperture in a side of the distal portion of catheter tube, and the tertiary lumen has a tertiary-lumen aperture in the side of the distal portion of the catheter tube proximal of the secondary-lumen aperture.

20. 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 a swivel 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 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;

withdrawing the introducer needle from the coupler 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 and into the blood-vessel lumen, thereby inserting the RICC into the blood-vessel lumen.

21. The method of claim 20, wherein establishing the needle tract includes flipping the swivel arm and, thus, the loop between a sinistral side of the RICC insertion assembly for a left-handed venipuncture and a dextral side of the RICC insertion assembly for a right-handed venipuncture with the RICC insertion assembly.

22. The method of either claim 20 or 21, wherein establishing the needle tract includes ensuring blood flashes back into a needle hub of the introducer needle, a syringe tip of a syringe fluidly connected to the introducer needle, a barrel of the syringe, or a combination thereof, thereby confirming the needle tract extends into the blood-vessel lumen.

23. The method of claim 22, wherein establishing the needle tract includes drawing a slight vacuum with the syringe while establishing the needle tract such that the blood flashes back into at least the needle hub of the introducer needle upon establishing the needle tract.

24. The method of either claims 22 or 23, further comprising aspirating blood with the syringe for confirmation the needle tract extends into the blood-vessel lumen before withdrawing 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.

25. The method of claim 24, wherein the valve module is sealed around a distal portion of the access guidewire and a sheath opening of the sheath, the sheath opening allowing the access guidewire to pass into the needle shaft by way of the needle slot in the ready-to-deploy state of the RICC insertion assembly.

26. The method of any claim of claims 20-25, wherein withdrawing the introducer needle from the coupler includes simultaneously cutting the sheath off the needle shaft with an integrated blade of the valve module while the introducer needle is withdrawn from the coupler, 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.

27. The method of any claim of claims 20-26, wherein separable pieces of the valve module around the needle shaft and the sheath in the ready-to-deploy state of the RICC

insertion assembly separate to allow the access guidewire to escape from the valve module when the introducer needle is withdrawn from the coupler.

28. The method of any claim of claims 20-27, wherein the coupler housing includes a longitudinal coupler-housing slot allowing the access guidewire to escape from the coupler housing when the introducer needle is withdrawn from the coupler.

29. The method of any claim of claims 20-28, further comprising withdrawing the access guidewire leaving the catheter tube in place in the blood-vessel lumen.

30. The method of claim 29, further comprising:
advancing a maneuver guidewire into the blood-vessel lumen by way of a primary lumen of the RICC;
advancing a distal portion of the catheter tube farther into the blood-vessel lumen over the maneuver guidewire to a lower $\frac{1}{3}$ of a superior vena cava ("SVC") of a heart of the patient; and
withdrawing the maneuver guidewire leaving the catheter tube in place in the lower $\frac{1}{3}$ of the SVC.