

RAPIDLY INSERTABLE CENTRAL CATHETERS INCLUDING ASSEMBLIES

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 63/045,599, filed June 29, 2020, which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] A central venous catheter (“CVC”) is formed of a material having a relatively low durometer, which contributes to the CVC having a lack of column strength. Due to the lack of column strength, CVCs are commonly introduced into patients and advanced through 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 steps are time consuming, handling the number of medical devices is awkward, and both of the foregoing can lead to patient trauma. In addition, there is a relatively high potential for touch contamination due to the number of medical devices that need to be interchanged during the number of steps of the Seldinger technique. As such, there is a need to reduce the number of steps and medical devices involved in introducing a catheter such as a CVC into a patient and advancing the catheter through a vasculature thereof.

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

SUMMARY

[0004] Disclosed herein is a RICC assembly including, in some embodiments, a RICC and an introducer. The RICC includes a soft catheter tube, a catheter hub, and one or more extension legs. The soft catheter tube has an introducing aperture through a side of the soft catheter tube in a distal-end portion of the soft catheter tube. The introducing aperture opens into an introducing portion of a primary lumen of the RICC, which portion extends from the introducing aperture to a distal end of the RICC. The catheter hub is coupled to a proximal-end portion of the soft catheter tube. Each extension leg of the one-or-more extension legs is coupled to the catheter hub by a distal-end portion of the extension leg. The introducer includes

an introducer catheter and an introducer needle. The introducer catheter includes a hard catheter tube having an introducing hole through a side of the hard catheter tube in a distal-end portion of the hard catheter tube. The introducing hole opens into an introducing portion of a single lumen of the introducer catheter, which portion extends from the introducing hole to a distal end of the introducer catheter. The introducer catheter is disposed in the primary lumen of the RICC such that the distal end of the introducer catheter extends past the distal end of the RICC when the RICC assembly is in a ready-to-deploy state of the RICC assembly. In addition, the introducer needle is disposed in the introducer catheter through both the introducing aperture and the introducing hole such that a beveled tip in a distal-end portion of the introducer needle extends past the distal end of the introducer catheter.

[0005] In some embodiments, the RICC assembly further includes an access guidewire. The access guidewire is disposed in the introducer needle such that a distal end of the access guidewire is proximal of the beveled tip but distal of the distal end of the RICC when the RICC assembly is in the ready-to-deploy state.

[0006] In some embodiments, the access guidewire includes a stop about a proximal-end portion of the access guidewire forming a stop end of the access guidewire. The stop end of the access guidewire is configured to provide a distal limit for advancing the access guidewire into the RICC.

[0007] In some embodiments, the RICC assembly further includes a maneuver guidewire. The maneuver guidewire is disposed in the introducer catheter such that a distal end of the maneuver guidewire is proximal of the introducing hole but distal of the catheter hub when the RICC assembly is in the ready-to-deploy state.

[0008] In some embodiments, the maneuver guidewire includes a stop about a proximal-end portion of the maneuver guidewire forming a stop end of the maneuver guidewire. The stop end of the maneuver guidewire is configured to provide a distal limit for advancing the maneuver guidewire into the RICC.

[0009] In some embodiments, the soft catheter tube is formed of a first material having a first durometer and the hard catheter tube is formed of a second material having a second durometer. The second durometer is greater than the first durometer, which provides the RICC assembly a column strength for advancing the RICC into a blood-vessel lumen over a guidewire.

[0010] In some embodiments, the RICC includes a set of three lumens. The set of three lumens includes the primary lumen, a secondary lumen, and a tertiary lumen formed of fluidly connected portions of three catheter-tube lumens, three hub lumens, and three extension-leg lumens.

[0011] In some embodiments, the primary lumen has a primary-lumen aperture in the distal end of the RICC. The secondary lumen has a secondary-lumen aperture in the side of the soft catheter tube proximal of the primary-lumen aperture. The tertiary lumen has a tertiary-lumen aperture in the side of the soft catheter tube proximal of the secondary-lumen aperture but distal of the introducing aperture.

[0012] Also disclosed herein is a RICC assembly including, in some embodiments, a RICC and an introducer. The RICC includes a soft catheter tube, a catheter hub, and one or more extension legs. The soft catheter tube has a primary-lumen aperture in a distal end of the soft catheter tube and a secondary-lumen aperture in a side of the soft catheter tube in a distal-end portion of the soft catheter tube. The catheter hub is coupled to a proximal-end portion of the soft catheter tube. Each extension leg of the one-or-more extension legs is coupled to the catheter hub by a distal-end portion of the extension leg. The introducer includes an introducer catheter and an introducer needle. The introducer catheter includes a hard catheter tube having an introducing hole through a side of the hard catheter tube in a distal-end portion of the hard catheter tube. The introducer catheter is disposed in a primary lumen of the RICC such that a distal end of the introducer catheter extends past a distal end of the RICC when the RICC assembly is in a ready-to-deploy state of the RICC assembly. In addition, the introducer needle is disposed in the introducer catheter through a combination of the secondary-lumen aperture, a septum dividing a secondary lumen from the primary lumen, and the introducing hole. Disposed as such, a beveled tip in a distal-end portion of the introducer needle extends past the distal end of the introducer catheter when the RICC assembly is in the ready-to-deploy state.

[0013] In some embodiments, the RICC assembly further includes an access guidewire. The access guidewire is disposed in the introducer needle such that a distal end of the access guidewire is proximal of the beveled tip but distal of the distal end of the RICC when the RICC assembly is in the ready-to-deploy state.

[0014] In some embodiments, the access guidewire includes a stop about a proximal-end portion of the access guidewire forming a stop end of the access guidewire. The stop end

of the access guidewire is configured to provide a distal limit for advancing the access guidewire into the RICC.

[0015] In some embodiments, the RICC assembly further includes a maneuver guidewire. The maneuver guidewire is disposed in the introducer catheter such that a distal end of the maneuver guidewire is proximal of the introducing hole but distal of the catheter hub when the RICC assembly is in the ready-to-deploy state.

[0016] In some embodiments, the maneuver guidewire includes a stop about a proximal-end portion of the maneuver guidewire forming a stop end of the maneuver guidewire. The stop end of the maneuver guidewire is configured to provide a distal limit for advancing the maneuver guidewire into the RICC.

[0017] In some embodiments, the soft catheter tube is formed of a first material having a first durometer and the hard catheter tube is formed of a second material having a second durometer. The second durometer is greater than the first durometer, which provides the RICC assembly a column strength for advancing the RICC into a blood-vessel lumen over a guidewire.

[0018] In some embodiments, the RICC includes a set of three lumens. The set of three lumens includes the primary lumen, the secondary lumen, and a tertiary lumen formed of fluidly connected portions of three catheter-tube lumens, three hub lumens, and three extension-leg lumens.

[0019] In some embodiments, the primary lumen has the primary-lumen aperture in the distal end of the RICC. The secondary lumen has the secondary-lumen aperture in the side of the soft catheter tube proximal of the primary-lumen aperture. The tertiary lumen has a tertiary-lumen aperture in the side of the soft catheter tube proximal of the secondary-lumen aperture.

[0020] Also disclosed is a method for using a RICC assembly. The method includes, in some embodiments, an RICC assembly-obtaining step, a needle tract-establishing step, an access guidewire-advancing step, and an introducer needle-withdrawing step. The RICC assembly-obtaining step includes obtaining a RICC assembly including the RICC and an introducer. The introducer includes an introducer catheter disposed in a primary lumen of the RICC such that a distal-end portion of the introducer catheter extends past a distal end of the RICC. The needle tract-establishing step includes establishing a needle tract from an area of

skin to a blood-vessel lumen of a patient with a beveled tip of an introducer needle of the introducer. The introducer needle extends through a side of a soft catheter tube of the RICC, through a side of a hard catheter tube of the introducer catheter, and out the distal end of the introducer catheter. The access guidewire-advancing step includes advancing an access guidewire through the introducer needle and into the blood-vessel lumen of the patient. The introducer needle-withdrawing step includes withdrawing the introducer needle from both the blood-vessel lumen and the RICC assembly leaving the access guidewire and the introducer catheter in the blood-vessel lumen.

[0021] In some embodiments, the method further includes an ensuring step of ensuring the distal end of the introducer catheter extends at least about 1-7 cm beyond the distal end of the RICC before performing the needle tract-establishing step.

[0022] In some embodiments, the method further includes a first RICC-advancing step of advancing the distal-end portion of the introducer catheter into the blood-vessel lumen over the access guidewire.

[0023] In some embodiments, the method further includes a maneuver guidewire-advancing step of advancing a maneuver guidewire through the introducer catheter and into the blood-vessel lumen.

[0024] In some embodiments, the maneuver guidewire-advancing step requires first withdrawing the introducer needle from both the blood-vessel lumen and the RICC assembly.

[0025] In some embodiments, the method further includes a second RICC-advancing step of advancing both the distal-end portion of the introducer catheter and a distal-end portion of the RICC farther into the blood-vessel lumen over the maneuver guidewire.

[0026] 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

[0027] FIG. 1 illustrates a RICC assembly with a RICC including an introducing aperture in accordance with some embodiments.

[0028] FIG. 2 illustrates a RICC assembly with a RICC lacking the introducing aperture in accordance with some embodiments.

[0029] FIG. 3 illustrates the RICC assembly of FIG. 1 or 2 with a maneuver guidewire therethrough in accordance with some embodiments.

[0030] FIG. 4 illustrates a distal-end portion of a soft catheter tube of the RICC of FIG. 1 or 2 in accordance with some embodiments.

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

[0032] FIG. 6 illustrates a second or third transverse cross section of the soft catheter tube in accordance with some embodiments.

[0033] FIG. 7 illustrates a fourth transverse cross section of the soft catheter tube with an introducer needle through septum thereof in accordance with some embodiments.

[0034] FIG. 8 illustrates a method of assembling the RICC assembly of FIG. 1 or 2 in accordance with some embodiments.

DESCRIPTION

[0035] 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.

[0036] Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, “first,” “second,” and “third” features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as “left,” “right,” “top,” “bottom,” “front,” “back,” and the like are used for convenience and are

not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of “a,” “an,” and “the” include plural references unless the context clearly dictates otherwise.

[0037] With respect to “proximal,” a “proximal portion” or a “proximal-end portion” of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near a clinician when the catheter is used on a patient. Likewise, a “proximal length” of, for example, the catheter includes a length of the catheter intended to be near the clinician when the catheter is used on the patient. A “proximal end” of, for example, the catheter includes an end of the catheter intended to be near the clinician when the catheter is used on the patient. The proximal portion, the proximal-end portion, or the proximal length of the catheter can include the proximal end of the catheter; however, the proximal portion, the proximal-end portion, or the proximal length of the catheter need not include the proximal end of the catheter. That is, unless context suggests otherwise, the proximal portion, the proximal-end portion, or the proximal length of the catheter is not a terminal portion or terminal length of the catheter.

[0038] With respect to “distal,” a “distal portion” or a “distal-end portion” of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near or in a patient when the catheter is used on the patient. Likewise, a “distal length” of, for example, the catheter includes a length of the catheter intended to be near or in the patient when the catheter is used on the patient. A “distal end” of, for example, the catheter includes an end of the catheter intended to be near or in the patient when the catheter is used on the patient. The distal portion, the distal-end portion, or the distal length of the catheter can include the distal end of the catheter; however, the distal portion, the distal-end portion, or the distal length of the catheter need not include the distal end of the catheter. That is, unless context suggests otherwise, the distal portion, the distal-end portion, or the distal length of the catheter is not a terminal portion or terminal length of the catheter.

[0039] 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.

[0040] As set forth above, 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. Disclosed herein are RICCs including catheter assemblies and methods thereof that address the foregoing.

[0041] FIG. 1 illustrates a RICC assembly 100 with a RICC 102 including an introducing aperture 104 in accordance with some embodiments. FIG. 2 illustrates a RICC assembly 200 with a RICC 202 lacking the introducing aperture 104 in accordance with some embodiments.

[0042] As shown, the RICC assembly 100 or 200 includes the RICC 102 or 202 and an introducer 106 coupled together in a ready-to-deploy state of the RICC assembly 100 or 200. The RICCs 102 and 202 and the introducer 106 are described, in turn, in sections set forth below; however, some crossover between the sections for the RICCs 102 and 202 and the introducer 106 exist in view of the interrelatedness of the RICCs 102 and 202 and the introducer 106 in the RICC assemblies 100 and 200.

[0043] The RICC 102 differs from the RICC 202 with respect to a presence of the introducing aperture 104 in the RICC 102, which introducing aperture 104 is dedicated to accommodating insertion of the introducer needle 126 of the introducer 106 therethrough for coupling the RICC 102 and the introducer 106 together in the RICC assembly 100. The RICC 202 lacks such a dedicated introducing aperture 104, thereby requiring a different mode of coupling the RICC 202 and the introducer 106 together in the RICC assembly 200 than in the RICC assembly 100.

[0044] The RICC 102 or 202 can be a monoluminal or multiluminal RICC (e.g., a diluminal RICC, a triluminal RICC, a tetraluminal RICC, a pentaluminal RICC, a hexaluminal RICC, etc.). For example, the RICC 202, which lacks the introducing aperture 104, can be monoluminal. Such a RICC also lacks the secondary-lumen aperture 116 and the tertiary-lumen aperture 118 set forth below. In another example, the RICC 102 or 202 can be multiluminal. As shown in FIG. 1 or 2, the RICC 102 or 202 is triluminal including a set of three lumens. Such a set of three lumens includes a primary lumen 108 (e.g., a distal lumen), a secondary lumen 110 (e.g., a medial lumen), and a tertiary lumen 112 (e.g., a proximal lumen) formed of fluidly connected portions of three catheter-tube lumens, three hub lumens, and three extension-leg lumens. (See FIGS. 4-7.)

[0045] Whether the RICC 102 or 202 is monoluminal or multiluminal, the RICC 102 or 202 includes at least the primary lumen 108. The primary lumen 108 typically extends from

a proximal end of the RICC 102 or 202 to a distal end of the RICC 102 or 202 such as from an opening of a corresponding Luer connector to a primary-lumen aperture 114 in a distal end of the soft catheter tube 120 or 220 set forth below. When the RICC 102 or 202 has two or more lumens, the RICC 102 or 202 further includes at least the secondary lumen 110. The secondary lumen 110 typically extends from the proximal end of the RICC 102 or 202 to a distal-end portion of the RICC 102 or 202 such as from an opening of a corresponding Luer connector to a secondary-lumen aperture 116 in the distal-end portion of the soft catheter tube 120 or 220 proximal of the primary-lumen aperture 114. When the RICC 102 or 202 has three or more lumens, the RICC 102 or 202 further includes at least the tertiary lumen 112. The tertiary lumen 112 typically extends from the proximal end of the RICC 102 or 202 to the distal-end portion of the RICC 102 or 202 such as from an opening of a corresponding Luer connector to a tertiary-lumen aperture 118 in the distal-end portion of the soft catheter tube 120 or 220 proximal of the secondary-lumen aperture 116. Notwithstanding the foregoing, each lumen of the secondary lumen 110 and the tertiary lumen 112 can distally extend slightly farther than the secondary-lumen aperture 116 and the tertiary-lumen aperture 118, respectively, in view of different manufacturing methods. (*See* FIGS. 4 and 6.)

[0046] Whether the RICC 102 or 202 includes the introducing aperture 104 or not, the RICC 102 or 202 further includes an introducing lumen coincident with a distal-end portion of the primary lumen 108. In other words, the introducing lumen is an introducing portion of the primary lumen 108 of the RICC 102 or 202. In the RICC 102, the introducing lumen is the distal-end portion of the primary lumen 108 extending from the introducing aperture 104 to the primary-lumen aperture 114. The introducing aperture 104, which can be distal of the secondary-lumen aperture 116, between the secondary-lumen aperture 116 and the tertiary-lumen aperture 118, or proximal of the tertiary-lumen aperture 118, opens directly into a proximal end of the introducing portion of the primary lumen 108 of the RICC 102. In the RICC 202, the introducing lumen is the distal-end portion of the primary lumen 108 extending from either the secondary-lumen aperture 116 or the tertiary-lumen aperture 118 to the primary-lumen aperture 114. Whether the introducing lumen extends from the secondary-lumen aperture 116 or the tertiary-lumen aperture 118 depends upon which aperture of the foregoing apertures accommodates the introducer needle 126 of the introducer 106. Neither the secondary-lumen aperture 116 nor the tertiary-lumen aperture 118 opens directly into a proximal end of the introducing portion of the primary lumen 108 of the RICC 202. Instead, the introducer needle 126 pierces the septum 128 between the secondary lumen 110 or the

tertiary lumen 112 and the primary lumen 108 respectively by way of the secondary-lumen aperture 116 or the tertiary-lumen aperture 118.

[0047] The RICC 102 or 202 includes a soft catheter tube 120 or 220, a catheter hub 122, and one or more extension legs 124.

[0048] FIG. 4 illustrates a distal-end portion of the soft catheter tube 120 or 220 of the RICC 102 or 202 of FIG. 1 or 2 in accordance with some embodiments. FIGS. 5-7 illustrate various transverse cross sections of the soft catheter tube 120 or 220 in accordance with some embodiments. FIG. 7 further illustrates an introducer needle 126 through a septum 128 of the catheter tube 220 in accordance with some embodiments.

[0049] The soft catheter tube 120 or 220 includes a distal tip 130 in a distal-end portion of the soft catheter tube 120 or 220 corresponding to the distal end of the RICC 102 or 202. Like that set forth above for the RICCs 102 and 202, the soft catheter tube 120 or 220 can be monoluminal or multiluminal. Indeed, the soft catheter tube 120 or 220 includes one or more catheter-tube lumens corresponding in name and number to those of the RICC 102 or 202. The one-or-more catheter-tube lumens extend through the soft catheter tube 120 or 220 as set forth above for the RICC 102 or 202.

[0050] The soft catheter tube 120 differs from the soft catheter tube 220 with respect to a presence of the introducing aperture 104 through a side of the soft catheter tube 120 in the distal-end portion thereof. Again, the introducing aperture 104 is dedicated to accommodating insertion of the introducer needle 126 of the introducer 106 therethrough for coupling the RICC 102 and the introducer 106 together in the RICC assembly 100. The soft catheter tube 220 lacks such a dedicated introducing aperture 104, thereby requiring a different mode of coupling the RICC 202 and the introducer 106 together in the RICC assembly 200 than in the RICC assembly 100.

[0051] Notwithstanding the foregoing, the soft catheter tube 120 or 220 can include $n-1$ side apertures through the side of the soft catheter tube 120 or 220 in accordance with a number of lumens n of the RICC 102 or 202. Indeed, in consideration of the RICC 102 or 202 set forth above having three lumens, the soft catheter tube 120 or 220 can include two side apertures including the secondary-lumen aperture 116 in the side of the soft catheter tube 120 or 220 proximal of the primary-lumen aperture 114 and the tertiary-lumen aperture 118 in the side of the soft catheter tube 120 or 220 proximal of the secondary-lumen aperture 116. In addition to

providing different apertures for aspirating blood, delivering fluids, or the like, such side apertures are important for establishing an introducing lumen for introducing RICCs such as the RICC 202.

[0052] The catheter hub 122 is coupled to a proximal-end portion of the soft catheter tube 120 or 220. The catheter hub 122 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 extend through an entirety of the catheter hub 122 from a proximal end of the catheter hub 122 to a distal end of the catheter hub 122.

[0053] Each extension leg of the one-or-more extension legs 124 is coupled to the catheter hub 122 by a distal-end portion of the extension leg. The one-or-more extension legs 124 respectively include one or more extension-leg lumens, which, in turn, correspond in number to the one-or-more catheter-tube 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.

[0054] Each extension leg of the one-or-more extension legs 124 typically includes a Luer connector coupled to the extension leg, through which Luer connector the extension leg and the extension-leg lumen thereof can be connected to another medical device.

[0055] The introducer 106 includes an introducer catheter 132 and the introducer needle 126.

[0056] The introducer catheter 132 includes a hard catheter tube 134, an introducer-catheter hub 136 about a proximal-end portion of the hard catheter tube 134, and a distal tip 138 in a distal-end portion of the hard catheter tube 134.

[0057] The introducer catheter 132 also includes an introducing hole 140 through a side of the hard catheter tube 134 in the distal-end portion thereof. The introducing hole 140 opens into an introducing portion of a single lumen of the introducer catheter 132, which introducing portion extends from the introducing hole 140 to a distal end of the introducer catheter 132. When the RICC assembly 100 or 200 is in the ready-to-deploy state, the introducer catheter 132 is disposed in the primary lumen 108 of the RICC 102 or 202 such that the distal end of the introducer catheter 132 extends at least about 1 - 7 cm beyond the distal end of the RICC

102 or 202, which is useful for dilation of tissue with the distal-end portion of the introducer catheter 132 or the hard catheter tube 134 thereof.

[0058] With respect to the soft catheter tube 120 or 220 of the RICC 102 or 202 and the hard catheter tube 134 of the introducer catheter 132, the soft catheter tube 120 or 220 is formed of a first material having a first durometer and the hard catheter tube 134 is formed of a second material having a second durometer. The first durometer is less than the second durometer, thereby making the soft catheter tube 120 or 220 relatively softer than the hard catheter tube 134. In other words, the second durometer is greater than the first durometer, thereby making the hard catheter tube 134 relatively harder than the soft catheter tube 120 or 220. The hard catheter tube 134 provides the RICC assembly 100 or 200 a column strength for advancing the RICC 102 or 202 into a blood-vessel lumen over a guidewire such as the maneuver guidewire 152 set forth below.

[0059] It should be understood the first durometer and the second durometer can be on different scales (e.g., Type A or Type D), so the first durometer of the first polymeric material might not be numerically less than the second durometer of the second polymeric material. Likewise, the second durometer of the second polymeric material might not be numerically greater than the first durometer of the first polymeric material in view of the different scales. That said, the hardness of the first polymeric material can still be less than the hardness of the second polymeric material or the hardness of the second polymeric material can still be greater than the hardness of the first polymeric material because 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.

[0060] Notwithstanding the foregoing, the soft catheter tube 120 or 220 and the hard catheter tube 134 can be formed of a same polymeric material or different polymeric materials having substantially equal durometers provided a column strength of the soft catheter tube 120 or 220 in combination with the hard catheter tube 134 is sufficient to prevent buckling of the soft catheter tube 120 or 220 when inserted into an insertion site and advanced through a vasculature of a patient.

[0061] The introducer needle 126 includes a shaft 142, an introducer-needle hub 144 about a proximal-end portion of the shaft 142, and a beveled tip 146 in a distal-end portion of the shaft 142.

[0062] When the RICC assembly 100 is in the ready-to-deploy state, the introducer needle 126 or the shaft 142 thereof is disposed in the single lumen of the introducer catheter 132 through a combination of the introducing aperture 104 of the RICC 102 or the soft catheter tube 120 thereof and the introducing hole 140 of the introducer catheter 132 or the hard catheter tube 134 thereof such that the beveled tip 146 of the introducer needle 126 extends past the distal end of the introducer catheter 132 for establishing a percutaneous puncture. However, when the RICC assembly 200 is in the ready-to-deploy state, the introducer needle 126 or the shaft 142 thereof is disposed in the single lumen of the introducer catheter 132 through a combination of the secondary-lumen aperture 116 or the tertiary-lumen aperture 118 of the RICC 202 or the soft catheter tube 220 thereof, the septum 128 dividing the secondary lumen 110 or tertiary lumen 112 from the primary lumen 108 of the RICC 202 or the soft catheter tube 220 thereof, and the introducing hole 140 of the introducer catheter 132 or the hard catheter tube 134 thereof. Disposed as such, the beveled tip 146 in the distal-end portion of the introducer needle 126 extends past the distal end of the introducer catheter 132 when the RICC assembly 100 or 200 is in the ready-to-deploy state.

[0063] The RICC assembly 100 or 200 further includes an access guidewire 148.

[0064] When the RICC assembly 100 or 200 is in at least the ready-to-deploy state, the access guidewire 148 is disposed in a needle lumen of the introducer needle 126 such that a distal end of the access guidewire 148 is proximal of the beveled tip 146 of the introducer needle 126 but distal of the distal end of the RICC 102 or 202, which allows for immediate advancement of the distal end of the access guidewire 148 beyond the beveled tip 146 of introducer needle 126 and into a blood-vessel lumen upon establishing access thereto.

[0065] The access guidewire 148 includes a stop (e.g., a hub, a ball, a slug, etc.) about a proximal-end portion of the access guidewire 148 forming a stop end 150 (e.g., a hub end, a ball end, a slug end, etc.) of the access guidewire 148. The stop end 150 of the access guidewire 148 is larger than any aperture of the RICC 102 or 202 or the soft catheter tube 120 or 220 thereof, thereby providing a distal limit for advancing the access guidewire 148 into the RICC 102 or 202.

[0066] FIG. 3 illustrates the RICC assembly 100 or 200 with a maneuver guidewire 152 therethrough in accordance with some embodiments.

[0067] The RICC assembly 100 or 200 further includes a maneuver guidewire 152 including an atraumatic tip 154 (e.g., a coiled or partially coiled tip) and a length sufficient for advancing the maneuver guidewire 152 to the lower $\frac{1}{3}$ of the superior vena cava (“SVC”) of the heart.

[0068] When the RICC assembly 100 or 200 is in at least the ready-to-deploy state, the maneuver guidewire 152 is disposed in the single lumen of the introducer catheter 132 such that a distal end of the maneuver guidewire 152 is proximal of the introducing hole 140 but distal of the catheter hub 122, which allows for immediate advancement of the distal end of the maneuver guidewire 152 into the blood-vessel lumen upon removing the introducer needle 126 or the shaft 142 thereof from the single lumen of the introducer catheter 132. Indeed, the maneuver guidewire 152 cannot be distally advanced farther into the single lumen of the introducer catheter 132 due the presence of the introducer needle 126 or the shaft 142 thereof in at least the ready-to-deploy state of the RICC assembly 100 or 200.

[0069] The maneuver guidewire 152 includes a stop (e.g., a hub, a ball, a slug, etc.) about a proximal-end portion of the maneuver guidewire 152 forming a stop end 156 (e.g., a hub end, a ball end, a slug end, etc.) of the maneuver guidewire 152. The stop end 156 of the maneuver guidewire 152 is larger than a proximal-end opening in the introducer-catheter hub 136, thereby providing a distal limit for advancing the maneuver guidewire 152 into the RICC 102 or 202.

Methods

[0070] Methods of the RICC assembly 100 or 200 include a method of assembling the RICC assembly 100 or 200 and a method of using the RICC assembly 100 or 200.

[0071] As to the method of assembling the RICC assembly 100 or 200, FIG. 8 illustrates the method of assembling the RICC assembly 100 or 200 in accordance with some embodiments.

[0072] As shown, the method of assembling the RICC assembly 100 or 200 includes an introducer-catheter insertion step, an introducer-needle insertion step, an access-guidewire insertion step, and a maneuver-guidewire insertion step.

[0073] The introducer-catheter insertion step includes inserting the introducer catheter 132 into the primary lumen 108 of the RICC 102 or 202 by way of the opening of the

corresponding Luer connector in the proximal end of the RICC 102 or 202. In addition, the introducer-catheter insertion step includes aligning the introducing hole 140 of the hard catheter tube 134 of the introducer catheter 132 with an aperture of the soft catheter tube 120 or 220 of the RICC 102 or 202. For the RICC 102, such aligning includes aligning the introducing hole 140 of the hard catheter tube 134 with the introducing aperture 104 of the soft catheter tube 120. For the RICC 202, such aligning includes aligning the introducing hole 140 of the hard catheter tube 134 with the secondary-lumen aperture 116 or the tertiary-lumen aperture 118 of the soft catheter tube 220. Lastly, the introducer-catheter insertion step includes ensuring the distal end of the introducer catheter 132 extends at least about 1 - 7 cm beyond the distal end of the RICC 102 or 202.

[0074] The introducer-needle insertion step includes inserting the introducer needle 126 into the single lumen of the introducer catheter 132 by way of the introducing hole 140 of the hard catheter tube 134, thereby locking the introducer and the RICC 102 or 202 together. For the RICC 102, the introducer-needle insertion step includes inserting the introducer needle 126 into the introducing aperture 104 of the soft catheter tube 120, then inserting the introducer needle 126 into the introducing hole 140 of the hard catheter tube 134. For the RICC 202, the introducer-needle insertion step includes inserting the introducer needle 126 into either the secondary-lumen aperture 116 or the tertiary-lumen aperture 118, then piercing the septum 128 between the secondary lumen 110 or the tertiary lumen 112 and the primary lumen 108 of the soft catheter tube 220, and finally inserting the introducer needle 126 into the introducing hole 140 of the hard catheter tube 134 disposed in the primary lumen 108. Lastly, the introducer-needle insertion step includes ensuring the beveled tip 146 of the introducer needle 126 extends past the distal end of the introducer catheter 132.

[0075] The access-guidewire insertion step includes inserting the access guidewire 148 into the introducer needle 126 by way of an opening of the introducer-needle hub 144 in a proximal end of the introducer needle 126. In addition, the access-guidewire insertion step includes positioning the access guidewire 148 in the introducer needle 126 such that the distal end of the access guidewire 148 is proximal of the beveled tip 146 of the introducer needle 126 but distal of the distal end of the RICC 102 or 202. Again, such a position for the access guidewire 148 allows for immediate advancement of the distal end of the access guidewire 148 beyond the beveled tip 146 of introducer needle 126 and into a blood-vessel lumen upon establishing access thereto.

[0076] The maneuver-guidewire insertion step includes inserting the maneuver guidewire 152 into the introducer catheter 132 by way of an opening of the introducer-catheter hub 136 in a proximal end of the introducer catheter 132. In addition, the maneuver-guidewire insertion step includes positioning the maneuver guidewire 152 in the introducer catheter 132 such that the distal end of the maneuver guidewire 152 is proximal of the introducing hole 140 but distal of the catheter hub 122. Again, such a position for the maneuver guidewire 152 allows for immediate advancement of the distal end of the maneuver guidewire 152 into the blood-vessel lumen upon removing the introducer needle 126 or the shaft 142 thereof from the single lumen of the introducer catheter 132.

[0077] As to the method of using the RICC assembly 100 or 200, the method of using the RICC assembly 100 or 200 includes an RICC assembly-obtaining step, a needle tract-establishing step, an access guidewire-advancing step, and an introducer needle-withdrawing step.

[0078] The RICC assembly-obtaining step includes obtaining the RICC assembly 100 or 200 including the RICC 102 or 202 and the introducer 106. As set forth above with respect to the ready-to-deploy state of the RICC assembly 100 or 200, the introducer 106 includes the introducer catheter 132 disposed in the primary lumen 108 of the RICC 102 or 202 such that the distal-end portion of the introducer catheter 132 extends past the distal end of the RICC 102 or 202.

[0079] The method can further include an ensuring step of ensuring the distal end of the introducer catheter 132 extends at least about 1 - 7 cm beyond the distal end of the RICC 102 or 202 before performing the needle tract-establishing step.

[0080] The needle tract-establishing step includes establishing a needle tract from an area of skin to a blood-vessel lumen of a patient with the beveled tip 146 of the introducer needle 126 of the introducer 106. As set forth above with respect to the ready-to-deploy state of the RICC assembly 100 or 200, the introducer needle 126 extends through the side of the soft catheter tube 120 or 220 of the RICC 102 or 202, through the side of the hard catheter tube 134 of the introducer catheter 132, and out the distal end of the introducer catheter 132.

[0081] The access guidewire-advancing step includes advancing the access guidewire 148 through the introducer needle 126 and into the blood-vessel lumen of the patient.

[0082] The method can further include a first RICC-advancing step of advancing the distal-end portion of the introducer catheter 132 into the blood-vessel lumen over the access guidewire 148.

[0083] The introducer needle-withdrawing step includes withdrawing the introducer needle 126 from both the blood-vessel lumen and the RICC assembly 100 or 200 leaving the access guidewire 148 and the introducer catheter 132 in the blood-vessel lumen.

[0084] The method can further include a maneuver guidewire 152-advancing step of advancing the maneuver guidewire 152 through the introducer catheter 132 and into the blood-vessel lumen. However, the maneuver guidewire 152-advancing step requires first withdrawing the introducer needle 126 from both the blood-vessel lumen and the RICC assembly 100 or 200.

[0085] The method can further include a second RICC-advancing step of advancing both the distal-end portion of the introducer catheter 132 and a distal-end portion of the RICC 102 or 202 farther into the blood-vessel lumen over the maneuver guidewire 152 such as to the SVC.

[0086] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.