RAPIDLY INSERTABLE CENTRAL CATHETERS INCLUDING CATHETER ASSEMBLIES AND METHODS THEREOF

PRIORITY

[0001] This application claims the benefit of priority to U.S. Patent Application No. 63/016,085, filed April 27, 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 number of steps are time consuming, handling the number of medical devices is awkward, and both of the foregoing can lead to patient trauma. In addition, there is a relatively high potential for touch contamination due to the number of medical devices that need to be interchanged during the number of steps of the Seldinger technique. As such, there is a need to reduce the number of steps and medical devices involved in introducing a catheter 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, an introducer, and a coupling system configured to couple the RICC and the introducer together. The RICC includes a catheter tube, a catheter hub, and one or more extension legs. The catheter tube includes a side aperture through a side of the catheter tube in a distal-end portion thereof. The side aperture opens into an introducing lumen of the catheter tube that extends from at least the side aperture to a distal end of the RICC. The catheter hub is coupled to a proximal-end portion of the catheter tube. Each extension leg of the one-or-more extension legs is coupled to the catheter hub by a distal-end portion thereof. The introducer includes an

introducer needle having a cannula. The coupling system includes a distal coupler slidably attached to the catheter tube proximal of the side aperture. The cannula extends through a longitudinal through hole of the distal coupler, through the side aperture of the catheter tube, along the introducing lumen of the catheter tube, and through the distal end of the RICC when the RICC assembly is in a ready-to-deploy state thereof.

[0005] In some embodiments, the cannula of the introducer needle extends at least about 2 - 7 cm from the distal end of the RICC in the ready-to-deploy state of the RICC for a venipuncture with the cannula.

[0006] In some embodiments, the distal coupler includes a tab configured to allow a clinician to single handedly advance the RICC off the cannula with a single finger of a hand while holding the guidewire conduit between a thumb and another finger or fingers of the hand.

[0007] In some embodiments, the introducer further includes a guidewire conduit and an access guidewire disposed in the guidewire conduit. The guidewire conduit is coupled to a needle hub of the introducer needle. The guidewire conduit is configured to maintain sterility of the access guidewire.

[0008] In some embodiments, the guidewire conduit includes a longitudinal slit and the access guidewire includes a handle coupled to a proximal-end portion of the access guidewire. The handle protrudes through the longitudinal slit for grasping the handle and advancing the access guidewire through the distal end of the RICC without directly touching the access guidewire.

[0009] In some embodiments, the longitudinal slit includes closed ends configured to provide stops for the handle. The stops prevent loss of the access guidewire in a blood-vessel lumen of a patient by over advancement of the access guidewire. The stops also prevent withdrawal of the access guidewire from the guidewire conduit by over withdrawal of the access guidewire.

[0010] In some embodiments, the introducer further includes a fluid-pressure indicator extending from a side arm of the needle hub. The fluid-pressure indicator is fluidly coupled to a needle lumen of the introducer needle by way of a side-arm lumen of the side arm for observing blood flashback.

[0011] In some embodiments, the coupling system further includes a proximal coupler removably attached to the catheter hub and slidably attached to the guidewire conduit. The coupling system is configured to couple the RICC and the introducer together by corresponding proximal-end and distal-end portions thereof in the ready-to-deploy state of the RICC assembly while allowing the introducer to slide relative to the RICC.

[0012] In some embodiments, the proximal coupler includes sloped sides configured to push the guidewire conduit out of the proximal coupler when a proximal coupler-interacting portion of the introducer interacts with the sloped sides while the cannula is withdrawn from the side aperture of the catheter tube.

[0013] In some embodiments, the proximal coupler includes posts and the catheter hub includes a suture wing with suture-wing holes. The posts are disposed in the suture-wing holes in the ready-to-deploy state of the RICC assembly.

[0014] In some embodiments, the RICC further includes a sterile barrier over the catheter tube between the proximal coupler and the distal coupler to which the sterile barrier is coupled. The sterile barrier is configured to split apart when the proximal coupler is removed from the catheter hub and the sterile barrier is pulled away from the catheter tube.

[0015] In some embodiments, the sterile barrier has sufficient tensile strength to pull the distal coupler off the catheter tube without breaking when the sterile barrier splits down to the distal coupler while being pulled away from the catheter tube.

[0016] In some embodiments, the RICC includes a set of three lumens including a distal lumen, a medial lumen, and a proximal lumen formed of fluidly connected portions of three catheter-tube lumens, three hub lumens, and three extension-leg lumens. The introducing lumen of the catheter tube is coincident with a distal-end portion of the distal lumen.

[0017] In some embodiments, the distal lumen has a distal-lumen aperture in a distal end of the RICC, the medial lumen has a medial-lumen aperture in the side of the catheter tube distal of the side aperture, and the proximal lumen has a proximal-lumen aperture in the side of the catheter tube distal of the side aperture but proximal of the medial-lumen aperture.

[0018] Also disclosed herein is a method for inserting a RICC into a blood-vessel lumen of a patient including a RICC assembly-obtaining step, needle tract-establishing step, a

first catheter-advancing step; and a cannula-withdrawing step. The RICC assembly-obtaining step obtaining a RICC assembly including the RICC, an introducer including an introducer needle, and a coupling system including a distal coupler that couples the RICC and the introducer together by distal-end portions thereof in a ready-to-deploy state of the RICC assembly. The needle tract-establishing step includes establishing a needle tract from an area of skin to the blood-vessel lumen of the patient with a cannula of the introducer needle. The cannula extends through a longitudinal through hole of the distal coupler, through a side aperture in a distal-end portion of a catheter tube of the RICC, along an introducing lumen of the catheter tube, and out a distal end of the RICC. The first catheter-advancing step includes advancing the distal-end portion of the catheter tube into the blood-vessel lumen over the cannula. The cannula-withdrawing step includes withdrawing the cannula from the introducing lumen by way of the side aperture of the catheter tube.

[0019] In some embodiments, the method further includes cannula-ensuring step of ensuring the cannula extends at least about 2 - 7 cm beyond the distal end of the RICC before the needle tract-establishing step.

[0020] In some embodiments, the needle tract-establishing step includes ensuring blood flashes back into a needle hub of the introducer needle, a side arm of the needle hub, or a fluid-pressure indicator extending from the side arm of the needle hub.

[0021] In some embodiments, the method further includes an access guidewire-advancing step of advancing an access guidewire by a handle coupled to a proximal-end portion of the access guidewire into the blood-vessel lumen beyond a distal end of the cannula. The handle protrudes through a longitudinal slit in a guidewire conduit coupled to the introducer needle.

[0022] In some embodiments, the first catheter-advancing step includes advancing the catheter tube into the blood-vessel lumen with a single finger of a hand while holding the guidewire conduit between a thumb and another finger or fingers of the hand. The distal coupler includes a tab configured for advancing the catheter tube into the blood-vessel lumen with the single finger.

[0023] In some embodiments, the first catheter-advancing step includes advancing the catheter tube into the blood-vessel lumen until a proximal coupler of the coupling system slidably attached to the guidewire conduit pushes the guidewire conduit out of the proximal

coupler. The introducer includes a proximal coupler-interacting portion configured to interact with sloped sides of the proximal coupler and push the guidewire conduit out of the proximal coupler.

[0024] In some embodiments, the method further includes a maneuver guidewire-advancing step of advancing a maneuver guidewire into the blood-vessel lumen by way of a distal lumen having a distal-lumen aperture in the distal end of the RICC. The introducing lumen of the catheter tube is coincident with a distal-end portion of the distal lumen.

[0025] In some embodiments, the method further includes a second catheter-advancing step of advancing the distal-end portion of the catheter tube further into the blood-vessel lumen over the maneuver guidewire. Concomitantly, the second catheter-advancing step includes sliding the distal coupler proximally towards the proximal coupler to uncover the catheter tube. The catheter tube is covered by a sterile barrier between the proximal coupler and the distal coupler in a ready-to-deploy state of the RICC assembly.

[0026] In some embodiments, the method further includes a sterile barrier-removing step of removing the sterile barrier and a remainder of the coupling system from the RICC. The sterile barrier-removing step includes removing the proximal coupler from a catheter hub of the RICC, pulling the sterile barrier away from the catheter tube to split the sterile barrier apart, and removing the distal coupler from the catheter tube to which the distal coupler is slidably attached.

[0027] 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

[0028] FIG. 1 illustrates a top view of a RICC assembly including a RICC, an introducer, and a coupling system in accordance with some embodiments.

[0029] FIG. 2 illustrates a bottom view of the RICC assembly in accordance with some embodiments.

[0030] FIG. 3 illustrates a side view of the RICC assembly in accordance with some embodiments.

[0031] FIG. 4 illustrates a detailed top view of the RICC assembly in accordance with some embodiments.

[0032] FIG. 5 illustrates a detailed side view of the RICC assembly in accordance with some embodiments.

[0033] FIG. 6 illustrates a distal-end portion of the RICC assembly in accordance with some embodiments.

[0034] FIG. 7 illustrates a distal-end portion of a catheter tube of the RICC in accordance with some embodiments.

[0035] FIG. 8 illustrates a first transverse cross section of the catheter tube in accordance with some embodiments.

[0036] FIG. 9 illustrates a second or third transverse cross section of the catheter tube in accordance with some embodiments.

DESCRIPTION

[0037] 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] Disclosed herein are rapidly insertable central catheters ("RICCs") including catheter assemblies and methods thereof that address the foregoing. However, it should be

understood the RICCs are but one type of catheter in which the concepts provided herein can be embodied or otherwise incorporated. Indeed, peripherally inserted central catheters ("PICCs"), dialysis catheters, or the like can also embody or otherwise incorporate the concepts provided herein for the RICCs, as well as catheter assemblies and methods thereof.

RICC assemblies

[0044] FIGS. 1-5 illustrate various views of a RICC assembly 100 including a RICC 102, an introducer 104, and a coupling system 106 in accordance with some embodiments. FIG. 6 illustrates a distal-end portion of the RICC assembly 100 in accordance with some embodiments. FIG. 7 illustrates a distal-end portion of a catheter tube 108 of the RICC 102 in accordance with some embodiments. FIGS. 8 and 9 illustrates various transverse cross-sections of the catheter tube 108 in accordance with some embodiments.

[0045] As shown, the RICC assembly 100 includes, in some embodiments, the RICC 102, the introducer 104, and the coupling system 106 configured to couple the RICC 102 and the introducer 104 together. The RICC 102, the introducer 104, and the coupling system 106 are described, in turn, in sections set forth below; however, some crossover between the sections for the RICC 102, the introducer 104, and the coupling system 106 exist in view of the interrelatedness of the RICC 102, the introducer 104, and the coupling system 106 in the RICC assembly 100.

[0046] The RICC 102 includes the catheter tube 108, a catheter hub 110, and one or more extension legs 112.

[0047] The catheter tube 108 includes one or more catheter-tube lumens, a side aperture 114 through a side of the catheter tube 108 in a distal-end portion of the catheter tube 108, and a tip 116 in the distal-end portion of the catheter tube 108.

[0048] The one-or-more catheter-tube lumens can extend through an entirety of the catheter tube 108; however, only one catheter-tube lumen typically extends from a proximal end of the catheter tube 108 to a distal end of the catheter tube 108 in a multiluminal RICC (e.g., a diluminal RICC, a triluminal RICC, a tetraluminal RICC, a pentaluminal RICC, a hexaluminal RICC, etc.). Indeed, the tip 116, typically includes a single lumen therethrough, whether or not the tip 116 is formed integrally with the catheter tube 108 or separately from the catheter tube 108 and coupled thereto. Optionally, the single lumen through the tip 116 can

be referred to as a "tip lumen," particularly if the tip 116 is formed separately from the catheter tube 108 and coupled thereto, the latter of which effectively blocks all catheter-tube lumens at the distal end of the catheter tube 108 excepting that coaxially aligned with the tip lumen.

[0049] The side aperture 114 opens into an introducing lumen 118 of the one-or-more catheter-tube lumens. The introducing lumen 118 extends from at least the side aperture 114 to the distal end of the RICC 102 (e.g., the distal end of the catheter tube 108 or a distal end of the tip 116). The introducing lumen 118 is coincident with a distal-end portion of the one catheter-tube lumen set forth above that typically extends from the proximal end of the catheter tube 108 to the distal end of the catheter tube 108.

[0050] The catheter hub 110 is coupled to a proximal-end portion of the catheter tube 108. The catheter hub 110 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 110 from a proximal end of the catheter hub 110 to a distal end of the catheter hub 110.

[0051] Each extension leg of the one-or-more extension legs 112 is coupled to the catheter hub 110 by a distal-end portion thereof. The one-or-more extension legs 112 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.

[0052] Each extension leg of the one-or-more extension legs 112 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.

[0053] As shown, the RICC 102 can be triluminal including a set of three lumens. The set of three lumens includes, for example, a distal lumen 120, a medial lumen 122, and a proximal lumen 124 formed of fluidly connected portions of three catheter-tube lumens, three hub lumens, and three extension-leg lumens. The distal lumen 120 has a distal-lumen aperture 126 in the distal end of the RICC 102 (e.g., the distal end of the catheter tube 108 or a distal end of the tip 116), the medial lumen 122 has a medial-lumen aperture 127 in the side of the catheter tube 108 distal of the side aperture 114, and the proximal lumen 124 has a proximal-lumen aperture 129 in the side of the catheter tube 108 distal of the side aperture 114 but

proximal of the medial-lumen aperture 127. The introducing lumen 118 of the catheter tube 108 is coincident with a distal-end portion of the distal lumen 120.

[0054] The introducer 104 includes an introducer needle 128 and a guidewire conduit 130 including an access guidewire 132 captively disposed in the guidewire conduit 130 to maintain sterility of the access guidewire 132. The introducer 104 can further include a fluid-pressure indicator 134 operably connected to the introducer needle 128.

[0055] The introducer needle 128 includes a needle hub 136 and a cannula 138 extending from the needle hub 136. The needle hub 136 is translucent and preferably colorless for observing blood flashback from a venipuncture with the cannula 138. When the RICC 102 is in a ready-to-deploy state of the RICC 102 as shown in FIGS. 1-5, the cannula 138 extends at least about 2 - 7 cm from the distal end of the RICC 102 for the venipuncture with the cannula 138. Indeed, the cannula 138 extends through the longitudinal through hole of the distal coupler 146 of the coupling system 106 set forth below, through the side aperture 114 of the catheter tube 108, along the introducing lumen 118 of the catheter tube 108, and through the distal end of the RICC 102 when the RICC assembly 100 is in the ready-to-deploy state thereof.

[0056] When present, the fluid-pressure indicator 134 extends from a side arm 140 of the needle hub 136. The fluid-pressure indicator 134 includes a closed end and an open end fluidly coupled to a needle lumen of the introducer needle 128 by way of a side-arm lumen of the side arm 140. The fluid-pressure indicator 134 is configured as a built-in accidental arterial indicator, wherein blood under sufficient pressure (e.g., arterial blood) can enter the fluid-pressure indicator 134 and compress a column of air within the fluid-pressure indicator 134. However, it is also possible to observe the blood flashback from the venipuncture with the cannula 138 in the fluid-pressure indicator 134.

[0057] The guidewire conduit 130 includes a closed proximal end and a distal-end portion coupled to the needle hub 136 of the introducer needle 128. The guidewire conduit 130 also includes a closed-ended longitudinal slit 142. The access guidewire 132 includes a handle 144 coupled to a proximal-end portion of the access guidewire 132. The handle 144 protrudes through the longitudinal slit 142 for grasping the handle 144 and advancing a distal-end portion of the access guidewire 132 through a distal-end portion of the cannula 138 where the access guidewire 132 resides (e.g., just short of a bevel of the cannula 138) in the ready-to-deploy state of the RICC 102. The foregoing components of the introducer 104 thusly provide a no-

touch mechanism for advancing the access guidewire 132 into the blood-vessel lumen of the patient upon establishing a needle tract thereto. The foregoing components of the introducer 104 also provide a no-touch mechanism for withdrawing the access guidewire 132 from the blood-vessel lumen of the patient, for example, after the catheter tube 108 has been advanced over the access guidewire 132. Advantageously, the closed ends of the longitudinal slit 142 provide stops for the handle 144 protruding through the longitudinal slit 142. The stops prevent the access guidewire 132 from being lost in the blood-vessel lumen of the patient by over advancement of the access guidewire 132, and the stops prevent the access guidewire 132 from being pulled out of the guidewire conduit 130 by over withdrawal of the access guidewire 132, which mitigates contamination.

[0058] The coupling system 106 includes a distal coupler 146 and a proximal coupler 148 configured to couple the RICC 102 and the introducer 104 together by corresponding proximal-end and distal-end portions thereof in the ready-to-deploy state of the RICC assembly 100 while allowing the introducer 104 to slide relative to the RICC 102 (or *vice versa*).

[0059] The distal coupler 146 is slidably attached to the catheter tube 108 proximal of the side aperture 114. The cannula 138 extends through a longitudinal through hole of the distal coupler 146, through the side aperture 114 of the catheter tube 108, along the introducing lumen 118 of the catheter tube 108, and through the distal end of the RICC 102 when the RICC assembly 100 is in a ready-to-deploy state thereof. The distal coupler 146 includes a tab 150 configured to allow a clinician to single handedly advance the RICC 102 off the cannula 138 with a single finger of a hand (e.g., with a flick-type motion of the finger) while holding the guidewire conduit 130 between a thumb and another finger or fingers of the same hand, thereby providing a no-touch mechanism for advancing the RICC 102, specifically the distal-end portion of the catheter tube 108, over the cannula 138 and into the blood-vessel lumen of the patient.

[0060] The proximal coupler 148 is removably attached to the catheter hub 110 and slidably attached to the guidewire conduit 130. Indeed, the proximal coupler 148 includes posts 149 and the catheter hub 110 includes a suture wing with suture-wing holes. The posts 149 of the proximal coupler 148 are disposed in the suture-wing holes of the catheter hub 110 in the ready-to-deploy state of the RICC assembly 100. The proximal coupler 148 also includes sloped sides configured to push the guidewire conduit 130 out of the proximal coupler 148 when a proximal coupler-interacting portion of the introducer 104 (e.g., the needle hub 136 of

the introducer needle 128, a wider portion of the guidewire conduit 130 such as a coupling that couples the guidewire conduit 130 to the needle hub 136, etc.) interacts with the sloped sides while the cannula 138 is withdrawn from the side aperture 114 of the catheter tube 108.

[0061] The RICC 102 can further includes a sterile barrier 152 (e.g., a bag, a casing, etc.) configured to maintain sterility of the catheter tube 108 between the distal and proximal couplers 146 and 148 prior to insertion of the catheter tube 108 into the blood-vessel lumen of the patient. In the ready-to-deploy state of the RICC assembly 100, the sterile barrier 152 is over the catheter tube 108, between the distal coupler 146 and the proximal coupler 148, and coupled to the distal and proximal couplers 146 and 148. The sterile barrier 152 is configured to split apart when the proximal coupler 148 is removed from the catheter hub 110 and the sterile barrier 152 is pulled away from the catheter tube 108, thereby providing a no-touch mechanism for removing the sterile barrier 152 from the catheter tube 108. The sterile barrier 152 has sufficient tensile strength to pull the distal coupler 146 off the catheter tube 108 without breaking when the sterile barrier 152 splits down to the distal coupler 146 while being pulled away from the catheter tube 108.

Methods

[0062] A method of the RICC assembly 100 includes a method for inserting the RICC 102 into a blood-vessel lumen of a patient. Such a method includes, in some embodiments, a RICC assembly-obtaining step, a needle tract-establishing step, a first catheter-advancing step; and a cannula-withdrawing step.

[0063] The RICC assembly-obtaining step includes obtaining the RICC assembly 100. As set forth above, the RICC assembly 100 includes the RICC 102, the introducer 104 including the introducer needle 128, and the coupling system 106 including the distal coupler 146 that couples the RICC 102 and the introducer 104 together by the distal-end portions thereof in the ready-to-deploy state of the RICC assembly 100.

[0064] The method can further include a cannula-ensuring step of ensuring the cannula 138 extends at least about 2 - 7 cm beyond the distal end of the RICC 102 before the needle tract-establishing step. As set forth above, the cannula 138 extends through the longitudinal through hole of the distal coupler 146, through the side aperture 114 in the distal-end portion of the catheter tube 108 of the RICC 102, along the introducing lumen 118 of the catheter tube 108, and out the distal end of the RICC 102.

[0065] The needle tract-establishing step includes establishing a needle tract from an area of skin to the blood-vessel lumen of the patient with the cannula 138 of the introducer needle 128. The needle tract-establishing step can also include ensuring blood flashes back into the needle hub 136 of the introducer needle 128, the side arm 140 of the needle hub 136, or the fluid-pressure indicator 134 extending from the side arm 140 of the needle hub 136.

[0066] The method can further include an access guidewire-advancing step of advancing the access guidewire 132 by the handle 144 into the blood-vessel lumen beyond the distal end of the cannula 138. As set forth above, the handle 144 is coupled to the proximal-end portion of the access guidewire 132 and protrudes through the longitudinal slit 142 in the guidewire conduit 130, which is coupled to the introducer needle 128. The access guidewire-advancing step should be performed before the first catheter-advancing step such that the distal-end portion of the catheter tube 108 can be advanced over the access guidewire 132 as well. The access guidewire 132 provides the catheter tube 108 columnar strength for the first catheter-advancing step.

[0067] The first catheter-advancing step includes advancing the distal-end portion of the catheter tube 108 into the blood-vessel lumen over the cannula 138. For example, the first catheter-advancing step can include advancing the catheter tube 108 into the blood-vessel lumen with a single finger of a hand (e.g., with a flick-type motion of the finger) while holding the guidewire conduit 130 between a thumb and another finger or fingers of the same hand. The distal coupler 146 includes the tab 150 configured for advancing the catheter tube 108 into the blood-vessel lumen with the single finger.

[0068] The first catheter-advancing step can also include advancing the catheter tube 108 into the blood-vessel lumen until the proximal coupler 148 of the coupling system 106 pushes the guidewire conduit 130 out of the proximal coupler 148. As set forth above, the introducer 104 includes the proximal coupler-interacting portion (e.g., the needle hub 136 of the introducer needle 128, a wider portion of the guidewire conduit 130 such as a coupling that couples the guidewire conduit 130 to the needle hub 136, etc.) configured to interact with the sloped sides of the proximal coupler 148 and push the guidewire conduit 130 out of the proximal coupler 148.

[0069] The method can further include an access guidewire-withdrawing step of withdrawing the access guidewire 132 by the handle 144 into the guidewire conduit 130. The

access guidewire-withdrawing step can be performed after the first catheter-advancing step such as after the distal-end portion of the catheter tube 108 is suitably placed within the blood-vessel lumen over both the cannula 138 and the access guidewire 132.

[0070] The cannula-withdrawing step includes withdrawing the cannula 138 from the introducing lumen 118 by way of the side aperture 114 of the catheter tube 108. Like the access guidewire-withdrawing step, the cannula-withdrawing step can be performed after the first catheter-advancing step such as after the distal-end portion of the catheter tube 108 is suitably placed within the blood-vessel lumen over both the cannula 138 and the access guidewire 132.

[0071] The method can further include an introducer-removing step of completely removing the introducer 104 from the RICC assembly 100 after the guidewire conduit 130 is pushed out of the proximal coupler 148. The cannula-withdrawing step can be part of the introducer-removing step.

[0072] The method can further include a maneuver guidewire-advancing step of advancing a maneuver guidewire into the blood-vessel lumen by way of, for example, the distal-lumen aperture 126 in the distal end of the RICC 102. As set forth above, the introducing lumen 118 of the catheter tube 108 is coincident with the distal-end portion of the distal lumen 120. As such, the introducer-removing step of completely removing the introducer 104 from the RICC assembly 100 should be performed before the maneuver guidewire-advancing step to ensure the distal lumen, or the introducing lumen 118 thereof, is free of both the cannula 138 and the access guidewire 132. That said, the maneuver guidewire-advancing step can be partially performed before the introducer-removing step. For example, the maneuver guidewire-advancing step can include a maneuver guidewire-loading step of loading the maneuver guidewire into the distal lumen 120 without advancing the maneuver guidewire into the portion of the distal lumen 120 coincident with the introducing lumen 118.

[0073] The maneuver guidewire of the maneuver guidewire-advancing step can have a length sufficient for advancing the catheter tube 108 of the RICC 102 to the lower ⅓ of the superior vena cava ("SVC") of the heart. The maneuver guidewire can be part of a guidewire management device configured to maintain sterility of the maneuver guidewire and facilitate the maneuver guidewire-advancing step. Alternatively, the maneuver guidewire is a stand-alone maneuver guidewire packaged in a sterile barrier (e.g., a bag, a casing, etc.) configured to maintain sterility of the maneuver guidewire. Such a maneuver guidewire can includes a

stopping means to stop advancement of the maneuver guidewire during the maneuver guidewire-advancing step, which obviates losing the maneuver guidewire in the patient. The stopping means can be a ball, a slug, or the like coupled to a proximal-end portion of the maneuver guidewire configured to not pass through, for example, the Luer connector of the extension leg in which at least the proximal-end portion of the maneuver guidewire is disposed during the maneuver guidewire-advancing step.

[0074] The method can further include a second catheter-advancing step of advancing the distal-end portion of the catheter tube 108 further into the blood-vessel lumen over the maneuver guidewire such as to the SVC. Concomitantly, the second catheter-advancing step includes sliding the distal coupler 146 proximally towards the proximal coupler 148 to uncover the catheter tube 108. As set forth above, the catheter tube 108 is covered by the sterile barrier 152 between the proximal coupler 148 and the distal coupler 146 in the ready-to-deploy state of the RICC assembly 100.

[0075] The method can further include a sterile barrier-removing step of removing the sterile barrier 152 and a remainder of the coupling system 106 from the RICC 102. The sterile barrier-removing step includes removing the proximal coupler 148 from the catheter hub 110 of the RICC 102 (e.g., pulling the posts 149 of the proximal coupler out of the suture-wing holes of the catheter hub 110), pulling the sterile barrier 152 away from the catheter tube 108 to split the sterile barrier 152 apart along its length, and removing the distal coupler 146 from the catheter tube 108 to which the distal coupler 146 is slidably attached.

[0076] The method can further include a maneuver guidewire-withdrawing step of withdrawing the maneuver guidewire from the blood-vessel lumen of the patient, as well as withdrawing the maneuver guidewire from the RICC 102.

[0077] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.

CLAIMS

What is claimed is:

1. A rapidly insertable central catheter ("RICC") assembly, comprising:
a RICC including:
a catheter tube including a side aperture through a side of the catheter tube in a distal-end portion thereof, the side aperture opening into an introducing lumen of the catheter tube that extends from at least the side aperture to a distal end of the RICC;
a catheter hub coupled to a proximal-end portion of the catheter tube; and
one or more extension legs, each extension leg of the one-or-more extension legs coupled to the catheter hub by a distal-end portion thereof;
an introducer including an introducer needle having a cannula; and
a coupling system including a distal coupler slidably attached to the catheter tube proximal of the side aperture, the cannula extending through a longitudinal through hole of the distal coupler, through the side aperture of the catheter tube, along the introducing lumen of the catheter tube, and through the distal end of the RICC when the RICC assembly is in a ready-to-deploy state thereof.

2. The RICC assembly of claim 1, wherein the cannula of the introducer needle extends at least about 2 - 7 cm from the distal end of the RICC in the ready-to-deploy state of the RICC for a venipuncture with the cannula.

3. The RICC assembly of either claim 1 or 2, the introducer further including:
a guidewire conduit coupled to a needle hub of the introducer needle; and
an access guidewire disposed in the guidewire conduit, the guidewire conduit configured to maintain sterility of the access guidewire.

4. The RICC assembly of claim 3, the distal coupler including a tab configured to allow a clinician to single handedly advance the RICC off the cannula with a single finger of a hand while holding the guidewire conduit between a thumb and another finger or fingers of the hand.

5. The RICC assembly of either claim 3 or 4, wherein the guidewire conduit includes a longitudinal slit and the access guidewire includes a handle coupled to a proximal-end portion of the access guidewire, the handle protruding through the longitudinal slit for grasping the handle and advancing the access guidewire through the distal end of the RICC without directly touching the access guidewire.

6. The RICC assembly of claim 5, wherein the longitudinal slit includes closed ends configured to provide stops for the handle that prevent loss of the access guidewire in a blood-vessel lumen of a patient by over advancement of the access guidewire or withdrawal of the access guidewire from the guidewire conduit by over withdrawal of the access guidewire.

7. The RICC assembly of any claim of claims 3-6, the introducer further including a fluid-pressure indicator extending from a side arm of the needle hub, the fluid-pressure indicator fluidly coupled to a needle lumen of the introducer needle by way of a side-arm lumen of the side arm for observing blood flashback.

8. The RICC assembly of any claim of claims 3-7, the coupling system further including a proximal coupler removably attached to the catheter hub and slidably attached to the guidewire conduit, the coupling system configured to couple the RICC and the introducer together by corresponding proximal-end and distal-end portions thereof in the ready-to-deploy state of the RICC assembly while allowing the introducer to slide relative to the RICC.

9. The RICC assembly of claim 8, wherein the proximal coupler includes sloped sides configured to push the guidewire conduit out of the proximal coupler when a proximal coupler-interacting portion of the introducer interacts with the sloped sides while the cannula is withdrawn from the side aperture of the catheter tube.

10. The RICC assembly of either claim 8 or 9, wherein the proximal coupler includes posts and the catheter hub includes a suture wing with suture-wing holes, the posts disposed in the suture-wing holes in the ready-to-deploy state of the RICC assembly.

11. The RICC assembly of any claim of claims 8-10, the RICC further including a sterile barrier over the catheter tube between the proximal coupler and the distal coupler to which the sterile barrier is coupled, the sterile barrier configured to split apart when the proximal coupler is removed from the catheter hub and the sterile barrier is pulled away from the catheter tube.

12. The RICC assembly of claim 11, wherein the sterile barrier has sufficient tensile strength to pull the distal coupler off the catheter tube without breaking when the sterile barrier splits down to the distal coupler while being pulled away from the catheter tube.

13. The RICC assembly of any claim of claims 1-12, wherein the RICC includes a set of three lumens including a distal lumen, a medial lumen, and a proximal lumen formed of fluidly connected portions of three catheter-tube lumens, three hub lumens, and three extension-leg lumens, the introducing lumen of the catheter tube coincident with a distal-end portion of the distal lumen.

14. The RICC assembly of claim 13, wherein the distal lumen has a distal-lumen aperture in a distal end of the RICC, the medial lumen has a medial-lumen aperture in the side of the catheter tube distal of the side aperture, and the proximal lumen has a proximal-lumen aperture in the side of the catheter tube distal of the side aperture but proximal of the medial-lumen aperture.

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

obtaining a RICC assembly including the RICC, an introducer including an introducer needle, and a coupling system including a distal coupler that couples the RICC and the introducer together by distal-end portions thereof in a ready-to-deploy state of the RICC assembly;

establishing a needle tract from an area of skin to the blood-vessel lumen of the patient with a cannula of the introducer needle, the cannula extending through a longitudinal through hole of the distal coupler, through a side aperture in a distal-end portion of a catheter tube of the RICC, along an introducing lumen of the catheter tube, and out a distal end of the RICC;

advancing the distal-end portion of the catheter tube into the blood-vessel lumen over the cannula; and

withdrawing the cannula from the introducing lumen by way of the side aperture of the catheter tube.

16. The method of claim 15, further comprising ensuring the cannula extends at least about 2 - 7 cm beyond the distal end of the RICC before establishing the needle tract.

17. The method of either claim 15 or 16, wherein establishing the needle tract includes ensuring blood flashes back into a needle hub of the introducer needle, a side arm of the needle hub, or a fluid-pressure indicator extending from the side arm of the needle hub.

18. The method of any claim of claims 15-17, further comprising advancing an access guidewire by a handle coupled to a proximal-end portion of the access guidewire into the blood-vessel lumen beyond a distal end of the cannula, the handle protruding through a longitudinal slit in a guidewire conduit coupled to the introducer needle.

19. The method of claim 18, wherein advancing the distal-end portion of the catheter tube into the blood-vessel lumen over the cannula includes advancing the catheter tube into the blood-vessel lumen with a single finger of a hand while holding the guidewire conduit between a thumb and another finger or fingers of the hand, the distal coupler including a tab configured for advancing the catheter tube into the blood-vessel lumen with the single finger.

20. The method of either claim 18 or 19, wherein advancing the distal-end portion of the catheter tube into the blood-vessel lumen over the cannula includes advancing the catheter tube into the blood-vessel lumen until a proximal coupler of the coupling system slidably attached to the guidewire conduit pushes the guidewire conduit out of the proximal coupler, the introducer including a proximal coupler-interacting portion configured to interact with sloped sides of the proximal coupler and push the guidewire conduit out of the proximal coupler.

21. The method of claim 20, further comprising advancing a maneuver guidewire into the blood-vessel lumen by way of a distal lumen having a distal-lumen aperture in the distal end of the RICC, the introducing lumen of the catheter tube coincident with a distal-end portion of the distal lumen.

22. The method of claim 21, further comprising advancing the distal-end portion of the catheter tube further into the blood-vessel lumen over the maneuver guidewire and concomitantly sliding the distal coupler proximally towards the proximal coupler to uncover the catheter tube, the catheter tube covered by a sterile barrier between the proximal coupler and the distal coupler in a ready-to-deploy state of the RICC assembly.

23. The method of claim 22, further comprising removing the sterile barrier and a remainder of the coupling system from the RICC by removing the proximal coupler from a

catheter hub of the RICC, pulling the sterile barrier away from the catheter tube to split the sterile barrier apart, and removing the distal coupler from the catheter tube to which the distal coupler is slidably attached.