

TWO-PIECE CATHETERS AND METHODS THEREOF**PRIORITY**

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 63/045,613, filed June 29, 2020, which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] Existing catheters are manufactured as whole ready-to-use catheters. Such catheters can have lengths ranging from 30 to 40 cm as measured from the proximal end to the distal end of any such catheter. Rapidly insertable central catheters (“RICCs”) currently under development are introduced over introducer needles; however, introduction of the RICCs over 30-40 cm introducer needles could be cumbersome for some clinicians. In addition, it could be difficult to timely discern whether blood flashback has occurred and access to a blood-vessel lumen established during any given RICC introduction with a 30-40 cm introducer needle. As such, catheters such as RICCs would benefit from being shorter than the existing catheters for at least their introduction.

[0003] Disclosed herein are two-piece catheters and methods thereof that address the foregoing need.

SUMMARY

[0004] Disclosed herein is a two-piece catheter including, in some embodiments, a proximal catheter piece and a distal catheter piece. The proximal catheter piece includes a proximal catheter-hub piece of a two-piece catheter hub and one or more extension legs. The one-or-more extension legs respectively include one or more extension-leg lumens. Each extension leg of the one-or-more extension legs is coupled to the proximal catheter-hub piece by a distal-end portion of the extension leg. The distal catheter piece includes a distal catheter-hub piece of the two-piece catheter hub and a catheter tube. The catheter tube includes one or more catheter-tube lumens. The catheter tube is coupled to the distal catheter-hub piece by a proximal-end portion of the catheter tube. The two-piece catheter has a connected state in which the proximal catheter-hub piece is connected to the distal catheter-hub piece such that the one-or-more catheter-tube lumens are respectively fluidly connected to the one-or-more extension-leg lumens across the two-piece catheter hub.

[0005] In some embodiments, the proximal catheter-hub piece includes one or more rigid tubes respectively disposed in one or more proximal catheter-hub lumens. The one-or-more rigid tubes extend from a distal end of the proximal catheter-hub piece.

[0006] In some embodiments, the distal catheter-hub piece includes one or more seals respectively disposed in one or more distal catheter-hub lumens. The one-or-more seals are configured to sit between the one-or-more rigid tubes and the one-or-more distal catheter-hub lumens, respectively, in the connected state of the two-piece catheter assembly.

[0007] In some embodiments, the distal catheter-hub piece includes one or more rigid tubes respectively disposed in one or more distal catheter-hub lumens. The one-or-more rigid tubes extend from a proximal end of the distal catheter-hub piece.

[0008] In some embodiments, the proximal catheter-hub piece includes one or more seals respectively disposed in one or more proximal catheter-hub lumens. The one-or-more seals are configured to sit between the one-or-more rigid tubes and the one-or-more proximal catheter-hub lumens, respectively, in the connected state of the two-piece catheter assembly.

[0009] In some embodiments, the distal catheter-hub piece includes an integral clip having tabbed arms proximally extending from the distal catheter-hub piece. The proximal catheter-hub piece includes surface recesses configured to seat tabs of the arms therein in the connected state of the two-piece catheter assembly.

[0010] In some embodiments, the proximal catheter-hub piece includes surface-undercut grooves configured to seat tips of the arms therein in the connected state of the two-piece catheter assembly.

[0011] In some embodiments, the arms extend from major sides of the distal catheter-hub piece and the surface recesses are in major surfaces of the proximal catheter-hub piece.

[0012] In some embodiments, the arms extend from minor sides of the distal catheter-hub piece and the surface recesses are in minor surfaces of the proximal catheter-hub piece.

[0013] In some embodiments, the proximal catheter-hub piece includes an integral clip having tabbed arms distally extending from the proximal catheter-hub piece. The distal catheter-hub piece includes surface recesses configured to seat tabs of the arms therein in the connected state of the two-piece catheter assembly.

[0014] In some embodiments, the distal catheter-hub piece includes surface-undercut grooves configured to seat tips of the arms therein in the connected state of the two-piece catheter assembly.

[0015] In some embodiments, the arms extend from major sides of the proximal catheter-hub piece and the surface recesses are in major surfaces of the distal catheter-hub piece.

[0016] In some embodiments, the arms extend from minor sides of the proximal catheter-hub piece and the surface recesses are in minor surfaces of the distal catheter-hub piece.

[0017] In some embodiments, the two-piece catheter includes a set of three lumens in the connected state of the two-piece catheter assembly. The set of three lumens includes a primary lumen, a secondary lumen, and a tertiary lumen.

[0018] In some embodiments, the primary lumen has a primary-lumen aperture in a distal end of the two-piece catheter, the secondary lumen has a secondary-lumen aperture in a side of the catheter tube proximal of the primary-lumen aperture, and the tertiary lumen has a tertiary-lumen aperture in the side of the catheter tube proximal of the secondary-lumen aperture.

[0019] Also disclosed is a method of using the two-piece catheter including, in some embodiments, a catheter-obtaining step, a needle tract-establishing step, a needle-withdrawing step, and a catheter hub-clipping step. The catheter-obtaining step includes obtaining a two-piece catheter including a distal catheter piece and a proximal catheter piece. The distal catheter piece includes a catheter tube coupled to a distal catheter-hub piece by a proximal-end portion of the catheter tube. The needle tract-establishing step includes establishing a needle tract from an area of skin to a blood-vessel lumen of a patient with an introducer needle disposed in an introducing lumen of the distal catheter piece. The introducer needle is disposed in the distal catheter piece such that a needle tip of the introducer needle extends out of an introducing-lumen aperture of the introducing lumen. The needle-withdrawing step includes withdrawing the introducer needle from the introducing lumen. The catheter hub-clipping step includes clipping together the distal catheter-hub piece and a proximal catheter-hub piece. Upon clipping together the distal catheter-hub piece and the proximal catheter-hub piece, one or more catheter-tube lumens of the catheter tube respectively connect to one or more extension-leg

lumens of one or more extension legs coupled to the proximal catheter-hub piece of the proximal catheter piece.

[0020] In some embodiments, the catheter hub-clipping step includes clipping an integral clip of the distal catheter-hub piece onto the proximal catheter-hub piece. Upon clipping the integral clip of the distal catheter-hub piece onto the proximal catheter-hub piece, tabs of arms of the integral clip seat in surface recesses in major or minor surfaces of the proximal catheter-hub piece.

[0021] In some embodiments, the catheter hub-clipping step includes clipping an integral clip of the proximal catheter-hub piece onto the distal catheter-hub piece. Upon clipping the integral clip of the proximal catheter-hub piece onto the distal catheter-hub piece, tabs of arms of the integral clip seat in surface recesses in major or minor surfaces of the distal catheter-hub piece.

[0022] In some embodiments, the method further includes an access guidewire-advancing step, a first catheter-advancing step, and an access guidewire-withdrawing step. The access guidewire-advancing step includes advancing an access guidewire disposed in a needle lumen of the introducer needle into the blood-vessel lumen beyond the needle tip. The first catheter-advancing step includes advancing a distal-end portion of a first section of the catheter tube into the blood-vessel lumen over the introducer needle using the access guidewire as a guide. The access guidewire-withdrawing step includes withdrawing the access guidewire together with the introducer needle when withdrawing the introducer needle from the introducing lumen.

[0023] In some embodiments, the method further includes a maneuver guidewire-advancing step, a second catheter-advancing step, and a maneuver guidewire-withdrawing step. The maneuver guidewire-advancing step includes advancing a maneuver guidewire into the blood-vessel lumen and to a target location by way of a primary lumen of the two-piece catheter. The primary lumen is established by clipping together the distal catheter-hub piece and the proximal catheter-hub piece. The second catheter-advancing step includes advancing a remainder of the distal-end portion of the first section of the catheter tube into the blood-vessel lumen up to a proximal-end portion of a second section of the catheter tube using the maneuver guidewire as a guide. Advancing the catheter in accordance with the second catheter-advancing step is stopped when a distal end of the two-piece catheter arrives at the target location. The

maneuver guidewire-withdrawing step includes withdrawing the maneuver guidewire and leaving the two-piece catheter in place in the patient.

[0024] 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

[0025] FIG. 1 illustrates a two-piece catheter in an unconnected state in accordance with some embodiments.

[0026] FIG. 2 illustrates the two-piece catheter in a connected state in accordance with some embodiments.

[0027] FIG. 3 illustrates a proximal catheter-hub piece and a distal catheter-hub piece of a two-piece catheter hub in the unconnected state in accordance with some embodiments.

[0028] FIG. 4 illustrates the proximal catheter-hub piece and the distal catheter-hub piece in the connected state in accordance with some embodiments.

[0029] FIG. 5 illustrates another proximal catheter-hub piece and another distal catheter-hub piece of another two-piece catheter hub in the connected state in accordance with some embodiments.

[0030] FIG. 6 illustrates a distal-end portion of a catheter tube of the two-piece catheter of FIGS. 1 and 2 in accordance with some embodiments.

[0031] FIG. 7 illustrates a first transverse cross section of the catheter tube of FIG. 6 in accordance with some embodiments.

[0032] FIG. 8 illustrates a second transverse cross section of the catheter tube of FIG. 6 in accordance with some embodiments.

[0033] FIG. 9 illustrates a third transverse cross section of the catheter tube of FIG. 6 in accordance with some embodiments.

[0034] FIG. 10 illustrates a fourth transverse cross section of the catheter tube of FIG. 6 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] As set forth above, existing catheters are manufactured as whole ready-to-use catheters having lengths ranging from 30 to 40 cm. The RICCs currently under development are introduced over introducer needles; however, introduction of the RICCs over 30-40 cm introducer needles could be cumbersome for some clinicians. In addition, it could be difficult to timely discern whether blood flashback has occurred and access to a blood-vessel lumen established during any given RICC introduction with a 30-40 cm introducer needle. As such, catheters such as RICCs, but not limited thereto, would benefit from being shorter than the existing catheters for at least their introduction. Disclosed herein are two-piece catheters and methods thereof that address the foregoing need.

[0040] 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.

Two-piece catheters

[0041] FIGS. 1 and 2 illustrate a two-piece catheter 100 in an unconnected state and a connected state in accordance with some embodiments.

[0042] As shown, the two-piece catheter 100 includes, in such embodiments, two pieces including a proximal catheter piece 102 and a distal catheter piece 110. It should be understood the two-piece catheter 100 can include different pieces or additional pieces to those in the illustrated embodiments. Indeed, the “two pieces” of the two-piece catheter 100 generally refer to at least two pieces resulting from dividing such a catheter along its length, in this case, at the two-piece catheter hub 106 set forth below.

[0043] The proximal catheter piece 102 includes a proximal catheter-hub piece 104 of a two-piece catheter hub 106 and one or more extension legs 108. The distal catheter piece 110 includes a distal catheter-hub piece 112 of the two-piece catheter hub 106 and a catheter tube 114. The two-piece catheter hub 106 is described first followed by description for the catheter tube 114, the one-or-more extension legs 108, and other aspects of the two-piece catheter 100.

[0044] FIGS. 3 and 4 illustrate the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 of the two-piece catheter hub 106 in the unconnected state and the connected state of the two-piece catheter 100 in accordance with some embodiments.

[0045] The proximal catheter-hub piece 104 of the two-piece catheter hub 106 includes one or more rigid tubes 116 (e.g., metal tubes) respectively disposed in one or more proximal catheter-hub lumens 118, thereby effectively extending the one-or-more proximal catheter-hub lumens 118 in connectors. The proximal catheter-hub piece 104 can be molded over the one-or-more rigid tubes 116 during manufacturing such that the one-or-more rigid tubes 116 extend from a distal end of the proximal catheter-hub piece 104. Alternatively, the one-or-more rigid tubes 116 are inserted into the one-or-more proximal catheter-hub lumens 118 during manufacturing such that the one-or-more rigid tubes 116 extend from the distal end of the proximal catheter-hub piece 104.

[0046] The distal catheter-hub piece 112 of the two-piece catheter hub 106 includes one or more distal catheter-hub lumens 120 including one or more mechanical gaskets 122 respectively disposed therein. The one-or-more mechanical gaskets 122 are configured to sit between abluminal surfaces of the one-or-more rigid tubes 116 and luminal surfaces of the one-or-more distal catheter-hub lumens 120 in the connected state of the two-piece catheter 100. The one-or-more mechanical gaskets 122 include, but are not limited to, 'O'-rings or cylinders. The one-or-more mechanical gaskets 122 can be formed of a compressible polymeric material such as a silicone. Use of a compressible polymeric material such as silicone is advantageous in that axial compression of the one-or-more mechanical gaskets 122 by compression annuli 123 when inserting the one-or-more rigid tubes 116 into the one-or-more distal catheter-hub lumens 120 forces the one-or-more mechanical gaskets 122 to radially expand in the limited space between the abluminal surfaces of the one-or-more rigid tubes 116 and the luminal surfaces of the one-or-more distal catheter-hub lumens 120, thereby creating one-or-more fluid-tight luminal seals between the proximal catheter-hub piece 104 and the distal catheter-

hub piece 112 of the two-piece catheter hub 106 and respectively continuing the one-or-more proximal catheter-hub lumens 118 into the one-or-more distal catheter-hub lumens 120.

[0047] In an alternative to the foregoing, the distal catheter-hub piece 112 can instead include the one-or-more rigid tubes 116 respectively disposed in the one-or-more distal catheter-hub lumens 120. Likewise, the proximal catheter-hub piece 104 can instead include the one-or-more mechanical gaskets 122 respectively disposed in the one-or-more proximal catheter-hub lumens 118. It should be understood the foregoing description for the one-or-more rigid tubes 116, the one-or-more mechanical gaskets 122, and the like for the illustrated embodiments of the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 apply to the one-or-more rigid tubes 116 when part of the distal catheter-hub piece 112, the one-or-more mechanical gaskets 122 when part of the proximal catheter-hub piece 104, and the like.

[0048] Continuing with the illustrated embodiments of the proximal catheter-hub piece 104 and the distal catheter-hub piece 112, the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 include complementary connectors of a connection system configured to securely and, in some embodiments, irreversibly connect the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 in the connected state of the two-piece catheter 100. “Irreversibly” connecting the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 in this context should be understood to mean the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 cannot be disconnected without tools or damage to the proximal catheter-hub piece 104 or the distal catheter-hub piece 112.

[0049] As to the connection system, the distal catheter-hub piece 112 can include an integral clip molded together with the distal catheter-hub piece 112 itself, the integral clip having tabbed arms 124 proximally extending from the distal catheter-hub piece 112. The proximal catheter-hub piece 104 can include complementary receivers such as surface recesses 126 configured to seat both the tabbed arms 124 and tabs 128 of the tabbed arms 124 therein in the connected state of the two-piece catheter 100. As best shown in FIG. 3, the tabbed arms 124 can extend from major sides of the distal catheter-hub piece 112 and the surface recesses 126 can be in major surfaces of the proximal catheter-hub piece 104. However, the tabbed arms 124 can alternatively extend from minor sides of the distal catheter-hub piece 112 and the surface recesses 126 can be in minor surfaces of the proximal catheter-hub piece 104. Due to greater design space across a width of the two-piece catheter hub 106, the complementary

receivers can instead be longitudinal cavities inboard of the minor surfaces of the proximal catheter-hub piece 104 into which the tabbed arms 124 extending from the minor sides of the distal catheter-hub piece 112 are configured to insert, which is similar to that of common plastic buckles on backpacks and the like.

[0050] FIG. 5 illustrates another proximal catheter-hub piece 130 and another distal catheter-hub piece 132 of another two-piece catheter hub 134 in the connected state of the two-piece catheter 100 in accordance with some embodiments.

[0051] As to irreversibly connecting the proximal catheter-hub piece 104 and the distal catheter-hub piece 112, the connection system can include additional features between the proximal catheter-hub piece 104 and the distal catheter-hub piece 112 configured for irreversibly connecting the proximal catheter-hub piece 104 and the distal catheter-hub piece 112. For example, the tabbed arms 124 of the distal catheter-hub piece 112 can include chamfered tips 136 like the tabbed arms 138 of the distal catheter-hub piece 132. The proximal catheter-hub piece 104 can include complementary receivers such as surface-undercut grooves 140 like those of the proximal catheter-hub piece 130, which are configured to seat therein the chamfered tips 136 of the tabbed arms 138 in the connected state of the two-piece catheter 100. When the chamfered tips 136 of the tabbed arms 138 are seated in the surface-undercut grooves 140, the tabbed arms 138 of the distal catheter-hub piece 132 cannot be readily lifted out of the complementary receivers of the proximal catheter-hub piece 130 without tools or damage to the proximal catheter-hub piece 130 or the distal catheter-hub piece 132, thereby irreversibly connecting the proximal catheter-hub piece 130 and the distal catheter-hub piece 132 in the connected state of the two-piece catheter 100.

[0052] In an alternative to the foregoing, the proximal catheter-hub piece 104 can instead include the integral clip having the tabbed arms 124 and, optionally, the chamfered tips 136 of the tabbed arms 138. Indeed, provided the one-or-more rigid tubes 116 are also disposed in the one-or-more proximal catheter-hub lumens 118 of the proximal catheter-hub piece 104, the integral clip effectively protects the one-or-more rigid tubes 116 from inadvertent damage. Likewise, the distal catheter-hub piece 112 can instead include the complementary receivers including the surface recesses 126 configured to seat the tabbed arms 124 and, optionally, the surface-undercut grooves 140 configured to seat the chamfered tips 136 of the tabbed arms 138. It should be understood the foregoing description for the tabbed arms 124 or 138, the complementary receivers, and the like for the illustrated embodiments of the proximal catheter-

hub piece 104 and the distal catheter-hub piece 112 apply to the tabbed arms 124 or 138 when part of the proximal catheter-hub piece 104, the complementary receivers when part of the distal catheter-hub piece 112, and the like.

[0053] FIG. 6 illustrates a distal-end portion of the catheter tube 114 of the two-piece catheter 100 in accordance with some embodiments. FIGS. 7-10 illustrate various transverse cross sections of the catheter tube 114 in accordance with some embodiments.

[0054] The catheter tube 114 is coupled to the distal catheter-hub piece 112 by a proximal-end portion of the catheter tube 114. As such, the one-or-more distal catheter-hub lumens 120 respectively continue as one or more catheter-hub lumens.

[0055] The catheter tube 114 can include a hard portion and a soft portion, wherein “hard” and “soft” are used in a relative sense in that the hard portion of the catheter tube 114 is harder than the soft portion of the catheter tube 114. For example, when the catheter tube 114 is part of a two-piece RICC, the catheter tube 114 includes the foregoing hard and soft portions; otherwise, the catheter tube 114 can be relatively soft with a compliance sufficient to advance the catheter tube 114 over a maneuver guidewire through a vasculature of a patient to a target location (e.g., the superior vena cava [“SVC”]).

[0056] The hard portion of the catheter tube 114 includes a first section 142 in a distal-end portion of the catheter tube 114, whereas the soft portion of the catheter tube 114 includes a second section 144 extending from the proximal-end portion of the catheter tube 114 to the distal-end portion thereof but proximal of the first section 142. Notwithstanding a tapered junction 146 of the catheter tube 114 including a proximal-end portion of the hard portion of the catheter tube 114 disposed therein, the soft portion of the catheter tube 114 is generally considered to include the junction 146 in view of its construction. Together, the foregoing arrangement of the first section 142 of the catheter tube 114, the second section 144 of the catheter tube 114, and the junction 146 possess both a column strength sufficient to prevent buckling of the catheter tube 114 when inserted into an insertion site established by a percutaneous puncture and a compliance sufficient to advance the catheter tube 114 through a vasculature of a patient to a target location (e.g., the SVC).

[0057] The first section 142 of the catheter tube 114 is in the distal-end portion of the catheter tube 114. The first section 142 includes a distal tip 148 having a relatively short taper configured to continue from a beveled tip of an introducer needle to an outer diameter of a

remainder of the first section 142 when the introducer needle is disposed in the catheter tube 114 of the distal catheter piece 110. The short taper of the distal tip 148 is configured for immediate dilation of tissue about a percutaneous puncture established with the introducer needle up to the outer diameter of the remainder of the first section 142 of the catheter tube 114. The first section 142 also includes a proximal-end portion disposed in the receptacle of the junction 146 and fixedly coupled (e.g., solvent bonded, adhered, welded, etc.) thereto.

[0058] The first section 142 of the catheter tube 114 is formed of a first polymeric material having a first durometer. The first polymeric material can be polytetrafluoroethylene, polypropylene, or polyurethane, but the first polymeric material is not limited to the foregoing polymers. Polyurethane is advantageous in that the first section 142 of the catheter tube 114 can be relatively rigid at room-temperature but become more flexible *in vivo* at body temperature, which reduces irritation to vessel walls and phlebitis.

[0059] The second section 144 of the catheter tube 114 extends from the proximal-end portion of the catheter tube 114 to the distal-end portion thereof but proximal of the first section 142 of the catheter tube 114. The second section 144 includes a distal end coupled to the junction 146 and the proximal-end portion disposed in the distal catheter-hub piece 112 and fixedly coupled (e.g., solvent bonded, welded, adhered, etc.) thereto.

[0060] The second section 144 of the catheter tube 114 is formed of a second polymeric material having a second durometer less than the first durometer. The second polymeric material can be polyvinyl chloride, polyethylene, polyurethane, or silicone, but the second polymeric material is not limited to the foregoing polymers. In addition to that set forth above for polyurethane in the first section 142 of the catheter tube 114, polyurethane is advantageous in that it can be less thrombogenic than some other polymers.

[0061] The junction 146 of the catheter tube 114 couples the first and second sections 142 and 144 of the catheter tube 114 together. The junction 146 includes a receptacle in a distal-end portion including the proximal-end portion of the first section 142 of the catheter tube 114 disposed therein and fixedly coupled (e.g., solvent bonded, welded, adhered, etc.) thereto. The junction 146 also includes a flat-faced proximal end fixedly coupled (e.g., solvent bonded, welded, adhered, etc.) to a flat-faced distal end of the second section 144 of the catheter tube 114, which, as coupled, effectively terminates lumens of the second section 144 of the catheter tube 114 other than that corresponding to the primary lumen 150 of the two-piece catheter 100

from passing through the junction 146. The junction 146 also includes a taper over its length from a distal end to the proximal end configured for immediate dilation of tissue about the percutaneous puncture up to an outer diameter of the second section 144 of the catheter tube 114. An abluminal surface of the junction 146 smoothly transitions from an abluminal surface of the proximal-end portion of the first section 142 without an edge that catches on skin when inserted into an insertion site of a patient. In addition to the edge being minimal to negligible, the edge can include solvent-interdiffused polymeric material of the first polymeric material and the polymeric material of the junction 146, which smoothens the transition from the first section 142 of the catheter tube 114 to the junction 146.

[0062] The junction 146 of the catheter tube 114 is formed of the second polymeric material or a third polymeric material having a third durometer closer to the second durometer than the first durometer. Again, the second polymeric material can be polyvinyl chloride, polyethylene, polyurethane, or silicone, but the second polymeric material is not limited to the foregoing polymers.

[0063] Again, the first section 142 of the catheter tube 114 is formed of a first polymeric material having a first durometer, the second section 144 of the catheter tube 114 is formed of a second polymeric material having a second durometer less than the first durometer, and the junction 146 of the catheter tube 114 is formed of the second polymeric material or a third polymeric material having a third durometer closer to the second durometer than the first durometer. Being that each durometer of the second durometer and the third durometer is less than the first durometer, the soft portion of the catheter tube 114 including the second portion of the catheter tube 114 and the junction 146 is softer than the hard portion of the catheter tube 114 including the first portion of the catheter tube 114. In other words, the first durometer is greater than each durometer of the second durometer and the third durometer. Being that the first durometer is greater than each durometer of the second durometer and the third durometer, the hard portion of the catheter tube 114 including the first portion of the catheter tube 114 is harder than the soft portion of the catheter tube 114 including the second portion of the catheter tube 114 and the junction 146.

[0064] 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), so the second durometer or the third durometer might not be numerically less than the first durometer. In other words,

the first durometer material might not be numerically greater than the second durometer or the third durometer in view of the different scales. That said, the hardness of the second or third polymeric material can still be less than the hardness of the first polymeric material or the hardness of the first polymeric material can still be greater than the hardness of the second or third 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.

[0065] Notwithstanding the foregoing, the first section 142 of the catheter tube 114, the second section 144 of the catheter tube 114, and the junction 146 can be formed of a same polymeric material or different polymeric materials having substantially equal durometers provided the column strength of the catheter tube 114 is sufficient to prevent buckling of the catheter tube 114 when inserted into an insertion site established by a percutaneous puncture and the compliance of the catheter tube 114 is sufficient to advance the catheter tube 114 through a vasculature of a patient to a target location.

[0066] Each extension leg of the one-or-more extension legs 108 is coupled to the proximal catheter-hub piece 104 by a distal-end portion of the extension leg. As such, the one-or-more proximal catheter-hub lumens 118 respectively continue as one or more extension-leg lumens.

[0067] Each extension leg of the one-or-more extension legs 108 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.

[0068] Whether the two-piece catheter 100 is monoluminal with one lumen or multiluminal with a set of multiple lumens, the two-piece catheter 100 includes at least a primary lumen 150 (e.g., a distal lumen) in the connected state of the two-piece catheter 100, in which connected state the one-or-more catheter-tube lumens in the distal catheter piece 110 are respectively fluidly connected to the one-or-more extension leg lumens in the proximal catheter piece 102 across the two-piece catheter hub 106. The primary lumen 150 typically extends from a proximal end of the two-piece catheter 100 to a distal end of the two-piece catheter 100 such as from an opening of a corresponding Luer connector to a primary-lumen aperture 152 (e.g., a distal-lumen aperture) in a distal end of the two-piece catheter 100. When the two-piece catheter 100 has two or more lumens, the two-piece catheter 100 further includes

at least a secondary lumen 154 (e.g., a medial lumen). The secondary lumen 154 typically extends from the proximal end of the two-piece catheter 100 to a distal-end portion of the two-piece catheter 100 such as from an opening of a corresponding Luer connector to a secondary-lumen aperture 156 (e.g., a medial-lumen aperture) in the distal-end portion of the catheter tube 114 proximal of the primary-lumen aperture 152. When the two-piece catheter 100 has three or more lumens, the two-piece catheter 100 further includes at least a tertiary lumen 158 (e.g., a proximal aperture). The tertiary lumen 158 typically extends from the proximal end of the two-piece catheter 100 to the distal-end portion of the two-piece catheter 100 such as from an opening of a corresponding Luer connector to a tertiary-lumen aperture 160 (e.g., a proximal-lumen aperture) in the distal-end portion of the catheter tube 114 proximal of the secondary-lumen aperture 156. Notwithstanding the foregoing, each lumen of the secondary lumen 154 and the tertiary lumen 158 can distally extend slightly farther than the secondary-lumen aperture 156 and the tertiary-lumen aperture 160, respectively, in view of different manufacturing methods. As set forth above, however, the flat-faced proximal end of the junction 146 is fixedly coupled (e.g., solvent bonded, welded, adhered, etc.) to the flat-faced distal end of the second section 144 of the catheter tube 114, which, as coupled, effectively terminates lumens such as the secondary and tertiary lumens 154 and 158 from passing through the junction 146.

[0069] A set forth above, it could be difficult to timely discern whether blood flashback has occurred and access to a blood-vessel lumen established during any given RICC introduction with a 30-40 cm introducer needle. As such, two-piece catheters configured as RICCs such those provided herein advantageously allow clinicians to use shorter, less cumbersome introducer needles with the distal catheter piece 110, which, in turn, also allows the clinicians to quickly discern whether blood flashback has occurred and access to a blood-vessel lumen established during any given RICC introduction.

[0070] Notably, the existing catheters set forth above (*see* Background) are inserted using the Seldinger technique. Such catheters do not benefit in the same way as the RICCs provided herein when the existing catheters are two-piece catheters. Indeed, increasing the number of catheter pieces in the existing catheters is disadvantageous in that one of the reasons the RICCs are currently being developed is to decrease the overall number of components and steps used in the Seldinger technique for the existing catheters.

Methods

[0071] Methods of the two-piece catheter 100 include a method of using the two-piece catheter 100. Such a method includes a catheter-obtaining step, a needle tract-establishing step, a needle-withdrawing step, and a catheter hub-clipping step.

[0072] The catheter-obtaining step includes obtaining the two-piece catheter 100 including the distal catheter piece 110 and the proximal catheter piece 102. As set forth above, the distal catheter piece 110 includes the catheter tube 114 coupled to the distal catheter-hub piece 112 by the proximal-end portion of the catheter tube 114.

[0073] The needle tract-establishing step includes establishing a needle tract from an area of skin to a blood-vessel lumen of a patient with an introducer needle disposed in an introducing lumen of the distal catheter piece 110. The introducing lumen is a combination of a distal catheter-hub lumen and a catheter-tube lumen making up a portion of the primary lumen 150 of the two-piece catheter 100—particularly in the unconnected state of the two-piece catheter 100. In the needle tract-establishing step, the introducer needle is disposed in the distal catheter piece 110 such that a needle tip of the introducer needle extends out of an introducing-lumen aperture (e.g., the primary-lumen aperture 152) of the introducing lumen.

[0074] The needle-withdrawing step includes withdrawing the introducer needle from the introducing lumen.

[0075] The catheter hub-clipping step includes clipping together the distal catheter-hub piece 112 and the proximal catheter-hub piece 104. If the integral clip is part of the distal catheter-hub piece 112 as shown in FIGS. 1 and 3, the catheter hub-clipping step includes clipping the integral clip of the distal catheter-hub piece 112 onto the proximal catheter-hub piece 104, in which the tabs 128 of the tabbed arms 124 of the integral clip seat in the surface recesses 126 in the major or minor surfaces of the proximal catheter-hub piece 104. If, however, the integral clip is part of the proximal catheter-hub piece 104, the catheter hub-clipping step includes clipping the integral clip of the proximal catheter-hub piece 104 onto the distal catheter-hub piece 112, in which the tabs 128 of the tabbed arms 124 of the integral clip seat in the surface recesses 126 in the major or minor surfaces of the distal catheter-hub piece 112. Regardless, upon clipping together the distal catheter-hub piece 112 and the proximal catheter-hub piece 104, the one-or-more catheter-tube lumens of the catheter tube 114 respectively

fluidly connect to the one-or-more extension-leg lumens of the one-or-more extension legs 108 coupled to the proximal catheter-hub piece 104 of the proximal catheter piece 102.

[0076] The method can further include an access guidewire-advancing step, a first catheter-advancing step, and an access guidewire-withdrawing step. The access guidewire-advancing step includes advancing an access guidewire disposed in a needle lumen of the introducer needle into the blood-vessel lumen beyond the needle tip. The first catheter-advancing step includes initially advancing the two-piece catheter 100 into the blood-vessel lumen over the access guidewire. If the two-piece catheter 100 is a RICC, the first catheter-advancing step includes advancing a distal-end portion of the first section 142 of the catheter tube 114 into the blood-vessel lumen over the introducer needle using the access guidewire as a guide. The access guidewire-withdrawing step includes withdrawing the access guidewire together with the introducer needle when withdrawing the introducer needle from the introducing lumen.

[0077] The method can further include a maneuver guidewire-advancing step, a second catheter-advancing step, and a maneuver guidewire-withdrawing step. The maneuver guidewire-advancing step includes advancing a maneuver guidewire into the blood-vessel lumen and to a target location by way of the primary lumen 150 of the two-piece catheter 100. Again, the primary lumen 150 is established by clipping together the distal catheter-hub piece 112 and the proximal catheter-hub piece 104. The second catheter-advancing step includes advancing the two-piece catheter 100 farther into the blood-vessel lumen over the maneuver guidewire. If the two-piece catheter 100 is a RICC, the second catheter-advancing step includes advancing a remainder of the distal-end portion of the first section 142 of the catheter tube 114 into the blood-vessel lumen up to a proximal-end portion of the second section 144 of the catheter tube 114 using the maneuver guidewire as a guide. Advancing the catheter in accordance with the second catheter-advancing step is stopped when the distal end of the two-piece catheter 100 arrives at the target location. The maneuver guidewire-withdrawing step includes withdrawing the maneuver guidewire and leaving the two-piece catheter 100 in place in the patient.

[0078] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader

aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.