SPLITTABLE NEEDLE AND DILATOR CATHETER PLACEMENT DEVICE AND ASSOCIATED METHODS

PRIORITY

[0001] This application claims the benefit of priority to U.S. Patent Application No. 63/060,639, filed August 3, 2020, which is incorporated by reference in its entirety into this application.

SUMMARY

[0002] Embodiments disclosed herein are directed to catheter placement systems including a splittable needle and a splittable dilator. The system includes a housing having one or more flexible sections and a pleated section. A user can grasp an elongate medical device using the flexible sections and transition the housing pleated section between an extended and a collapsed configuration to urge the elongate medical device proximally or distally. Further, the housing includes a needle retraction mechanism configured to split the needle along a longitudinal axis and roll up the separate portions to allow one or more elongate medical devices to pass therebetween. The system also includes a dilator splitter configured to separate a dilator along a longitudinal axis and radially displace the dilator portions to allow one or more elongate medical devices to pass therebetween. Advantageously, the system maintains the elongate medical device in a sterile environment, mitigating the introduction of pathogens and the like.

[0003] Disclosed herein is a catheter placement system including, a catheter housing defining a longitudinal axis, an elongate medical device disposed within an interior cavity of the catheter housing, and a needle housing including a needle extending distally therefrom, the needle housing releasably coupled to a distal end of the catheter housing and including a needle retraction mechanism configured to split the needle along a longitudinal axis and retract the needle into the needle housing.

[0004] In some embodiments, the needle housing includes a needle retraction lever hingedly coupled thereto and configured to actuate a gear mechanism disposed within the needle retraction mechanism. In some embodiments, the needle retraction mechanism is configured to roll up a portion of the needle about an axis extending perpendicular to the longitudinal axis. In some embodiments, the needle includes a sheath disposed on an outer

surface thereof, one of the needle or the sheath includes a breach line. In some embodiments, the elongate medical device includes one of a dilator, a catheter, or a guidewire. In some embodiments, one of the dilator or the catheter includes one of a polyether ether ketone (PEEK) material, or a fluorinated ethylene propylene (FEP) material. In some embodiments, the catheter housing includes a flexible section configured to elastically deform along an axis extending perpendicular to the longitudinal axis.

[0005] In some embodiments, the catheter housing includes an aperture extending through a side wall of the catheter housing and including a flexible film barrier disposed thereover. In some embodiments, the catheter housing includes a pleated section transitionable along the longitudinal axis between an extended configuration and a collapsed configuration. In some embodiments, the catheter housing is configured to rotate about the longitudinal axis to detach from the needle housing and split the needle housing along a longitudinal axis. In some embodiments, the catheter placement system further includes a dilator wedge splitter disposed within the catheter housing and configured split the dilator along the longitudinal axis. In some embodiments, the catheter housing includes a blood flash indicator releasably coupled to a proximal end thereof. In some embodiments, the catheter housing includes a guidewire housing extending from a proximal end thereof and configured to receive a portion of the guidewire therein. In some embodiments, a portion of one of the housing or the guidewire housing includes transparent material.

[0006] Also disclosed is a method of placing a catheter including, providing a catheter placement system having, a catheter housing including a flexible section and a pleated section, an elongate medical device, a portion thereof disposed within the catheter housing, and a needle housing releasably coupled to a distal end of the catheter housing and including a needle extending therefrom, accessing a vasculature of a patient, deforming the flexible section to grasp the portion of the elongate medical device disposed therebelow, transitioning the pleated section between an extended configuration and a collapsed configuration, releasing the flexible section to release the portion of the elongate medical device, and transitioning the pleated section between a configuration and an extended configuration.

[0007] In some embodiments, the elongate medical device includes one of a dilator, a catheter, or a guidewire. In some embodiments, the method further includes compressing a blood flash indicator to draw a fluid flow through the needle and confirm vascular access. In some embodiments the method further includes deforming a distal flexible section to grasp a

first portion of the elongate medical device, transitioning the pleated section from the extended configuration to the collapsed configuration, deforming a proximal flexible section to grasp a second portion of the elongate medical device, releasing the first flexible section, and transitioning the pleated section from the collapsed configuration to the extended configuration to withdraw the elongate medical device proximally.

[0008] In some embodiments, the method further includes withdrawing the elongate medical device proximally, over a splitter disposed within the housing to split the elongate medical device along a longitudinal axis. In some embodiments the method further includes actuating a needle retraction mechanism to retract the needle into the needle housing. In some embodiments, actuating the needle retraction mechanism includes rotating a needle retraction lever that is hingedly coupled to the needle housing, the needle retraction lever actuating a gear mechanism within the needle retraction mechanism. In some embodiments, retracting the needle into the needle housing includes splitting the needle along a longitudinal axis and rolling up the needle about an axis extending perpendicular to the longitudinal axis. In some embodiments, the method further includes rotating the catheter housing to detach the catheter housing from the needle housing. In some embodiments, detaching the catheter housing from the needle housing includes splitting the needle housing along a longitudinal axis to separate a first portion of the needle housing from a second portion of the needle housing. In some embodiments, the method further includes attaching a connector set to a hub of the catheter. In some embodiments, coupling the connector set to the catheter hub includes one of an interference fit, a push fit, a snap fit, a threaded engagement, or a bayonet fitting.

DRAWINGS

[0009] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0010] FIG. 1 illustrates a perspective view of a catheter placement system, in accordance with embodiments disclosed herein.

[0011] FIGS. 2A-2B illustrate cross-sectional side views of a catheter placement system, in accordance with embodiments disclosed herein.

[0012] FIGS. 3A-3C illustrate cross-sectional side views of a catheter placement system, in accordance with embodiments disclosed herein.

[0013] FIGS. 4A-4C illustrate cross-sectional side views of a catheter placement system, in accordance with embodiments disclosed herein.

[0014] FIGS. 5A-5B illustrate perspective views of a needle housing of a catheter placement system, in accordance with embodiments disclosed herein.

[0015] FIG. 5C illustrates a cross-sectional view of a needle and sheath of a catheter placement system, in accordance with embodiments disclosed herein.

[0016] FIG. 5D illustrates a perspective view of a needle being rolled up, in accordance with embodiments disclosed herein.

[0017] FIG. 5E illustrates a cross-sectional view of a needle and sheath of a catheter placement system, in accordance with embodiments disclosed herein.

[0018] FIG. 5F illustrates a perspective view of a needle being rolled up, in accordance with embodiments disclosed herein.

[0019] FIGS. 6A-6J illustrate various steps in an exemplary method of use of a catheter placement system, in accordance with embodiments disclosed herein.

DESCRIPTION

[0020] 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.

[0021] 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.

[0022] With respect to "proximal," a "proximal portion" or a "proximal end portion" of, for example, a needle disclosed herein includes a portion of the needle intended to be near a clinician when the needle is used on a patient. Likewise, a "proximal length" of, for example, the needle includes a length of the needle intended to be near the clinician when the needle is used on the patient. A "proximal end" of, for example, the needle includes an end of the needle intended to be near the clinician when the needle is used on the patient. The proximal portion, the proximal end portion, or the proximal length of the needle can include the proximal end of the needle; however, the proximal portion, the proximal end portion, or the proximal length of the needle need not include the proximal end of the needle. That is, unless context suggests otherwise, the proximal portion, the proximal end portion, or the proximal length of the needle is not a terminal portion or terminal length of the needle.

[0023] With respect to "distal," a "distal portion" or a "distal end portion" of, for example, a needle disclosed herein includes a portion of the needle intended to be near or in a patient when the needle is used on the patient. Likewise, a "distal length" of, for example, the needle includes a length of the needle intended to be near or in the patient when the needle is used on the patient. A "distal end" of, for example, the needle includes an end of the needle intended to be near or in the patient when the needle is used on the patient. The distal portion, the distal end portion, or the distal length of the needle can include the distal end of the needle; however, the distal portion, the distal end portion, or the distal length of the needle need not include the distal end of the needle. That is, unless context suggests otherwise, the distal portion, the distal end portion, or the distal length of the needle is not a terminal portion or terminal length of the needle.

[0024] As shown in FIG. 1, and to assist in the description of embodiments described herein, a longitudinal axis extends substantially parallel to an axial length of a needle 140. A lateral axis extends normal to the longitudinal axis, and a transverse axis extends normal to both the longitudinal and lateral axes. A horizontal plane is defined by the longitudinal and lateral axes. A vertical plane can extend normal to the horizontal plane.

[0025] 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.

[0026] The present disclosure relates generally to a catheter placement system 100 including a splittable needle and dilator, and associated methods thereof. As used herein, a catheter placement system 100 can be used to place a central venous catheter (CVC) to access a vasculature of a patient. However, it will be appreciated that embodiments disclosed herein can be used to place various catheters, cannulas, single lumen catheters, multi-lumen catheters, intravenous (IV) catheters, peripherally inserted central catheters (PICC), Rapid Insertion Central Catheter (RICC), dialysis catheters, drainage catheters, and the like, without limitation.

[0027] FIG. 1 shows an exemplary embodiment of a catheter placement system ("system") 100 that generally includes a catheter housing 110 and a splittable needle housing 130, releasably coupled to a distal end of the catheter housing 110. The system 100 further includes a needle 140, a dilator 150, a guidewire 160, and a catheter 170. The catheter housing 110 defines a substantially elongate, cylindrical shape including a circular cross-sectional shape. However, it will be appreciated that other elongate and cross-sectional shapes including triangular, square, hexagonal, polygonal, or combinations thereof, are also contemplated. In an embodiment, a portion of the catheter housing 110 can define a polygonal cross-sectional shape to provide a gripping surface and facilitate rotation of a catheter housing 110.

[0028] In an embodiment, the catheter housing 110 can be formed of a rigid or semi-rigid material including metal, alloy, polymer, plastic, thermoplastic, elastomer, rubber, silicone rubber, combinations thereof, or the like. In an embodiment, an outer surface of the catheter housing 110 includes a compliant material, elastomer, or the like, to provide a comfortable gripping surface and facilitate manipulation of the system 100. In an embodiment, the catheter housing 110 can be formed of a translucent or transparent material to allow a user to observe structures, components, or elongate medical devices, disposed therein.

[0029] In an embodiment, the catheter housing 110 can include a barrier 116 extending over an outer surface thereof. The barrier 116 can extend from the needle housing 130, disposed at a distal end, to a proximal end of the catheter housing 110, and extend annularly about a longitudinal axis of the catheter housing 110. In an embodiment, the barrier 116 can be formed of a thin polymer film or similar flexible material configured to allow a user to manipulate one of the catheter housing 110, or an elongate medical device disposed therein. As used herein, an "elongate medical device" can include one or more of the needle 140, dilator 150, catheter 170, guidewire 160, or one or more advancement assemblies configured to manipulate one of the needle 140, dilator 150, catheter 170, guidewire 160, combinations thereof, or the like. In an embodiment, the barrier 116, or portion thereof, can be transparent to allow a user to observe one of the catheter housing 110, or an elongate medical device, disposed therein.

[0030] In an embodiment, the catheter housing 110 can include one or more flexible sections 112, for example a distal flexible section 112A and a proximal flexible section 112B. As used herein a "flexible section" can include a portion of the catheter housing that can be elastically deformed along an axis that is perpendicular to a longitudinal axis of the system 100. The flexible section 112 can include a portion of the wall of the catheter housing 110 that defines more flexible mechanical properties. In an embodiment, as shown in FIG. 1A, a flexible section 112 can include a portion of a side wall of the catheter housing 110, e.g. a top side wall. In an embodiment, the flexible section 112 can include a first portion of a side wall and a second portion of the side wall, disposed opposite the first portion across a central longitudinal axis 80, e.g. laterally where the flexible section includes a left portion and a right portion, transversely where the flexible section includes a top portion and a bottom portion, or combinations thereof. In an embodiment the flexible section 112 can include a portion of the side wall that extends annularly about the longitudinal axis.

[0031] In an embodiment, the flexible section 112 can include a different material from that of the catheter housing 110. In an embodiment, the flexible section 112 can define a different wall thickness of material from that of the catheter housing 110. In an embodiment, a user can elastically deform the flexible section 112 to grasp or manipulate an elongate medical device or advancement assembly disposed within the catheter housing 110.

[0032] For example, as shown in FIG. 2A, a user can deform a portion of the flexible section 112 to constrict the interior cavity of the catheter housing 110 disposed therebelow.

The constricted portion can be distally or proximally of an end of an elongate medical device (e.g. dilator 150) or an advancement assembly coupled to an elongate medical device, disposed within the catheter housing 110. The deformed portion can constrict the interior diameter of the catheter housing 110 to a diameter that is less than an outer diameter of the elongate medical device 150.

[0033] As shown in FIG. 2B, the user can then slide the deformed portion along a longitudinal axis of the flexible section 112 in a "wave-like" action. Worded differently, a user can constrict adjacent portions of the flexible section 112 along a longitudinal axis of the flexible section 112. As such, the elongate medical device 150 can be urged through the interior cavity of the catheter housing 110 in front of the deformed portion.

[0034] In an embodiment the flexible section 112 can include more transparent properties relative to the catheter housing 110 to allow a user to observe an elongate medical device disposed therebelow. Advantageously, a user can manipulate the elongate medical device, disposed within the catheter housing 110 without having to directly contact the elongate medical device. This maintains the elongate medical device in a sealed environment and mitigates the introduction of pathogens, or similar infection causing agents.

[0035] In an embodiment, the flexible section 112 can include an aperture extending through a side wall of the catheter housing 110. For example, as shown in FIGS. 3A-3C, in an embodiment, the aperture flexible section 112 can include a flexible barrier 116 disposed thereover to maintain a sterile environment. As shown in FIG. 3B, a user can compress a portion of the barrier 116 through one or more flexible section apertures 112 to grasp an elongate medical device, (e.g. dilator 150), disposed within the catheter housing 110. As shown in FIG. 3C, a user can then slide the grasped portion longitudinally to advance proximally, or withdraw distally, the elongate medical device though the catheter housing 110. Advantageously, the aperture flexible section 112 together with the barrier 116 disposed thereover can allow a user to manipulate an elongate medical device disposed within the catheter housing 110 while maintaining a sterile barrier therebetween.

[0036] In an embodiment, the catheter housing 110 can include a pleated section 114. As used herein a "pleated section" includes a portion of the catheter housing 110 that can be expanded or collapsed along a longitudinal axis. In an embodiment, the pleated section 114 can include one or more folded pleats configured to allow the catheter housing 110 to transition

between an extended configuration and a collapsed configuration, extending or collapsing along a longitudinal axis. However, it will be appreciated that other configurations of the catheter housing 110 configured to extend or collapse along a longitudinal axis, such as a telescoping section, sliding section, folding section, combinations thereof, or the like, are also contemplated to fall within the scope of the present invention.

[0037] FIGS. 4A-4C show a cross-sectional view of the catheter housing 110 including a distal flexible section 112A, a proximal flexible section 112B, a pleated section 114, and an elongate medical device, e.g. a dilator 150, disposed within the catheter housing 110. In an exemplary method of use, a user can compress a proximal flexible section 112B to grasp a portion of the dilator 150 disposed therein. The user can transition the pleated section 114 from the extended configuration (FIG. 4A) to the collapsed configuration (FIG. 4B). As such, the dilator 150 grasped within the housing 110, can be advanced distally. The user can then release the proximal flexible section 112B and transition the pleated section 114 from the collapsed configuration (FIG. 4B) to the extended configuration (FIG. 4C). Optionally, a user can compress the distal flexible section 112A to grasp the dilator 150 in the distal position as the pleated section 114 transitions from the collapsed configuration to the extended configuration to prevent retrograde movement of the dilator 150 during the transition. As will be appreciated, a user can repeat the process as necessary to continue to advance the dilator 150 in a proximal direction.

[0038] In like manner, to withdraw the elongate medical device proximally, a user can compress a distal flexible section 112A to grasp a portion of the dilator 150 disposed therein. The user can then transition the pleated section 114 from the extended configuration to the collapsed configuration. A user can release the portion of the dilator 150 disposed adjacent the distal flexible section 112A and deform the proximal flexible section 112B to grasp a second portion of the dilator 150. The user can then transition the pleated section 114 from the collapsed configuration to the extended configuration to withdraw the dilator 150 proximally. A user can repeat the process as necessary to continue to withdraw the dilator 150 in a proximal direction. As will be appreciated, the dilator 150 is an exemplary elongate medical device and that the dilator 150, guidewire 160, catheter 170, combinations thereof, or the like can be advanced distally, or withdrawn proximally, as described herein. As will be appreciated, while a compressible flexible section 112 is shown, one or more aperture flexible sections 112 (e.g.

FIGS. 3A-3C) can be also be used in place of one or more compressible flexible sections 112 and still fall within the scope of the present invention.

[0039] With continued reference to FIG. 1, the system 100 can include a needle 140, supported by a needle hub 142, coupled to a distal end of the needle housing 130. The needle 140 can define a needle lumen 144 and, in an embodiment, include a needle sheath 146 disposed on an outer surface thereof. In an embodiment, the sheath 146 can be a peripherally inserted venous (PIV) catheter that can define a smaller outer diameter than the catheter 170. The sheath 146 can maintain access to the insertion site as one or more of the needle 140, dilator 150, guidewire 160 or catheter 170 are exchanged. In an embodiment, the sheath 146 can be configured to support a first half and a second half of a needle 140 to define a needle lumen 140, as described in more detail herein. In an embodiment, the sheath 146 can be formed of a plastic, polymer, elastomer, urethane, or similar suitable material.

[0040] In an embodiment, the system 100 can further include a dilator 150 disposed within the catheter housing 110. The dilator 150 can be supported by a dilator hub 152 and define a dilator lumen 154. In an embodiment, the dilator 150 can include a plastic, polymer, polyether ether ketone (PEEK) material, or a fluorinated ethylene propylene (FEP) material, or similar suitable material. In an embodiment, the dilator 150 can be supported by a dilator advancement assembly (not shown) configured to facilitate manipulation of the dilator 150 within the catheter housing 110 by way of one of the flexible sections 112, or pleated section 114, as described herein.

[0041] In an embodiment, a catheter 170 can be disposed within the catheter housing 110 and can be supported by a catheter hub 172. The catheter 170 can be configured to fit through the dilator lumen 154. The catheter hub 172 can be configured to be manipulated by a user, through one or more of the flexible sections 112 to advance or withdraw the catheter 170, as described herein. In an embodiment, the catheter 170 can be supported by a catheter advancement assembly (not shown) configured to facilitate manipulation of the catheter 170 within the catheter housing 110 by way of one of the flexible sections 112, or pleated section 114, as described herein. In an embodiment, the catheter 170 can include a plastic, polymer, polyether ether ketone (PEEK) material, or a fluorinated ethylene propylene (FEP) material, or similar suitable material.

[0042] In an embodiment, a guidewire housing 120 can extend from a proximal end of the catheter housing 110 and define an interior cavity that communicates with an interior cavity of the catheter housing 110. The guidewire housing 120 can be configured to receive a portion of the guidewire 160 disposed therein. In an embodiment, the guidewire housing 120 can be formed of a flexible material and can allow a user to manipulate the guidewire 170 disposed therein. In an embodiment, the guidewire housing 120 is formed of flexible plastic, polymer, elastomer, or the like. A user can compress a portion of the guidewire housing 120 disposed proximally of the proximal end of the guidewire 160 to occlude the interior cavity of the guidewire housing 120. The user can then slide the occluded portion of the guidewire housing 120 distally in a "wave-like" manner, as described herein, to urge the guidewire 160 distally, ahead of the occluded portion.

[0043] In an embodiment, the guidewire housing 120 is formed of a thin film or similar collapsible barrier. A user can grasp the guidewire 160 by compressing an outer portion of the guidewire housing 120. The user can then urge the guidewire 160 distally into the catheter housing 110. The portion of guidewire housing 120 disposed distally of the grasped portion of guidewire 160 can collapse to allow distal advancement of the guidewire 160. In an embodiment, the guidewire housing 120 can be formed of a transparent material to allow a user to observe a portion of the guidewire 170 disposed therein. In an embodiment, the guidewire 170 can extend from the guidewire housing 120 through one of the catheter 170, dilator 150, needle 140, or portion thereof, disposed within the catheter housing 110.

[0044] In an embodiment, the system 100 can further include a blood flash indicator 122. The blood flash indicator 122 can include a tube or similar structure formed from a flexible, transparent material and can extend from a proximal end of the catheter body 110. The blood flash indicator 122 can define an interior cavity. In an embodiment, the interior cavity can be configured to maintain a vacuum therein. The blood flash indicator 122 can be in fluid communication with a lumen of the needle 140 by way of a communicating tube 124. As a distal tip of the needle 140 accesses a vasculature of the patient, a fluid (e.g. blood) can flow proximally into the blood flash indicator 122 to be observed by a user. In an embodiment, a vacuum disposed within the blood flash indicator 122 can draw a fluid (e.g. blood) proximally through the communicating tube 124 and into the blood flash indicator 122. A user can then observe a color or pulsatile flow characteristics to confirm correct vascular access.

[0045] In an embodiment, the system 100 further includes a cap 108 configured to releasably engage with a distal end of one of the catheter housing 110 or the needle housing 130, and cover a distal portion of one or more of the needle 140, needle sheath 146, or the dilator 150. The cap 108 can mitigate accidental needle stick injuries during storage or transport and maintains the needle 140, needle sheath 146, the dilator 150 etc. in a sterile environment. The system 100 can further include a connector set 180 configured to engage a proximal end of the catheter 170. The connector set 180 can include a connector hub 182 and one or more extension legs 184 configured to provide fluid communication with one or more lumen of the catheter 170.

[0046] FIGS. 5A-5D show further details of the needle 140 and the splittable needle housing 130. The needle housing 130 can include a coupling 132 configured to releasably couple the needle housing 130 to the catheter housing 110. The needle housing 130 can further include one or more stabilization wings ("wings") 134, e.g. a right stabilization wing 134A and a left stabilization wing 134B. The wing(s) 134 can extend laterally from the needle housing 130 and define an extended lower surface configured to engage a skin surface of the patient and mitigate rotational movement about the longitudinal axis. Optionally, the wing(s) 134 can include one or more apertures configured to engage a strap, tape, dressing, bandage, or similar securement device to facilitate securing the needle housing 130 to a skin surface of the patient. In an embodiment, a surface of the needle housing 130 can include an adhesive layer disposed thereon and configured to secure the needle housing 130 to a skin surface of the patient. Optionally the strap, tape, dressing, bandage, adhesive layer or the like can provide a sterile barrier between catheter placement system 100 and the insertion site.

[0047] The needle housing 130 can further include a needle retraction mechanism 190. The needle retraction mechanism 190 can include one or more levers, gear mechanisms, ratchet mechanisms, sector gears, over-run slip clutches, or the like, configured to couple with the needle hub 142 and retract the needle 140 proximally into one of the needle housing 130 or the catheter housing 110 leaving the sheath 146 within the insertion site to maintain patency of the insertion site. In an embodiment, the guidewire 160 can be advanced through the needle lumen 144 to maintain patency of the insertion site and one or both of the needle 140 and the sheath 146 can be retracted into the needle housing 130, as described herein.

[0048] In an embodiment, the needle retraction mechanism 190 can be configured to split the needle 140 along a longitudinal axis and roll up the needle 140 on itself. The needle

140 can then be stored within the needle housing 130. Splitting and storing the needle 140 in this manner displaces the needle radially outward from a central longitudinal axis 80, and provides a clear channel for one or more elongate medical devices to advance distally therebetween.

[0049] As shown in FIGS. 5C-5F, in an embodiment, one of the needle 140 or the sheath 146 can include a breach line 148 extending longitudinally. As used herein, a "breach line" can include a laser cut line, perforation, groove, score line, or the like configured to facilitate separation therealong. As shown in FIGS. 5C-5D, in an embodiment, the needle 140 can include a single breach line 148 extending longitudinally through one side of the needle 140. The needle 140 can be split along this breach line 148 to form a first side edge 148A and a second side edge 148B. The cylindrical shape of the needle 140 extending longitudinally can then be transitioned to a planar shape extending along an axis from the first side edge 148A to the second side edge 148A. The needle 140 can then be rolled up on itself along an axis extending perpendicular to the longitudinal axis and sequestered within the needle housing 130.

[0050] In an embodiment, the needle retraction mechanism 190 can be configured to split the needle 140 along two breach lines 148 to separate the needle 140 in to a first portion 140A and a second portion 140B. In an embodiment, as shown in FIG. 5E, the needle 140 can be formed as two separate portions 140A, 140B extending longitudinally that co-operate to form a needle lumen 144 and are held in place by the needle sheath 146. The needle retraction mechanism 190 then breaches the needle sheath 146 to separate the needle portions 140A, 140B. As shown in FIG. 5F, each of the needle portions 140A, 140B can be then be transitioned from a semi-cylindrical shape to a planar shape before being rolled up on itself along an axis that extends perpendicular to the longitudinal axis.

[0051] In an embodiment, as shown in FIG. 5B, the needle retraction mechanism 190 can include one or more levers 192 hingedly coupled to the needle housing 130 and configured to rotate through a horizontal plane. However, it will be appreciated that the one or more levers 192 may also rotate through a vertical plane, or along a plane extending at an angle therebetween. Rotating the one or more levers 192 can split the needle hub 142 and proximally retract the needle 140 into the needle housing 130. In an embodiment, a single rotation of the lever(s) 192 can split and fully retract the needle 140. In an embodiment, the needle retraction mechanism 190 can include a ratchet mechanism configured to allow one or more rotations of the lever(s) 192 to split and fully retract the needle 140. In an embodiment, the retraction

mechanism 190 can link the first retraction lever 192A and the second retraction lever 192B such that actuating one of the first retraction lever 192A or the second retraction lever 192B causes both of the retractions levers 192A, 192B to rotate. In an embodiment, the needle retraction mechanism 190 can further include a biasing member to bias the levers towards a starting position, e.g. as shown in FIG. 5A. A user can then actuate the levers 192 from the starting position to an actuated position. Releasing the retraction levers 192 can then allow the biasing member to transition the retraction levers 192 from the actuated position to the starting position.

[0052] FIGS. 6A-6J show an exemplary method of use for a catheter placement system 100 as described herein. Initially, as shown in FIG. 6A, a user can flush the connector set 180 and cap off the ends of the connector set 180 and set to one side. The catheter placement system cap 108 can be removed from the needle housing 130 to expose the needle 140. As shown in FIGS. 6A-6B, a user can grasp the catheter housing 110 and urge the needle tip 141 into a vasculature 90 of a patient. It is important to note that the catheter placement system 100 provides all of the components for placing a catheter 170, i.e. needle 140, blood flash indicator 122, PIV sheath 146, dilator 150, guidewire 160, as well as the catheter 170 itself (e.g. a CVC catheter), contained within a single sterile unit. This maintains all components that may be exposed to the patient's vasculature 90 within a sterile environment and contrasts with existing procedures that require multiple components, which are exposed, and risk introducing infection at every stage. Further, the catheter placement system 100 maintains a barrier between the user and exposure to the patients' blood that also protects the user from potential exposure.

[0053] As shown in FIG. 6B, as the needle tip 141 accesses a vasculature 90 a blood flow can flow proximally through the needle lumen 144. In an embodiment, the vacuum disposed within the blood flash indicator 122 draws the blood flow through the communicating tube 124 and into the blood flash indicator 122. A user can then observe a color and pulsatile flow characteristics of the fluid disposed within the blood flash indicator 122 to confirm correct vascular access. For example a bright red color or strong pulsatile flow can indicate arterial access, a dark red color and low pulsatile flow can indicate venous access. Optionally, a user can compress the flexible blood flash indicator tube 122 to induce blood to flow therein.

[0054] As shown in FIG. 6C, with the vascular access confirmed, the blood flash indicator 122 can be urged proximally to disengage the blood flash indicator 122 from the proximal end of the catheter housing 110. A portion of the communicating tube 124 is also

withdrawn from the catheter housing 110 which in turn withdraws a distal end of the communicating tube 124, disengaging the communicating tube 124 from the needle lumen 144. The blood flash indicator 122 can then be removed and discarded, or secured to an outer surface of the catheter housing 110 using a clip or similar suitable means.

[0055] With the communicating tube 124 disengaged from the needle lumen 144, one of the catheter 170 or the dilator 150 can be advanced slightly so that a distal tip of the dilator 150 can engage a proximal end of the needle lumen 144. As shown in FIG. 6D, a distal tip 171 of the catheter 170 engages a proximal end of the dilator 150. As such the catheter 170, dilator 150 and needle 140 co-operate to provide a continuous path for the guidewire 160 to be advanced into the vasculature 90 of the patient.

[0056] In an embodiment, the catheter housing 110 includes a locking mechanism 126 configured to engaged the guidewire 160 extending therethrough and lock the guidewire 160 relative to the catheter housing 110. A user can unlock the guidewire 160, advance a portion of the guidewire 160 and then lock the guidewire 160 in position to prevent the guidewire being drawn into the vasculature 90 of the patient. In an embodiment, the guidewire 160 can advance through the catheter 170, through the dilator 150, through the needle 140 until a guidewire distal tip 161 advances distally of a needle distal tip 141. In an embodiment, the guidewire tip 161 can be advanced to a target location within the vasculature 90 of the patient. In an embodiment, the guidewire lock 126 can include either rotational locking mechanism or a push-button locking mechanism.

[0057] As shown in FIG. 6E, with the guidewire tip 161 advanced into the vasculature 90 of the patient, the needle 140 can be withdrawn out of the way to allow the dilator 150 to advance. In an embodiment, the dilator 150 and the catheter 170 can be withdrawn slightly to disengage a dilator tip 151 from the needle lumen 144. A user can then manipulate the needle retraction levers 192A, 192B, to retract the needle 140 proximally.

[0058] Actuating the needle retraction levers 192A, 192B can retract and split the needle hub 142 and the needle 140 into two separate portions 140A, 140B. Each portion 140A, 140B can then be rolled up on itself within the needle housing 130 to sequester the needle 140 away from the central longitudinal axis 80 to allow one or more elongate medical devices to pass axially therebetween. As described herein, the needle retraction mechanism 190 can

include a biasing member, ratchet mechanism and the like to provide mechanical advantage and facilitate splitting and removal of the needle 140.

[0059] In an embodiment, the sheath 146 can be split and rolled up along with the needle 140. In an embodiment, the needle 140 is formed from two separate halves 140A, 140B, which are held together by the sheath 146. As such, removal of the needle 140 includes splitting the sheath 146 along a longitudinal axis and rolling up a first half of the sheath with a first half of the needle 140A, and a second half of the sheath with a second half of the needle 140B. In an embodiment, the needle is withdrawn, split and rolled up, and the sheath 146 is left in place within the insertion site to maintain patency of the vascular access site.

[0060] As shown in FIG. 6F, with the needle 140 withdrawn and sequestered into the needle housing 130, the dilator 150 can be advanced distally over the guidewire 160, and optionally over the sheath 146 into the vasculature 90 of the patient to dilate the vascular access site. The dilator 150 can be advanced by manipulating the dilator hub 152 through the flexible sections 112A, 112B and/or pleated section 114 as described herein. In an embodiment, the dilator hub 152 can be coupled to a distal end of a dilator advancement assembly (not shown) that extends proximally through the catheter housing 110. The user can then manipulate the dilator advancement assembly to advance or withdraw the dilator 150, through the flexible sections 112A, 112B and/or pleated section 114, as described herein.

[0061] As shown in FIG. 6G, with the insertion site dilated, the dilator 150 can be withdrawn proximally either by manipulating the dilator hub 152 through the distal flexible section 112A, or by manipulating the dilator advancement assembly, as described herein. As the dilator 150 is being urged proximally into the catheter housing 110, the dilator 150 can be urged over a dilator splitter 158. As shown in FIG. 6D, the splitter 158 can include a wedge-shaped distal tip configured to split the dilator 150 along a longitudinal axis as the dilator 150 is urged proximally thereover. In an embodiment, the dilator 150 can further include a breach line 148 to facilitate separation of the dilator 150 into two halves. In an embodiment, the splitter 158 can be urged distally by manipulating a splitter arm 156 through the proximal flexible section 112B. The two dilator halves can be displaced radially outward relative to a central axis to allow one of the catheter 170 or guidewire 160 to pass longitudinally therebetween.

[0062] As shown in FIG. 6H, the catheter 170 can be advanced distally, over the guidewire 160 until a distal tip enters the vasculature 90 of the patient. The guidewire 170 can then be unlocked, using the guidewire lock 126, and withdrawn back into the catheter housing 110 and guidewire housing 120. When a distal tip of the guidewire 161 is disposed within the catheter housing 110, the guidewire 160 can then be locked into place using guidewire lock 126.

[0063] As shown in FIG. 6I, the catheter housing 110 with the dilator 150, splitter 158, and guidewire 160, disposed therein, can be detached from the needle housing 130 and discarded. In an embodiment, the catheter housing 110 can be detached by rotating the catheter housing 110 about the central longitudinal axis 80. With the catheter housing 110 detached from the needle housing 130, the needle housing 130 can be split along a longitudinal axis into two separate halves 130A, 130B. Each half 130A, 130B can then be separated perpendicular to the longitudinal axis to disengage the catheter hub 172. In an embodiment, the needle housing 130 can include a breach line 138 extending longitudinally and configured to facilitate separation of the needle housing first half 130A from the needle housing second half 130B. In an embodiment, the coupling 132 between the catheter housing 110 and the needle housing 130 can be configured to separate the needle housing 130 into two halves as the catheter housing 110 is rotated. For example, a distal end of the catheter housing 110 can include a cam lobe structure that engages needle housing 130 as the catheter housing 110 is rotated about the longitudinal axis. The cam lobe can provide a mechanical advantage to facilitate separation of the needle housing 130.

[0064] As shown in FIG. 6J, with the catheter housing 110 and needle housing 130 disengaged from the catheter 170, the connector set 180 can be coupled to the catheter hub 172. Each of the one or more extension legs 184 can fluidly communicate with a lumen of the catheter 170. In an embodiment, the connector set 180 can coupled to the catheter hub 172 with an interference fit, push fit, snap fit, threaded engagement, bayonet fitting, or the like.

[0065] 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 catheter placement system, comprising:
   a catheter housing defining a longitudinal axis;
   an elongate medical device disposed within an interior cavity of the catheter housing; and
   a needle housing including a needle extending distally therefrom, the needle housing releasably coupled to a distal end of the catheter housing and including a needle retraction mechanism configured to split the needle along a longitudinal axis and retract the needle into the needle housing.

2. The catheter placement system according to claim 1, wherein the needle housing includes a needle retraction lever hingedly coupled thereto and configured to actuate a gear mechanism disposed within the needle retraction mechanism.

3. The catheter placement system according to any one of claims 1-2, wherein the needle retraction mechanism is configured to roll up a portion of the needle about an axis extending perpendicular to the longitudinal axis.

4. The catheter placement system according to any one of claims 1-3, wherein the needle includes a sheath disposed on an outer surface thereof, one of the needle or the sheath includes a breach line.

5. The catheter placement system according to any one of claims 1-4, wherein the elongate medical device includes one of a dilator, a catheter, or a guidewire.

6. The catheter placement system according to claim 5, wherein one of the dilator or the catheter includes one of a polyether ether ketone (PEEK) material, or a fluorinated ethylene propylene (FEP) material.

7. The catheter placement system according to any one of claims 5-6, further including a dilator wedge splitter disposed within the catheter housing and configured split the dilator along the longitudinal axis.

8. The catheter placement system according to any one of claims 1-7, wherein the catheter housing includes a flexible section configured to elastically deform along an axis extending perpendicular to the longitudinal axis.

9. The catheter placement system according to any one of claims 1-8, wherein the catheter housing includes an aperture extending through a side wall of the catheter housing and including a flexible film barrier disposed thereover.

10. The catheter placement system according to any one of claims 1-9, wherein the catheter housing includes a pleated section transitionable along the longitudinal axis between an extended configuration and a collapsed configuration.

11. The catheter placement system according to any one of claims 1-10, wherein the catheter housing is configured to rotate about the longitudinal axis to detach from the needle housing and split the needle housing along a longitudinal axis.

12. The catheter placement system according to any one of claims 1-11, wherein the catheter housing includes a blood flash indicator releasably coupled to a proximal end thereof.

13. The catheter placement system according to any one of claims 5-12, wherein the catheter housing includes a guidewire housing extending from a proximal end thereof and configured to receive a portion of the guidewire therein.

14. The catheter placement system according to claim 13, wherein a portion of one of the housing or the guidewire housing includes transparent material.

15. A method of placing a catheter, comprising:

providing a catheter placement system comprising:

a catheter housing including a flexible section and a pleated section;

an elongate medical device, a portion thereof disposed within the catheter housing; and

a needle housing releasably coupled to a distal end of the catheter housing and including a needle extending therefrom;

accessing a vasculature of a patient;

deforming the flexible section to grasp the portion of the elongate medical device disposed therebelow;

transitioning the pleated section between an extended configuration and a collapsed configuration;

releasing the flexible section to release the portion of the elongate medical device; and

transitioning the pleated section between a configuration and an extended configuration.

16. The method according to claim 15, wherein the elongate medical device includes one of a dilator, a catheter, or a guidewire.

17. The method according to any one of claims 15-16, further including compressing a blood flash indicator to draw a fluid flow through the needle and confirm vascular access.

18. The method according to any one of claims 15-17, further including:

deforming a distal flexible section to grasp a first portion of the elongate medical device;

transitioning the pleated section from the extended configuration to the collapsed configuration;

deforming a proximal flexible section to grasp a second portion of the elongate medical device;

releasing the first flexible section; and

transitioning the pleated section from the collapsed configuration to the extended configuration to withdraw the elongate medical device proximally.

19. The method according to any one of claims 15-18, further including withdrawing the elongate medical device proximally, over a splitter disposed within the housing to split the elongate medical device along a longitudinal axis.

20. The method according to any one of claims 15-19, further including actuating a needle retraction mechanism to retract the needle into the needle housing.

21. The method according to claim 20, wherein actuating the needle retraction mechanism includes rotating a needle retraction lever that is hingedly coupled to the needle

housing, the needle retraction lever actuating a gear mechanism within the needle retraction mechanism.

22. The method according to any one of claims 20-21, wherein retracting the needle into the needle housing includes splitting the needle along a longitudinal axis and rolling up the needle about an axis extending perpendicular to the longitudinal axis.

23. The method according to any one of claims 15-22, further including rotating the catheter housing to detach the catheter housing from the needle housing.

24. The method according to claim 23, wherein detaching the catheter housing from the needle housing includes splitting the needle housing along a longitudinal axis to separate a first portion of the needle housing from a second portion of the needle housing.

25. The method according to claim 24, further including attaching a connector set to a hub of the catheter.

26. The method according to claim 25, wherein coupling the connector set to the catheter hub includes one of an interference fit, a push fit, a snap fit, a threaded engagement, or a bayonet fitting.