

EXTENSION SET AND RELATED SYSTEMS AND METHODS

BACKGROUND

[0001] Catheters are commonly used for a variety of infusion therapies. For example, catheters may be used for infusing fluids, such as normal saline solution, various medicaments, and total parenteral nutrition, into a patient. Catheters may also be used for withdrawing blood from the patient to obtain a blood sample.

[0002] A common type of catheter is an over-the-needle peripheral intravenous (“IV”) catheter. As its name implies, the over-the-needle catheter may be mounted over an introducer needle having a sharp distal tip. The catheter and the introducer needle may be assembled so that the distal tip of the introducer needle extends beyond the distal tip of the catheter with the bevel of the needle facing up away from skin of the patient. The catheter and introducer needle are generally inserted at a shallow angle through the skin into vasculature of the patient.

[0003] In order to verify proper placement of the introducer needle and/or the catheter in the blood vessel, a clinician generally confirms that there is “flashback” of blood in a flashback chamber of the catheter assembly. Once placement of the needle has been confirmed, the clinician may temporarily occlude flow in the vasculature and remove the needle, leaving the catheter in place for future blood withdrawal, fluid infusion, or probe access.

[0004] Blood withdrawal or infusion using the catheter may be difficult for several reasons, particularly when a dwelling time of the catheter within the patient is more than one day. For example, when the catheter is left inserted in the patient for a prolonged period of time, the catheter may be more susceptible to narrowing, collapse, kinking, blockage by debris (e.g., fibrin, platelet clots, or thrombus), and adhering of a tip of the catheter to the vasculature. Due to this, catheters may often be used for acquiring a blood sample at a time of catheter placement but are much less

frequently used for acquiring a blood sample during the catheter dwell period. Therefore, when a blood sample is desired, an additional needle stick is used to provide vein access for blood collection, which may be painful for the patient and result in higher material costs.

[0005] The subject matter claimed herein is not limited to embodiments that solve any disadvantages or that operate only in environments such as those described above. Rather, this background is only provided to illustrate one example technology area where some implementations described herein may be practiced.

BRIEF SUMMARY

[0006] The present disclosure relates generally to an extension set including a tube that may house an instrument such as a probe or a tubing, for example. In some embodiments, the tube may include or correspond to any suitable housing that includes a lumen extending there through. The instrument may access a patient's vascular system for medication and fluid delivery and/or blood acquisition during a dwell time of a vascular access device, such as a catheter assembly. In some embodiments, the instrument may access a fluid pathway of the catheter assembly. In other embodiments, the instrument may extend through the catheter assembly to access the vasculature of a patient.

[0007] In some embodiments, the extension set may include a tube, which may include a proximal end, a distal end, and an outer surface. In some embodiments, an instrument, such as the probe or the tubing, may be disposed within the tube and may include a proximal end and a distal end. In some embodiments, the tube may shield the instrument from contaminants and/or isolate any blood or other fluids that may remain on the instrument after accessing the fluid pathway of the catheter assembly. In some embodiments, the tube may protect the instrument from a surrounding external environment.

[0008] In some embodiments, a translation handle may be coupled to the outer surface of the tube. In some embodiments, the translation handle may move along the outer surface between a proximal position and a distal position. In some embodiments, the translation handle may thus translate the distal end of the instrument between a retracted position and an advanced position. In some embodiments, in the advanced position, the distal end of the instrument may extend beyond the distal end of the tube.

[0009] In some embodiments, a fluid path assembly may include the instrument, a proximal end, and a distal end. In some embodiments, an extension tube may be coupled to the proximal end of the instrument. In some embodiments, the proximal end of the fluid path assembly may include a proximal connector configured to connect to a blood collection device. In some embodiments, the fluid path assembly may extend through the tube.

[0010] In some embodiments, the distal end of the tube may include a distal connector. In some embodiments, the distal end of the tube and/or the distal connector may include a fluid seal to seal the tube and create a closed fluid path.

[0011] In some embodiments, the instrument may extend distally from a coupler element to facilitate translating the instrument within the tube without requiring direct contact. In some embodiments, the extension tube may be coupled to the instrument via the coupler element. In some embodiments, the tube may be axially-compressible such that the translation handle compresses a portion of the tube between the coupler element and the translation handle. In some embodiments, the compressed portion of the tube may engage with the coupler element such that movement of the translation handle along the outer surface of the tube translates the distal end of the instrument between the retracted position and the distal position.

[0012] In some embodiments, the coupler element and/or the tube may include a lubricant to facilitate translation of the instrument within the tube. In these and other embodiments, the translation handle may include one or more features to provide localized compression of the tube to engage the coupler element through the tube. In some embodiments, the features may include ball bearings, wheels, low-friction sliders, or other suitable features to facilitate localized compression of the tube and sliding along the tube. In some embodiments, the features may be coated with a lubricant or composed of a lubricious material.

[0013] In some embodiments, the instrument may be disposed within the tube and may include a proximal end and a distal end. In some embodiments, in response to the translation handle moving to the distal end of the tube, the distal end of the instrument may extend beyond the distal end of the tube.

[0014] In some embodiments, a method to provide access to a patient's vascular system may include coupling the extension set to a catheter assembly. In some embodiments, the extension set may include the tube, an instrument disposed within the tube, and the translation handle coupled to the outer surface of the tube. In some embodiments, coupling the extension set to the catheter assembly may include coupling the distal end of the tube to the catheter assembly. In some embodiments, the method may further include moving the translation handle along the tube from the proximal position to the distal position. In some embodiments, in the distal position, the distal end of the instrument may extend beyond the distal end of the tube into the catheter assembly.

[0015] In some embodiments, coupling the distal end of the tube to the catheter assembly may include coupling the distal connector of the tube to the catheter assembly. In some embodiments, the catheter assembly may include a catheter extending from a distal end thereof. In some

embodiments, in response to the translation handle moving to the distal position, the instrument may extend through a distal end of the catheter and/or into the vasculature.

[0016] In some embodiments, the extension set may include the blood collection device. In some embodiments, after blood has been collected in the blood collection device, the method may include moving the translation handle from the distal position to the proximal position. In some embodiments, moving the translation handle to the proximal position may retract the distal end of the instrument into the tube.

[0017] It is to be understood that both the foregoing general description and the following detailed description are examples and explanatory and are not restrictive of the invention, as claimed. It should be understood that the various embodiments are not limited to the arrangements and instrumentality shown in the drawings. It should also be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural changes, unless so claimed, may be made without departing from the scope of the various embodiments of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0018] Example embodiments will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0019] Figure 1 is an upper perspective view of an example extension set, illustrating an example instrument in an advanced position, according to some embodiments;

[0020] Figure 2 is an upper perspective view of the extension set coupled to an example catheter assembly, according to some embodiments;

[0021] Figure 3 is a partial cutaway view of the extension set, illustrating the instrument in a retracted position according to some embodiments;

[0022] Figure 4 is a partial cutaway view of the extension set, illustrating the instrument in an advanced position according to some embodiments;

[0023] Figure 5A is a cross-sectional view of an example translation device, according to some embodiments;

[0024] Figure 5B is a cross-sectional view of another example translation device of the extension set, according to some embodiments;

[0025] Figure 6 is a partially exploded view of the extension set, according to some embodiments;

[0026] Figure 7 is an upper perspective view of the extension set, illustrating the instrument in the retracted position according to some embodiments;

[0027] Figure 8 is an upper perspective view of the extension set, illustrating the instrument in the advanced position, according to some embodiments;

[0028] Figure 9A is an upper perspective view of an example translation handle and example coupler element, according to some embodiments;

[0029] Figure 9B is a cross-sectional view of the translation handle and the coupler element of Figure 9A, according to some embodiments;

[0030] Figure 10A is an upper perspective view of another example translation handle, according to some embodiments;

[0031] Figure 10B is a side view of another example translation handle, according to some embodiments;

[0032] Figure 10C is a side view of another example translation handle, according to some embodiments;

[0033] Figure 10D is a side view of another example translation handle, according to some embodiments;

[0034] Figure 11A is an upper perspective view of an example wheel, according to some embodiments;

[0035] Figure 11B is an upper perspective view of another example wheel, according to some embodiments;

[0036] Figure 11C is a cross-sectional view of another example translation device of the extension set, according to some embodiments;

[0037] Figure 12A is an upper perspective view of another example coupler element;

[0038] Figure 12B is an upper perspective view of another example coupler element;

[0039] Figure 12C is an upper perspective view of another example coupler element;

[0040] Figure 12D is an upper perspective view of another example coupler element;

[0041] Figure 12E is an upper perspective view of another example coupler element;

[0042] Figure 12F is an upper perspective view of another example coupler element;

[0043] Figure 13A is a cross sectional view of the extension set, illustrating the instrument in the retracted position, according to some embodiments;

[0044] Figure 13B is a cross sectional view of the extension set, illustrating another example instrument in the retracted position, according to some embodiments;

[0045] Figure 14A is an upper perspective view of an example cap disposed on an example blunt cannula, according to some embodiments;

[0046] Figure 14B is a cross-sectional view of the cap disposed on the blunt cannula, according to some embodiments; and

[0047] Figure 14C is a cross-sectional view of the cap disposed on the blunt cannula, according to some embodiments.

DETAILED DESCRIPTION

[0048] As used herein, the terms “proximal” and “distal” may refer to the direction closer to and away from, respectively, a clinician who would place the catheter system into contact with a patient. Thus, for example, the end of the catheter system first touching the body of the patient would be the distal end, while the opposite end of the catheter system would be the proximal end of the catheter system.

[0049] An extension set in accordance with some embodiments may provide access to a patient's vascular system. As discussed in more detail below, in some embodiments, the extension set may provide access to a fluid pathway of a catheter assembly. In some embodiments, the extension set may provide access to the vasculature of a patient throughout a dwell time of the catheter assembly for infusion, blood draw, or delivering a sensor for measurement.

[0050] As previously mentioned, a catheter with significant dwell time within the vasculature of the patient may be susceptible to narrowing, collapse, kinking, blockage by debris (e.g., fibrin, platelet clots, or thrombus), and adhering of a tip of the catheter to vasculature of a patient. Thus, blood withdrawal using the catheter may be difficult. Advantageously, in some embodiments, the extension set may include an instrument, such as another catheter or a probe, disposed within a tube. In some embodiments, the instrument may provide access to the vasculature of the patient without any additional needle sticks. Thus, in some embodiments, the extension set 100 may be used for needle-free blood collection and/or fluid infusion.

[0051] Referring now to Figure 1, in some embodiments, the extension set 100 may include the tube 102, which may include a proximal end 104, a distal end 106, and an outer surface 108. In some embodiments, the tube 102 may be flexible, rigid, or semi-rigid. In some embodiments, the instrument 110 may be disposed within the tube 102 and may include a proximal end 112 and a distal end 114. The distal end 114 may be atraumatic or blunt in some embodiments. In some embodiments, the extension set 100 may provide a non-fluid path through the tube 102 to shield the instrument 110 from contaminants and the surrounding external environment. The non-fluid path may be configured such that blood withdrawn from the patient does not contact the non-fluid path. In some embodiments, the extension set 100 may also isolate blood or other fluids that may remain on the instrument 110 after use. Further, in some embodiments, the extension set 100 may provide support, alignment, and aseptic delivery of the instrument 110 through the catheter assembly and into the patient's vascular system.

[0052] In some embodiments, a translation handle 116 may be coupled to the outer surface 108 of the tube 102 to facilitate moving the instrument 110 without requiring direct contact with the instrument 110. In some embodiments, the translation handle 116 may move along a length of the outer surface 108 of the tube 102 between a proximal position and a distal position. In some embodiments, the tube 102 may include an axially-compressible, bio-compatible, and an elastomeric or polymeric material. In this manner, in some embodiments, the translation handle 116 may create localized compression of the tube 102.

[0053] As discussed in more detail below, in some embodiments, a compressed portion of the tube 102 may engage with a coupler element 117 coupled to the proximal end 112 of the instrument 110 such that the translation handle 116 may translate the distal end 114 of the instrument 110 in the direction of movement of the translation handle 116. In some embodiments, the translation

handle 116 may translate the distal end 114 of the instrument 110 between a retracted position and an advanced position. In the advanced position 124, as illustrated in Figure 1, the distal end 114 of the instrument 110 may extend beyond the distal end 106 of the tube 102 and into a catheter assembly and/or vasculature of a patient, for example.

[0054] Referring now to Figure 2, in some embodiments, the extension set 100 may be coupled to a catheter assembly 200, which may include a distal end 204. In some embodiments, the instrument 110 may extend through the distal end 204 of the catheter assembly 200 in response to the translation handle 116 moving to the distal position. In some embodiments, the extension set 100 may be permanently coupled to, integrated with, or monolithically formed as a single unit with the catheter assembly 200.

[0055] In some embodiments, the instrument 110 may include a probe having one or more openings and/or sensors to provide in-vein patient and device monitoring. In some embodiments, the probe openings and/or the sensors may be disposed towards the distal end 114. In some embodiments, the openings may serve as fluid inlets and/or outlets. In some embodiments, the sensors may measure one or more parameters and/or detect one or more elements related to, for example, diagnostic information, blood chemistry, pH, temperature, pressure, flow rate, drug identification, microbes, placement of an implantable stent, in-vein catheter tip stabilization feature, or other devices or physiological measures. In some embodiments, the extension set 100 may facilitate placement of a portion of the probe that includes the sensors within the fluid pathway of the catheter assembly and/or the vasculature of the patient.

[0056] In some embodiments, the instrument 110 may include tubing and may function as both a probe and a catheter, including elements of both. In some embodiments, the instrument 110 may include the tubing to provide fluid infusion and/or withdrawal. In some embodiments, the tubing

may include a standard catheter tip or an asymmetrical catheter tip. In some embodiments, diffuser holes may be disposed in a tip of the tubing. In some embodiments, the tubing may include polyurethane, FEP, Teflon, silicon, TPE, TPU, fluorinated polymers, polyimide, or any other suitable materials or combination thereof. In some embodiments, the tubing material may be hydrophilic, hydrophobic, and/or may include any other desired properties or features, such as an anti-fouling material. Some embodiments of the tubing may include a coating such as an anti-thrombogenic and/or antimicrobial coating or other coating to impart other desired properties to the tubing.

[0057] In some embodiments, an extension tube 206 may be coupled to a proximal end of the translation handle 116 and/or the proximal end 112 of the instrument 110. In some embodiments, the extension tube 206 may be flexible. In some embodiments, the extension tube 206 may include TPE, TPU, PVC, or other suitable medical tubing material. In some embodiments, the extension tube 206 may be substantially clear and/or may include markers to inform a clinician of the position of the instrument 110 relative to the catheter or catheter features. In some embodiments, the extension tube 206 may include a textured surface to reduce contact friction. Some embodiments of the extension tube 206 may be vented by, for example, an open air pathway, a breathable filter membrane, porous venting material, micro-channels, or the like.

[0058] In some embodiments, a proximal connector 208 may be coupled to or integrated with the proximal end of the extension tube 206 to connect to a blood collection device 210 (see, for example, Figure 3), infusion device, or monitoring device, for example. In some embodiments, the blood collection device may include any suitable blood collection device, such as, for example, a VACUTAINER® or a VACUTAINER® LUER-LOK™ Access Device (LLAD), available from Becton Dickinson and Company of Franklin Lakes, New Jersey. The proximal connector 208 may

include, for example, a male or female luer, a blunt cannula, or another suitable connector. In some embodiments, the blood collection device 210 may be selectively coupled to the proximal connector 208. In some embodiments, the blood collection device 210 may be pre-connected to the proximal connector 208 during manufacture or assembly. In some embodiments, the blood collection device 210 may be permanently coupled to, integrated with, or monolithically formed as a single unit with the proximal connector 208.

[0059] In some embodiments, the distal end 106 of the tube 102 may be coupled to or integrated with the distal connector 212, which may include a fluid seal 214 to seal the tube 102 and create a closed fluid path. In some embodiments, the distal connector 212 may include, for example, a male or female luer, a blunt cannula, or another suitable connector. In some embodiments, the distal connector 212 may include lever arms and/or clips to aid with securement.

[0060] In some embodiments, the extension tube 206 may extend through a proximal connector 209 integrated with or coupled to the proximal end 104 of the tube 102. In some embodiments, there may be a tight fit or septum between the extension tube 206 and the proximal connector 209, which may create a seal but still allow motion of the extension tube 206 with respect to the proximal connector 209. In some embodiments, the translation handle 116 may be moved from the proximal position to the distal position such that the distal end 114 of the instrument 110 is distally advanced beyond the tube 102 and/or the proximal connector 208 is moved closer to the proximal connector 209. In some embodiments, after blood has been collected in the blood collection device 210, the translation handle 116 may be moved from the distal position to the proximal position such that the distal end 114 of the instrument 110 retracts into the tube 102 and/or the proximal connector 208 is moved away from the proximal connector 209. In some embodiments, the translation handle 116 may include any suitable translation handle, which may

be described, for example, in further detail in U.S. Patent Application No. 17/127,588, filed December 17, 2020, entitled “FLUSH INSTRUMENT WITH BLOOD EXPOSURE PROTECTION AND RELATED METHODS” and U.S. Patent Application No. 17/127,623, filed December 17, 2020, entitled “MULTI-LUMEN EXTENSION SYSTEM,” which are incorporated by reference in their entirety.

[0061] In some embodiments, the extension set 100 may reduce hemolysis of a blood sample collected via the fluid path. In some embodiments, the extension set 100 may provide an adequate fluid flow rate. Blood cell experiences shear stress as it flows in a fluid pathway. The maximum shear stress is along the wall of the blood cell, or wall shear stress. Wall shear stress on blood cells is considered a major source of mechanical damage to blood cells. For a cylindrical fluid path, the wall shear stress is typically expressed as:

$$T = \frac{1}{2} \cdot \frac{\Delta P}{L} \cdot (kr)$$

in which ΔP is the pressure drop along a path with a length of L and an interior radius of r . k is shrinkage index.

[0062] To fill a certain volume of collection tube, V , with a flow rate of Q , the time needed can be simply assessed by:

$$t = \frac{V}{Q} = 8\mu v \cdot \frac{1}{\pi r^4} / \left(\frac{\Delta P}{L} \right)$$

in which μ is the dynamic viscosity of the fluid. Hemolysis is typically associated with both the wall shear stress and the time a blood cell is exposed to wall shear stress. From literature, it has been widely considered that hemolysis index can be approached as a function of:

$$HI(\%) = A * t^\alpha * T^\beta$$

in which A , α , and β are coefficients.

[0063] In principle, the hemolysis index is related to pressure gradient and cross-sectional characteristic dimension:

$$HI(\%) \propto \left(\frac{\Delta P}{l}\right)^{\beta-\alpha} \cdot \left(\frac{1}{r}\right)^{4\alpha-\beta}$$

[0064] In some embodiments, a length of the instrument 110 may be selected based on one or more of the following: a gauge of a particular catheter, a particular catheter assembly configuration, or a clinical setup. In some embodiments, the instrument 110 may include a length L. In some embodiments, the instrument 110 may include an inner diameter D.

[0065] Fluid flow in instrument 110 can be analyzed using Poiseuille's equation when the instrument 110 is tubular:

$$Q = \frac{\pi D^4 \Delta P}{128 \mu L} = \frac{\Delta P}{R_f}$$

where ΔP is a change in pressure gradient across the length of a fluid pathway of the instrument 110, D and L are the inner diameter and length, respectively, of the fluid pathway of the instrument 110, μ is the viscosity of a fluid, and $R_f = \frac{128 \mu L}{\pi D^4}$ is the fluid resistance. Since μ is the viscosity of the fluid and not part of the extension tube geometry, a geometric factor G_f is defined such that R_f (the fluid resistance) is $R_f = \frac{128 \mu}{\pi} G_f$, where $G_f = \frac{L}{D^4}$.

[0066] In some embodiments, the instrument 110 may have multiple sections with lengths (L1, L2, L3) and inner diameters of (D1, D2, D3), the geometric factor is then:

$$G_f = \frac{L1}{D1^4} + \frac{L2}{D2^4} + \frac{L3}{D3^4}$$

In some embodiments, the instrument 110 may have an inner diameter that changes over the length of the instrument 110, the geometric factor is then:

$$G_f = \int_0^L \frac{dl}{D(l)^4}$$

In some embodiments, the instrument 110 may have a cross section that is not circular or complicated inner diameter profile. The geometric factor can be determined by measuring the flow rate (Q) at given pressure (ΔP) with known viscosity (μ) fluid:

$$G_f = \frac{\pi \Delta P}{128 \mu Q}$$

[0067] The G_f value of the instrument 110 may be selected to reduce the max shear stress for each catheter gauge to be the same or less than the max shear stress of a BD 21G VACUTAINER® UltraTouch™ push button blood collection set (available from Becton, Dickinson & Company of Franklin Lakes, New Jersey), which was previously considered the gold standard for blood draws. In some embodiments, G_f value of the fluid pathway of the instrument 110 may be selected to reduce the max shear stress for each catheter gauge to be the same or less than the max shear stress of a BD 25G VACUTAINER® UltraTouch™ push button blood collection set (available from Becton, Dickinson & Company of Franklin Lakes, New Jersey).

[0068] In some embodiments, a fluid pathway of a blood collection system, which may include one or more of the blood collection device 210, the tube 102, the instrument 110, and the catheter assembly 200, may include an entirety of a blood collection pathway through which blood flows during blood collection after leaving vasculature of a patient. The system geometric factor G_{fs} for the fluid pathway of the blood collection system can be determined in similar fashion as described earlier. In some embodiments, the system geometric factor G_{fs} may be equal to or more than $7.34E+06$ ($1/\text{in}^3$). In some embodiments, G_{fs} may include another value. In some embodiments, the system geometric factor G_{fs} may be equal to or more than $7.34E+06$ ($1/\text{in}^3$) when the instrument 110 is in an advanced position. In some embodiments, the system geometric factor G_{fs} may be $7.34E+06$ ($1/\text{in}^3$) plus or minus 10 percent, plus or minus 25 percent, plus or minus 50 percent, or

plus or minus 75 percent. In some embodiments, G_{fs} may include another value, which may be selected based on a gauge and/or length of the catheter.

[0069] In some embodiments, the distal connector 212 may couple the extension set 100 to the catheter assembly 200. In some embodiments, the catheter assembly 200 may include a catheter adapter 220, which may include a distal end 221, a proximal end 222, and a lumen extending there through. In some embodiments, the catheter adapter 220 may include a side port 224, from which another extension tube may extend. In some embodiments, the other extension tube may be coupled to an adapter, such as a Y-adapter or a T-adapter, for example. In some embodiments, the distal end 106 of the tube 102 may be coupled to the proximal end 222 of the catheter adapter 220, the side port 224, the adapter, or another portion of the catheter assembly 200. In some embodiments, the distal end 204 of the catheter assembly 200 may include a catheter 223, which may be secured within the catheter adapter 220 and extend distally from the distal end 221 of the catheter adapter 220. In some embodiments, the catheter 223 may include a peripheral IV catheter, a midline catheter, or a peripherally-inserted central catheter.

[0070] In some embodiments, the catheter 223 may include a standard catheter tip or an asymmetrical catheter tip. In some embodiments, the catheter 223 may include one or more diffuser holes may be disposed in a tip of the catheter 223. In some embodiments, the catheter 223 may include polyurethane, FEP, Teflon, silicon, TPE, TPU, fluorinated polymers, polyimide, or any other suitable materials or combination thereof. In some embodiments, the catheter 223 material may be hydrophilic, hydrophobic, and/or may include any other desired properties or features, such as an anti-fouling material. Some embodiments of the catheter 223 may include a coating such as an anti-thrombogenic and/or anti-microbial coating or other coating to impart other desired properties to the catheter 223.

[0071] In some embodiments, the extension set 100 may provide needle free delivery of the instrument 110 to a patient's vascular system for blood collection, fluid delivery, patient or device monitoring, or other clinical needs by utilizing an existing vascular access device (VAD), such as the catheter 223. In some embodiments, the extension set 100 and the instrument 110 may reduce trauma to the vein and overcome thrombus and fibrin sheath in or around the VAD or vein that may otherwise prevent infusion or blood draw. In some embodiments, the instrument 110 may push past any obstructions in the VAD or the vein in order to open a pathway for vascular access. In some embodiments, a suction device such as a LLAD or syringe may be attached to the proximal end of the extension set 100 in order to complete a blood draw. After completing a blood draw or infusion the user may retract the instrument 110 by rolling the translation handle 116 proximally. This allows the clinician to disconnect the extension set 100 from the VAD without exposing themselves to blood.

[0072] Referring now to Figures 3 - 4, in some embodiments, the fluid seal 214 may permit advancement and/or retraction of the instrument 110 there through while maintaining a closed fluid path. In some embodiments, the fluid seal 214 may include silicone rubber, an elastomer, or another suitable material. In some embodiments, the fluid seal 214 may include an aperture, slit, or the like to accommodate the instrument 110 there through.

[0073] In some embodiments, the compressed portion 302 of the tube 102 may engage with the coupler element 117 such that movement of the translation handle 116 along the outer surface 108 of the tube 102 translates the distal end 114 of the instrument 110 between the retracted position, illustrated in Figure 3, and the advanced position, illustrated in Figure 4. In some embodiments, the coupler element 117 may be coupled to the instrument 110 and/or the extension tube 206 by, for example, an interference fit, adhesive, or both. In some embodiments, the extension tube 206

and the instrument 110 may be monolithically formed as a single unit and may extend through the coupler element 117.

[0074] Referring now to Figures 5A and 5B, in some embodiments, the coupler element 117 may engage or otherwise engage with one or more features of the translation handle 116 through the tube 102 to allow translation of the instrument 110 without any direct contact between the translation handle 116 and the coupler element 117 that is coupled to the instrument 110. For example, in some embodiments, as illustrated in Figure 5A, the coupler element 117 may include a disc or ellipsoid shape 506 with a flattened or concave center portion 504. The flattened or concave center portion 504 may align with opposing features 500 of the translation handle 116 to facilitate smooth translation. In some embodiments, the features 500 may include rollers, ball bearings, low-friction sliding surfaces, or the like. In some embodiments, the features 500 may be rounded, angled, spherical, or cylindrical.

[0075] In some embodiments, a distance between features 500 that oppose each other may be less than an outer diameter of the tube 102 such that the tube 102 is pinched between the features 500 and the coupler element 117. In some embodiments, as illustrated in Figure 5B, the coupler element 117 may include a disc or ellipsoid shape having tapered ends 508. The tapered ends 508 may accommodate the features 500 of the translation handle 116 to facilitate smooth translation.

[0076] In some embodiments, the features 500 may be coupled to the translation handle 116 to provide localized compression of the tube 102. In some embodiments, the features 500 may engage with the coupler element 117 via the tube 102 to facilitate smooth translation of the instrument 110 within the tube 102. In some embodiments, the features 500 may be coupled to an interior edge of the translation handle 116. In some embodiments, the surface of the coupler element 117 that

interfaces with the features 500 may be substantially concave to facilitate smooth bi-lateral movement along the outer surface 108 of the tube 102.

[0077] According to various embodiments, the coupler element 117 may include the tapered ends 508 to improve its ability to round corners during movement between the proximal end 104 and the distal end 106 of the tube 102. In these and other embodiments, the coupler element 117 may include fins to facilitate travel down the tube 102. In some embodiments, the coupler element 117 may include fenestrations, ribs, or channels to facilitate fluid flow, such as air and/or liquid. In some embodiments, air may flow around the coupler element 117 such as through the fenestrations, ribs, or channels, so a vacuum is reduced or eliminated in response to moving the coupler element 117 distally or proximally. In other embodiments, the coupler element 117 may include a bore to accommodate fluid flow, such as fluid infused into the patient's vascular system, for example, or blood aspirated from the patient's vascular system. In some embodiments, the coupler element 117 may include one or more colors or patterns to increase its visibility.

[0078] In some embodiments, longitudinal ribs may be molded onto an outer surface of the coupler element 117 to keep the coupler element 117 oriented parallel to the tube 102, thus facilitating unobstructed bi-directional movement of the coupler element 117 through the tube 102. In some embodiments, the longitudinal ribs may contact opposing features on an inner surface of the tube 102 to prevent the coupler element 117 from rotating within the tube 102.

[0079] In some embodiments, the coupler element 117 and/or an inner surface of the tube 102 may include a lubricant 304 to facilitate translation of the instrument 110 within the tube 102. In some embodiments, the lubricant 304 may be disposed around the coupler element 117 and/or inside a non-fluid path lumen 510 of the tube 102. In other embodiments, the lubricant 304 may be applied external to the non-fluid path lumen 510 around the features 500 of the translation

handle 116. In some embodiments, the coupler element 117 may include lubricious material to facilitate movement within the non-fluid path lumen 510. In these and other embodiments, the extension set 100 may include venting to maintain atmospheric pressure and allow movement of air within the non-fluid path lumen 510 during bi-directional translation of the instrument 110. In some embodiments, the non-fluid path lumen 510 may include venting to allow airflow into and out of the non-fluid path lumen 510, which may facilitate movement of the translation handle 116 and coupler element 117. In some embodiments, one or more vents to provide the venting may be reduced in size to allow air movement while still maintaining good aseptic protection of the instrument 110 and/or other portions of the extension set 100.

[0080] Referring now to Figures 6-8, in some embodiments, the extension set 100 and the catheter assembly 200 may include a fluid path assembly 600 that facilitates blood collection. In some embodiments, the fluid path assembly 600 may include the instrument 110, which may include the tubing, such as, for example, micro-tubing. In some embodiments, tubing may include a polymer material, polyimide, or another suitable material. In some embodiments, the proximal connector 208 may be coupled to a needle-less connector or a female luer connector. In some embodiments, blood may flow through the instrument 110 and through the extension tube 206 into the blood collection device.

[0081] In some embodiments, a non-fluid path extension assembly 602 may provide support, alignment, and aseptic delivery of the instrument 110 through a catheter (see, for example, the catheter 223 of Figure 2) dwelling within the vasculature. In some embodiments, a majority of the non-fluid path extension assembly 602 or a portion of the non-fluid path extension assembly 602 proximal to the fluid seal 214 may not contact blood being withdrawn from the patient through the extension set 100. In some embodiments, a portion of the non-fluid path extension assembly distal

to the fluid seal 214 may have some contact with blood or saline solution that may be in a fluid path of the catheter. In some embodiments, the non-fluid path extension assembly 602 may include one or more of: the tube 102, the translation handle 116, the distal connector 212 at the distal end 106, and the proximal connector 209 disposed at the proximal end. In some embodiments, the distal end 106 of the tube 102 and/or the distal connector 212 may include the fluid seal 214 to seal the distal end of the non-fluid path extension assembly 602. In some embodiments, the fluid seal 214 may form a seal around the instrument 110, which may extend there through. Advantageously, the extension set 100 in accordance with some embodiments may be easy to scale in length, based on, for example, a size or length of the catheter 123 or the catheter assembly 200.

[0082] Referring now to Figures 9A and 9B, in some embodiments, the translation handle 116 may include a collar 900 around the tube 102. The tube 102 is illustrated as transparent in Figure 9B for illustrative purposes. In some embodiments, the collar 900 may extend fully or partially around the tube 102. In some embodiments, the collar 900 may move bi-directionally along the tube 102. In some embodiments, the collar 900 and the coupler element 117 may be magnetically attracted to each other through the tube 102 to facilitate movement of the instrument 110 without direct contact. These and other embodiments of the collar 900 may include the features 500 to improve ease of movement along the outer surface 108 of the tube 102. In some embodiments, an outer surface of the collar 900 may include one or more grips, such as, for example, ribs, textured surfaces, push tabs, or other protrusions to provide ease of handling.

[0083] In some embodiments, the features 500 may include one, two, or three ball bearings distributed radially symmetrically about the longitudinal axis of the tube 102. In some embodiments, the features 500 may be coupled to an inside surface of the collar 900 to mediate contact between the collar 900 and the outer surface 108 of the tube 102. In other embodiments,

any number of the features 500 may be present and may be arranged in a variety of symmetrical and asymmetrical arrangements.

[0084] Referring now to Figures 10A-11C, the translation handle 116 may include a housing 1000, which may include a distal opening 1002 and a proximal opening 1004. In some embodiments, the tube 102 may extend through the distal opening 1002 and the proximal opening 1004. In some embodiments, the housing 1000 may extend around the tube 102. In some embodiments, the housing 1000 may move bi-directionally along the tube 102. In some embodiments, the housing 1000 and the coupler element 117 may be magnetically attracted to each other through the tube 102 to facilitate movement of the instrument 110 without direct contact of the instrument 110 by the clinician.

[0085] In some embodiments, the translation handle 116 may compress a portion of the tube 102 in between the coupler element 117 and the translation handle 116. In some embodiments, the portion of the tube 102 may engage the coupler element 117 such that movement of the translation handle 116 along the outer surface 108 of the tube 102 translates the coupler element 117 within the tube 102 and the distal end 114 of the instrument 110 is moved between the retracted position and the advanced position.

[0086] In some embodiments, the housing 1000 may include the features 500 to improve movement of the translation handle 116 along the outer surface 108 of the tube 102. In some embodiments, the features 500 may be coupled to an inside surface of the housing 1000 to mediate contact between the housing 1000 and the outer surface 108 of the tube 102. In some embodiments, any number of the features 500 may be present and may be arranged in a variety of symmetrical and asymmetrical arrangements.

[0087] In some embodiments, the features 500 which may include ball bearings, wheels, low-friction sliders, or other suitable features to provide localized compression of the tube 102 to engage the coupler element 117. In some embodiments, the features 500 may be coupled to the translation handle 116. In some embodiments, the features 500 may be directly coupled to the translation handle 116. In some embodiments, the features 500 and the translation handle 116 may be molded together or monolithically formed as a single unit. In some embodiments, the features 500 and the translation handle 116 may be integrated or fitted together.

[0088] In some embodiments, the features 500 may include a pinch mechanism and may be positioned to pinch or press against the outer surface 108 of the tube 102. In some embodiments, one or more of the features 500 may oppose or be on opposite sides of the tube 102 as one or more other of the features 500. In some embodiments, an interior surface of the tube 102 within the translation handle 116 may be too small to permit passage of the coupler element 117 there through. In some embodiments, the housing 1000 may be rigid or semi-rigid, which may provide more support to the clinician for one-handed advancement of the instrument 110 by the clinician.

[0089] As illustrated, for example, in Figures 11A-11B, the features 500 may include wheels 1100, which may be rotatably coupled to the translation handle 116. In some embodiments, an axle 1102 may extend through the features 500. In some embodiments, the features 500 may include sliders, which may be slick and/or constructed of plastic, and which may slide along the tube 102. In some embodiments, the sliders may be stationary or static with respect to the translation handle 116.

[0090] As illustrated, for example in Figure 11C, the features 500 may include the ball bearings, which may be rotatable within sockets formed in the translation handle 116. In some embodiments, each of the sockets may include ridges or bumps around a circumference of the

socket, which may limit contact of the ball bearings with the socket and reduce friction. In some embodiments, the ball bearings may have the ridges or bumps, which may be disposed between the ball bearing and the housing 1000. In some embodiments, the bumps may be evenly spaced around the circumference. In some embodiments, lubricant may be applied to the coupler element 117 and/or the features to reduce friction.

[0091] In some embodiments, an outer surface of the housing 1000 may include one or more grips 1006, such as, for example, ribs, textured surfaces, push tabs, protrusions, or indents to provide ease of handling. In some embodiments, the grips 1006 may be disposed on sides of the housing 1000, as illustrated, for example, in Figures 10A-10D. In some embodiments, the grips 1006 may be disposed on sides and/or the top of the housing 1000, as illustrated, for example, in Figure 10C. In some embodiments, the housing 1000 may include various shapes, such as, for example, rectangular, square, cylindrical, elliptical, or another suitable shape. In some embodiments, a middle portion of the housing 1000 may include a diameter that is less than a diameter of a first end of the housing 1000 and/or a diameter of the second end of the housing 1000 opposite the first end. In these and other embodiments, the shape of the housing 1000 may facilitate gripping of the housing 1000 by the clinician.

[0092] In some embodiments, the coupler element 117 may include fenestrations, ribs, or channels to facilitate fluid flow, such as air and/or liquid. Thus, in some embodiments, the tube 102 may be in fluid communication with the proximal connector 209. In some embodiments, the proximal connector 209 may be coupled to a needleless connector 1104, which may include a septum. In some embodiments, the blood collection device may be coupled to the needleless connector 1104, and blood may be withdrawn proximally through one or more of the following: the tube 102, the coupler element 117, the proximal connector 209, and the needleless connector

1104. In some embodiments, the needleless connector 1104 may be coupled to the proximal connector 209 via a luer adapter. In some embodiments, the needleless connector 1104 may be permanently connected to the proximal connector 209, which may include the luer adapter, with adhesive or another suitable means to prevent intentional or unintentional removal by the clinician.

[0093] Referring now to Figures 12A-12F, the coupler element 117 may include various shapes. In some embodiments, the coupler element 117 may include a distal end 1200 from which the instrument 110 may extend. As illustrated, for example, in Figure 12A, the coupler element 117 may include a cylinder or barrel shape. As illustrated, for example, in Figures 12B-12D, the coupler element 117 may include a tapered exterior. As illustrated, for example, in Figures 12C-12D, the coupler element 117 one or more rounded ridges to improve ability to round corners. In some embodiments, the coupler element 117 may include fins to help the coupler element 117 travel down the tube 102. In some embodiments, the coupler element 117 may include fenestrations in it to allow fluid to flow around it. In some embodiments, a flow path around the coupler element 117 may be selected such that a hydraulic diameter is greater than an inner diameter of the blood collection device or tube 102 to reduce shear stress during blood draw.

[0094] As illustrated, for example, in Figure 12F, the coupler element 117 may include a dog bone or bow shape so that it can be used with two pinch points, two ball bearings, or two wheels, as opposed to four. In some embodiments, the coupler element 117 may be attached to the instrument 110 by an interference fit, adhesive, or both. In some embodiments, the instrument 110 may be tapered so that a large outer diameter end of the instrument 110 serves as the coupler element 117 or wedge. In some embodiments, the coupler element 117 may be colored to increase visibility.

[0095] Referring now to Figure 13A, in some embodiments, the blood collection device may be coupled to the proximal connector 209 and/or a needleless connector coupled to the proximal connector 209. In some embodiments, the instrument 110 may include a tube, and a channel 1300 may extend through the coupler element 117. In some embodiments, the tube may create a closed path for blood flow and prevent contamination of the blood due to drug adsorption in the VAD. In some embodiments, the instrument 110 may be colored to increase visibility.

[0096] In some embodiments, such as Figures 13A-13B, a fluid pathway may be disposed between an outer surface of the instrument 110 and an inner surface of the tube 102 and may extend through the distal connector 212 and the proximal connector 209. Thus, in some embodiments, the distal end 106 may not include the fluid seal 214. In some embodiments, blood may flow proximally through the instrument 110 and/or the fluid pathway between the outer surface of the instrument 110 and the inner surface of the tube 102. In some embodiments, the blood in the fluid pathway may flow into the blood collection device coupled to the proximal connector 209. In some embodiments, the blood collection device may be coupled directly to the proximal connector 209 or coupled to the proximal connector 209 via a needleless connector or another suitable device. In some embodiments, during infusion, fluid may flow distally through the fluid pathway between the outer surface of the instrument 110 and the inner surface of the tube 102, and through the distal connector 212.

[0097] In some embodiments, in some embodiments, the extension set may be coupled to various portions of a particular catheter assembly, and the instrument 110 may gain access to the vasculature of the patient via various routes. As an example, the instrument 110 may be advanced through the adapter, such as the Y-adapter or the T-adapter, and/or the other extension tube. In some embodiments, the instrument 110 may be advanced through a particular side port of a

catheter adapter. In some embodiments, a route of the instrument 110 may be straight and aligned with a longitudinal axis of the particular catheter assembly. In some embodiments, blood may flow into the blood collection device via various routes, such as via one or more of the adapter, the other extension tube, and the side port.

[0098] In some embodiments, in order for fluid to flow through the fluid pathway between the outer surface of the instrument 110 and the inner surface of the tube 102, the fluid may flow around and/or through the coupler element 117. In some embodiments, one or more fenestrations, ribs, or other channels may facilitate fluid flow from a distal side of the coupler element 117 to a proximal side of the coupler element 117.

[0099] Referring now to Figure 13B, in some embodiments, the instrument 110 may include a guidewire and/or spring, which may be constructed of metal or another suitable material. In some embodiments, the spring may have a varying pitch along its length. For example, the pitch of the spring distal to the tip of the catheter may allow more blood flow and increase flow rate. In some embodiments, the spring may have a smaller pitch near the tip of the catheter to prevent blood clots from entering the VAD, but still allow blood flow through it. In some embodiments, the spring may include the guidewire through the center or along one or more sides of the spring for added stiffness to ease insertion.

[00100] Referring now to Figures 14A-14C, in some embodiments, the distal connector 1400 may include a blunt cannula 1400, which may form a distal opening 1402. In some embodiments, a cap 1406 may surround the blunt cannula 1400. In some embodiments, the cap 1406 may include one or more protrusions 1408, which may facilitate gripping of the cap 1406 by the clinician prior to removal of the cap 1406 from the blunt cannula 1400 by the clinician. As illustrated, for example, in Figures 14B-14C, a distal end 1410 of the cap 1406 may be closed. As illustrated, for

example, in Figure 14C, the cap 1406 may be adjacent or proximate a proximal end of the blunt cannula 1400, which may prevent the instrument 110 from moving distal to the blunt cannula 1400 during shipping and/or priming. In some embodiments, the cap 1406 may include one or more vent holes extending through the cap 1406 proximal to the distal end 1410.

[00101] All examples and conditional language recited herein are intended for pedagogical objects to aid the reader in understanding the invention and the concepts contributed by the inventor to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Although embodiments of the present disclosure have been described in detail, it should be understood that the various changes, substitutions, and alterations could be made hereto without departing from the spirit and scope of the disclosed embodiments.