

SYSTEMS AND METHODS FOR FACILITATING INSTRUMENT DELIVERY THROUGH A PERIPHERAL INTRAVENOUS CATHETER

[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.

[0002] A common type of catheter is an over-the-needle peripheral intravenous catheter (“PIVC”). As its name implies, the over-the-needle PIVC may be mounted over an introducer needle having a sharp distal tip. The PIVC and the introducer needle may be assembled so that the distal tip of the introducer needle extends beyond the distal tip of the PIVC with the bevel of the needle facing up away from skin of the patient. The PIVC 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 PIVC in the blood vessel, a user generally confirms that there is “flashback” of blood in a flashback chamber of a PIVC assembly. Once placement of the needle has been confirmed, the user may temporarily occlude flow in the vasculature and remove the introducer needle, leaving the PIVC in place for future blood withdrawal and/or fluid infusion.

[0004] Currently, there may be several limitations to the use of a PIVC for fluid infusion and blood draw. The PIVC may narrow, collapse, or clog with time, leading to failure of the PIVC. Due to this, PIVCs may often be used for acquiring a blood sample at a time of PIVC placement, but they are much less frequently used for acquiring a blood sample during the PIVC dwell period. Therefore, when a blood sample is needed, an additional needle stick may be used to provide vein access for blood collection, which may be painful for the patient. In order to extend the life of the

PIVC and allow for fluid infusion and/or blood withdrawal through the PIVC assembly, in some instances, an instrument delivery device may be used to deliver an additional catheter through the PIVC.

[0005] Delivery of the additional catheter through the PIVC may be difficult in current integrated catheter systems having an integrated extension tube, such as, for example, the BD NEXIVA™ Closed IV Catheter System, the BD NEXIVA™ DIFFUSICS™ Closed IV Catheter System, the Becton Dickinson PEGASUS™ Safety Closed IV Catheter System, or other integrated catheter systems. In further detail, it may be difficult to advance the additional catheter through a length of the integrated extension tube and/or through a septum disposed in a lumen of a catheter adapter of the system in order to place the additional catheter within or beyond the PIVC.

[0006] 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.

SUMMARY

[0007] The present disclosure relates generally to devices, systems, and methods for facilitating delivery of an instrument through a PIVC. In some embodiments, the instrument may include an additional catheter for fluid infusion or blood draw, a guidewire, a probe with a sensor, or a light tube for disinfection. In some embodiments, a system for facilitating instrument delivery through the PIVC may include a catheter adapter, which may include a proximal end, a distal end, and a lumen extending there through. In some embodiments, the PIVC may extend distally from the catheter adapter. In some embodiments, the catheter adapter may include a side port. In some embodiments, an extension tube may extend from the side port. In some embodiments, a blood control valve may be disposed in the lumen of the catheter adapter.

[0008] In some embodiments, the blood control valve may be disposed proximal to the side port. In these and other embodiments, the blood control valve may not allow air venting. In some embodiments, the blood control valve may be disposed distal to the side port. In these and other embodiments, the blood control valve may allow air venting.

[0009] In some embodiments, the system may include a Y-adapter coupled to a proximal end of the extension tube. In some embodiments, the Y-adapter may include a first port and a second port. In some embodiments, a needleless connector may be coupled to the first port, and a needleless connector may be coupled to the second port. In these and other embodiments, the blood control valve may allow air venting, which may facilitate observation of blood flashback by the user.

[0010] In some embodiments, the system may include a cap, which may be coupled to the proximal end of the catheter adapter. In some embodiments, the system may include a needleless connector coupled to the proximal end of the catheter adapter.

[0011] In some embodiments, the proximal end of the catheter adapter may include a luer adapter or a non-luer adapter. In some embodiments, an extension set may be coupled to the proximal end of the catheter adapter. In some embodiments, the extension set may include a distal connector coupled to the proximal end of the catheter adapter, and a proximal connector. In some embodiments, the extension set may include tubing disposed between the distal connector and the proximal connector. In some embodiments, the proximal connector may include a needleless connector.

[0012] In some embodiments, the distal connector may include a cannula that penetrates the blood control valve in response to the distal connector being coupled to the proximal end of the catheter adapter. In some embodiments, the cannula may be blunt. In some embodiments, the cannula may be constructed of plastic or metal, such as, for example, steel.

[0013] In some embodiments, the distal connector may include a male luer, which may provide a fluid tight seal. In some embodiments, the male luer may include an extension, which may penetrate the blood control valve in response to the distal connector being coupled to the proximal end of the catheter adapter. In some embodiments, the extension and/or the cannula may include one or more flushing windows. In some embodiments, the cannula and the extension may each correspond to an actuator of the blood control valve. In some embodiments, the lumen of the catheter adapter may not include an actuator of the blood control valve other than the cannula or the extension.

[0014] In some embodiments, the system may include an instrument delivery device, which may be coupled to the proximal end of the catheter adapter. In some embodiments, the instrument delivery device may include the instrument, which may be configured to advance distally through the blood control valve and the PIVC. In some embodiments, a distal portion of the lumen of the

catheter adapter may be narrowed to provide a guide feature for the instrument as the instrument is advanced distally.

[0015] In some embodiments, the system may include a needle assembly removably coupled to the proximal end of the catheter adapter. In some embodiments, an introducer needle of the needle assembly may extend through the blood control valve.

[0016] It is to be understood that both the foregoing general description and the following detailed description are exemplary 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

[0017] Example embodiments will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0018] Figure 1A is an upper perspective view of an example catheter system, illustrating an example needle assembly coupled to a proximal end of an example catheter assembly, according to some embodiments;

[0019] Figure 1B is an exploded view of the needle assembly and the catheter assembly, according to some embodiments;

[0020] Figure 1C is a cross-sectional view of the catheter assembly, illustrating an example blood control valve disposed proximal to an example side port, according to some embodiments;

[0021] Figure 1D is another cross-sectional view of the catheter assembly, illustrating the blood control valve disposed distal to the side port, according to some embodiments;

[0022] Figure 1E is an upper perspective view of an example needleless connector coupled to the proximal end of the catheter assembly, according to some embodiments;

[0023] Figure 2A is an upper perspective view of an example extension set coupled to the proximal end of the catheter assembly, according to some embodiments;

[0024] Figure 2B is an upper perspective view of an example instrument delivery device coupled to the extension set;

[0025] Figure 2C is a cross-sectional view of an example distal connector of the extension set coupled to the proximal end of the catheter assembly, according to some embodiments;

[0026] Figure 2D is a cross-sectional view of another example distal connector of the extension set coupled to the proximal end of the catheter assembly, according to some embodiments;

[0027] Figure 2E illustrates an example actuator prior to coupling of the distal connector to the proximal end of the catheter assembly, according to some embodiments; and

[0028] Figure 2F illustrates the actuator penetrating the blood control valve, according to some embodiments.

DESCRIPTION OF EMBODIMENTS

[0029] The present disclosure relates generally to devices, systems, and methods for facilitating delivery of an instrument through a PIVC. In some embodiments, the instrument may include an additional catheter for fluid infusion or blood draw, a guidewire, a probe with a sensor, or a light tube for disinfection.

[0030] Referring now to Figure 1A, in some embodiments, a system 10 for facilitating instrument delivery through a PIVC 14 may include a catheter adapter 12, the PIVC 14 extending distally from the catheter adapter 12, and an extension tube 16 extending from the catheter adapter 12. In some embodiments, the catheter adapter 12 may include a side port 18. In some embodiments, the extension tube 16 may extend from the side port 18. In some embodiments, the catheter adapter 12 may include a proximal end 20 and a distal end 22.

[0031] In some embodiments, the system 10 may include a Y-adapter 24, which may include a distal end 26, a first port 28, and a second port 30. In some embodiments, the distal end 26 of the Y-adapter 24 may be coupled to the extension tube 16. In some embodiments, the extension tube 16 may include a clamp 17, which may selectively close off the extension tube 16 to prevent blood or another fluid from flowing through the extension tube 16.

[0032] In some embodiments, the system 10 may be integrated, having the integrated extension tube 16. In other embodiments, the system 10 may be non-integrated. In some embodiments, the system 10 may include a needle assembly, which may include a needle hub 34 and an introducer needle 36. In some embodiments, in response to the introducer needle 36 being inserted into a vein of the patient, flashback of blood may flow through a sharp distal tip 38 of the introducer needle 36 and out of a distal notch of the introducer needle 36 into a portion of the system 10. For example, the blood flashback may flow through the distal tip 38 and out of the distal notch into a space between an exterior surface of the introducer needle 36 and an interior surface of the PIVC 14 (this may be referred to as “primary flashback”). In some embodiments, blood flashback may flow into the extension tube 16 (this may be referred to as “secondary flashback”). Primary and/or secondary blood flashback may confirm that the introducer needle 36 and/or a distal tip 48 of the PIVC 14 are located within the vein of the patient. In some embodiments, the needle assembly may be

removably coupled to the proximal end 20 of the catheter adapter 12. In some embodiments, the introducer needle 36 of the needle assembly may extend through the blood control valve 44.

[0033] In some embodiments, a first needleless connector 40a may be coupled to the first port 28, and/or a second needleless connector 40b may be coupled to the second port 30. In these and other embodiments, a blood control septum or valve disposed within the lumen 46 of the catheter adapter 12 may allow air venting. Some non-limiting examples of needleless connectors are described in U.S. Patent No. 8,066,670, filed November 5, 2007, entitled “VASCULAR ACCESS DEVICE SEPTUM VENTING,” which is hereby incorporated by reference. In some embodiments, the system 10 may not include a vent-plug. In some embodiments, the system 10 may include a vent plug. In some embodiments, the vent plug may be coupled to one of the first port 29 and the second port 30, and a particular needleless connector may be coupled to another of the first port 29 and the second port 30. In some embodiments, the system 10 may be pre-assembled as illustrated in Figure 1A such that the user removes the system 10 illustrated in Figure 10 from a package.

[0034] Referring now to Figures 1A-1B, in some embodiments, the needle assembly may not include a safety mechanism. In some embodiments, the needle assembly may include a safety mechanism (not illustrated), which may shield the sharp, distal tip 38 of the introducer needle 36 in response to the needle assembly being removed from the system 10. The safety mechanism may include any safety mechanism configured to shield the sharp, distal tip 38.

[0035] The safety mechanism may be coupled to the catheter adapter 12 in any number of ways. In some embodiments, the safety mechanism may include a spring mechanism. In some embodiments, the safety mechanism may be similar to that of the BD INSYTE™ AUTOGUARD™ BC Shielded IV Catheter. In some embodiments, the safety mechanism may

include an internal interlock in which the safety mechanism is coupled to an internal surface of a catheter adapter 12. Coupling may include threading, fitting, snapping, connecting, attaching, fastening, clipping, hooking, or any other suitable means of coupling. Non-limiting examples of safety mechanisms that include an internal interlock are provided in: U.S. Patent No. 8,496,623, titled BI-DIRECTIONAL CANNULA FEATURE CAPTURE MECHANISM, filed March 2, 2009; U.S. Patent No. 9,399,120, titled BI-DIRECTIONAL CANNULA FEATURE CAPTURE MECHANISM, filed July 11, 2013; U.S. Patent Application No. 62/314,262, titled CANNULA CAPTURE MECHANISM, filed March 28, 2016, each of which is herein incorporated by reference in its entirety. In some embodiments, the safety mechanism may include a clip disposed within the catheter adapter 14, a non-limiting example of which is provided in U.S. Patent No. 6,117,108, titled SPRING CLIP SAFETY IV CATHETER, filed June 12, 1998, which is herein incorporated by reference in its entirety.

[0036] In some embodiments, the safety mechanism may include an external interlock in which the safety mechanism is coupled to an external surface of the catheter adapter 12. In some embodiments, the safety mechanism may be coupled to an external surface of the catheter adapter and an internal and/or external surface of the needle hub 34. Coupling may include threading, fitting, snapping, connecting, attaching, fastening, clipping, hooking, or any other suitable means of coupling. Non-limiting examples of safety mechanisms that include an external interlock are provided in U.S. Patent Application No. 14/295,953, titled PORTED IV CATHETER HAVING EXTERNAL NEEDLE SHIELD AND INTERNAL BLOOD CONTROL SEPTUM, filed June 4, 2014, which is herein incorporated by reference in its entirety. In some embodiments, the safety mechanism may include a V-clip or a similar clip. A non-limiting example of a V-clip is provided in U.S. Patent Application No. 14/295,953, titled PORTED IV CATHETER HAVING

EXTERNAL NEEDLE SHIELD AND INTERNAL BLOOD CONTROL SEPTUM, filed June 4, 2014, which is herein incorporated by reference in its entirety. The V-clip may selectively retain a portion of the catheter adapter 12.

[0037] Referring now to Figure 1C, in some embodiments, a blood control septum or valve 44 may be disposed in the lumen 46 of the catheter adapter 12. In some embodiments, the blood control valve 44 may be single-use or multi-use. In some embodiments, the blood control valve 44 may provide a physical barrier to control the flow of blood and other fluids between a distal chamber 50 and the proximal chamber 52 of the catheter adapter 12. For example, upon insertion of the distal tip 38 of the introducer needle 36 and the distal tip 48 of the PIVC 14 into the patient's vein and the removal of the needle 50, blood from the patient may flow through the PIVC 14 and into the distal chamber 50, but may be prevented from bypassing the blood control valve 44. In some embodiments, the blood control valve 44 may be secured within the lumen 46 of the catheter adapter 12 in any number of ways, including, for example, an annular groove, adhesive, plastic weld, retainer clip, mechanical connection, etc.

[0038] In some embodiments, the blood control valve 44 may include any structural configuration that is capable of dividing the lumen 46 into the distal chamber 50 and the forward chamber 52. In some embodiments, the blood control valve 44 may include a membrane. In some embodiments, the blood control valve 44 may include a disc. In some embodiments, the blood control valve 44 may include one or more slits, which form a pathway through the blood control valve 44. In some embodiments, the blood control valve 44 may constructed of a material that is resilient and elastic.

[0039] In some embodiments, the blood control valve 44 may differ from a septum of one or more of the following in one or more ways: the BD NEXIVA™ Closed IV Catheter System, the

BD CATHENA™ Catheter System, and the BD INSYTE™ AUTOGUARD™ BC Shielded IV Catheter. In the BD NEXIVA™ Closed IV Catheter System, the septum may include a distal piece having a first barrier against blood flow and a proximal piece having a second barrier against blood flow. The septum of the BD NEXIVA™ Closed IV Catheter System may be disposed within a canister and/or constructed of polyisoprene.

[0040] In some embodiments, the blood control valve 44 may be disposed proximal to the side port 18. In further detail, in some embodiments, the blood control valve 44 may be disposed proximal to an opening of the side port 18 into the lumen 46. In these and other embodiments, the blood control valve 44 may not allow air venting such that air is not permitted to pass between the distal and proximal chambers 50, 52, which may prevent blood and/or priming fluid leakage.

[0041] In some embodiments, the blood control valve 44 may allow air venting, which may facilitate observation of blood flashback by the user. In some embodiments, the blood control valve 44 may allow air venting in any number of ways. For example, an outer surface of the blood control valve 44 may include one or more grooves permeable to air but not fluid. As another example, an inner surface of the catheter adapter 12 disposed along a length of the blood control valve 44 may include one or more grooves permeable to air but not fluid. In these embodiments, the blood control valve 44 may not be permeable to fluid when in a closed position.

[0042] In some embodiments, a distal portion of the lumen 46 of the catheter adapter 12 may be narrowed to provide a guide feature 51 for the instrument as the instrument is advanced distally.

[0043] Referring now to Figure 1D, in some embodiments, the blood control valve 44 may be disposed distal to the side port 18. In further detail, in some embodiments, the blood control valve 44 may be disposed distal to the opening of the side port 18 into the lumen 46. In these and other embodiments, the blood control valve 44 may allow air venting.

[0044] Referring now to both Figures 1C-1D, in some embodiments, the system 10 may include a cap 54, which may be coupled to the proximal end 20 of the catheter adapter 12 to seal the proximal end 20 of the catheter adapter 12 to both air and fluid.

[0045] Referring now to Figure 1E, in some embodiments, the system 10 may include a needleless connector 40 coupled to the proximal end 20 of the catheter adapter 12.

[0046] Referring now to Figure 2A, in some embodiments, an extension set 56 may be coupled to the proximal end 20 of the catheter adapter 12. In some embodiments, the proximal end 20 of the catheter adapter 12 may include a luer adapter, such as, for example, a slip or thread male or female luer adapter, or a non-luer adapter. In some embodiments, the extension set 56 may include a distal connector 58 coupled to the proximal end 20 of the catheter adapter, and a proximal connector 60.

[0047] In some embodiments, the extension set 56 may include tubing 62 disposed between the distal connector 58 and the proximal connector 60. In some embodiments, the tubing 62 may include a clamp 17. In some embodiments, a distal end of the tubing 62 may be secured within the distal connector 58, and a proximal end of the tubing 62 may be secured within the proximal connector 60. In some embodiments, the proximal connector 60 may include a needleless connector 40. In some embodiments, the distal connector 58 and/or the proximal connector 60 may include a luer adapter, such as, for example, such as a slip or thread male or female luer adapter, or a non-luer adapter.

[0048] In some embodiments, the tubing 62 may be rigid, semi-rigid, or flexible. In some embodiments, one or more of the following may form a straight or nearly straight pathway for delivery of the instrument to the PIVC 14: the PIVC 14, the catheter adapter 12, the distal connector 58, the proximal connector 60, and the tubing 62. In some embodiments, the straight or

nearly straight pathway may be smooth such that the instrument is prevented from disturbance by any catches, such as any sharp edges or snag points.

[0049] Referring now to Figure 2B, in some embodiments, the system 10 may include an instrument delivery device 64, which may be removably coupled to the proximal end 20 of the catheter adapter 12. In some embodiments, the instrument delivery device 64 may be coupled to the proximal end 20 of the catheter adapter 12 directly or via the extension set 56 or via the needleless connector 40 (such as in Figure 1E, for example). In further detail, in some embodiments, the instrument delivery device 64 may be coupled directly to the proximal connector 60 of the extension set 56 or coupled directly to the needleless connector 40. In some embodiments, the instrument delivery device 64 may include the instrument 66, which may be configured to advance distally through the blood control valve 44 and into or through the PIVC 14. Non-limiting examples of instrument delivery devices are described in U.S. Patent No. 9,750,446, filed February 4, 2013, entitled “SYSTEMS AND METHODS FOR PHLEBOTOMY THROUGH A PERIPHERAL IV CATHETER,” and U.S. Patent Application No. 62/534,552, filed July 19, 2017, entitled “EXTENSION HOUSING A PROBE OR INTRAVENOUS CATHETER,” which are hereby incorporated by reference. In some embodiments, a blood collection device may be coupled to a proximal end of the instrument 66.

[0050] Referring now to Figure 2C, in some embodiments, the distal connector 58 may include a cannula 68 that penetrates the blood control valve 44 in response to the distal connector 58 being coupled to the proximal end 20 of the catheter adapter 12. In some embodiments, the cannula 68 may be blunt. In some embodiments, the cannula 68 may be constructed of plastic or metal, such as, for example, steel. In some embodiments, the cannula 68 may include one or more flushing windows 72 through which fluid may travel.

[0051] Referring now to Figure 2D, in some embodiments, the distal connector 58 may include a male luer, which may include an extension 70 or modified tip. In some embodiments, the extension 70 may penetrate the blood control valve 44 in response to the distal connector 58 being coupled to the proximal end 20 of the catheter adapter 12. In some embodiments, the extension 70 may include one or more flushing windows 72 through which fluid may travel. In some embodiments, the cannula 68 of Figure 2C and the extension 70 of Figure 2D may each correspond to an actuator of the blood control valve. In some embodiments, the lumen 46 of the catheter adapter 12 may not include an actuator of the blood control valve other than the cannula 68 or the extension 70. In further detail, in some embodiments, the lumen 46 of the catheter adapter 12 may not include an actuator of the blood control valve when the distal connector 58 is not coupled to the catheter adapter 12. It is understood that in some embodiments, the male luer having the cannula 68 or the extension 70 may be part of a particular instrument, the distal connector 58, or the needleless connector 40.

[0052] Referring now to Figure 2E-2F, in some embodiments, the lumen 46 of the catheter adapter 12 may include an actuator 76, which may penetrate the blood control valve 44 in response to coupling of the distal connector 58 to the proximal end 20 of the catheter adapter 12. In some embodiments, the actuator 76 may be a separate element and/or not coupled with the distal connector 58 or the needleless connector 40. In some embodiments, the actuator 76 may be positioned within the lumen 46 and may not penetrate the blood control valve 44 when the extension set 56 is removed from the catheter adapter 12. In some embodiments, the actuator 76 may not be present when the distal connector 58 includes the male luer having the extension 70 or the cannula 68. In some embodiments, the actuator 76 may include one or more flushing windows 72 through which fluid may travel.

[0053] In some embodiments, the system 10 may include one or more means of returning the actuator 76 to an unactuated position, allowing the blood control valve 44 to close and seal. For example, the blood control valve 44 may provide a restoring force to move the actuator 76 proximally to the unactuated position.

[0054] As another example, the lumen 46 of the catheter adapter 12 may include a spring 74 and the actuator 76. In some embodiments, the actuator 76 may be attached to the spring 74. In some embodiments, when a male luer is connected to the catheter adapter 12, the actuator 76 may be pushed distally and may open a slit of the blood control valve 44, allowing infusion or blood draw. In some embodiments, the spring 74 may be unactuated or compressed in response to contact from the male luer. In some embodiments, when the male luer is disconnected from the catheter adapter 12, the spring 74 may be actuated and may push the actuator 76 back in the proximal direction, thus closing the slit of the blood control valve 44 and sealing the fluid path. In some embodiments, the distal connector 58 of the extension set 56 may include the male luer. In some embodiments, the needleless connector 40 may include the male luer. In some embodiments, a particular instrument, such as, for example, the instrument 66, may include the male luer.

[0055] 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 inventions 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 invention.