

CATHETER SYSTEM TO FACILITATE BLOOD SAMPLING AND RELATED METHODS

BACKGROUND

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

[0002] Common types of intravenous catheter are peripheral IV catheters (“PIVCs”), peripherally inserted central catheters (“PICCs”), and midline catheters. Intravenous catheters may include “over-the needle” catheters, which may be mounted over a needle having a sharp distal tip. The sharp distal tip may be used to pierce skin and the vasculature of the patient. Insertion of the intravenous catheter into the vasculature may follow the piercing of the vasculature by the needle. The needle and the intravenous catheter are generally inserted at a shallow angle through the skin into the vasculature of the patient with a bevel of the needle facing up and away from the skin of the patient.

[0003] In order to verify proper placement of the introducer needle and/or the intravenous catheter in the vasculature, a user generally confirms that there is flashback of blood, which may be visible to the user. In some instances, the introducer needle may include a notch disposed towards a distal end of the introducer needle, and in response to the distal tip of the introducer needle being positioned within the vasculature, blood may flow proximally through a needle lumen, exit the needle lumen through the notch, and then travel proximally between an outer surface of the introducer needle and an inner surface of the intravenous catheter.

[0004] Accordingly, where the intravenous catheter is at least partially transparent, the user may visualize a small amount of blood “flashback” and thereby confirm placement of the intravenous catheter within the vasculature. Presence of a vasculature entrance indicator, such as flashback, may facilitate successful placement of intravenous catheters. Once placement of the introducer needle within the vasculature has been confirmed, the user may temporarily occlude flow in the vasculature and withdraw the introducer needle, leaving the intravenous catheter in place for future blood withdrawal and/or fluid infusion.

[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.

SUMMARY

[0006] The present disclosure generally relates to devices, systems, and methods to facilitate blood sampling. In some embodiments, a catheter system may include a catheter assembly, which may include a catheter adapter and a catheter. In some embodiments, the catheter adapter may include a distal end, a proximal end, and a lumen extending through the distal end of the catheter adapter and the proximal end of the catheter adapter. In some embodiments, the catheter may be secured within the catheter adapter and may extend distally from the distal end of catheter adapter.

[0007] In some embodiments, the catheter system may include a needle assembly, which may include a needle hub, which may include a distal end coupled to the proximal end of the catheter adapter. In some embodiments, the needle hub may include a proximal end and a flashback chamber extending through the proximal end of the needle hub. In some embodiments, the needle

hub may include a through-hole disposed at a distal end of the flashback chamber. In some embodiments, an introducer needle may be press-fit within the through-hole.

[0008] In some embodiments, the catheter system may include a plug coupled to the proximal end of the needle hub. In some embodiments, the plug may plug a proximal opening of the flashback chamber and provide venting of the flashback chamber. In some embodiments, the plug may include a distal end, a proximal end, a lumen extending through the distal end of the plug and the proximal end of the plug, and a tubular section disposed between the distal end of the plug and the proximal end of the plug. In some embodiments, the distal end of the plug may include a neck portion and a skirt, which may each extend from the tubular section to define an annular channel between the skirt and the neck portion.

[0009] In some embodiments, the neck portion may be inserted into the proximal end of the needle hub. In some embodiments, an outer surface of the neck portion may include one or more air vent channels, which may be configured to provide venting of the flashback chamber. In some embodiments, the proximal end of the plug may include a luer adapter. In some embodiments, the proximal end of the plug may include a septum, which may be disposed within the luer adapter.

[0010] In some embodiments, the septum may include a resiliently deformable piston element. In some embodiments, the piston element may include a piston head coupled to one or more bellows. In some embodiments, the piston head may include a slit or bore.

[0011] In some embodiments, the septum may include a proximal portion, which may be disposed outside the luer adapter. In some embodiments, the septum may include a distal portion, which may extend across the tubular section. In some embodiments, the septum may include an intermediate portion, which may be disposed between the proximal portion and the distal portion. In some embodiments, the septum may include a slit, which may extend longitudinally through

the proximal portion, the distal portion, and the intermediate portion. In some embodiments, a cross-section of the proximal portion, the distal portion, and the intermediate portion may form a general H-shape.

[0012] In some embodiments, a portion of a wall of the tubular section may include a hole, which may extend through the wall. In some embodiments, a hydrophobic membrane may be disposed within the hole towards an outside of the plug. In some embodiments, a hydrophilic membrane may be disposed within the hole towards an inside of the plug and/or proximate the hydrophobic membrane. In some embodiments, the hydrophilic membrane may prevent fluid leakage through the hole, and the hydrophobic membrane may provide venting of the flashback chamber. In some embodiments, the hole may be distal to the distal portion of the septum.

[0013] In some embodiments, as an alternative to the hydrophobic membrane and the hydrophilic membrane, a porous membrane may be disposed within the hole. In some embodiments, the porous membrane may be configured to pass air but not blood.

[0014] In some embodiments, a distal end of the catheter may include a notch configured to receive blood. In some embodiments, the notch may be in fluid communication with the flashback chamber. In some embodiments, the needle assembly may include a grip extending outwardly from the needle hub and distal to the distal end of the needle hub. In some embodiments, the introducer needle may include multiple inner diameters.

[0015] In some embodiments, a method of blood sampling or collecting blood may include inserting the catheter system into vasculature of a patient. In some embodiments, the method may include coupling a blood collection device to the proximal end of the plug. In some embodiments, the method may include collecting blood from the vasculature within the blood collection device. In some embodiments, the method may include priming the catheter system prior to insertion of

the catheter system into the vasculature. In some embodiments, the distal end of the catheter may include the notch in fluid communication with the flashback chamber, and the blood from the vasculature may be collected within the blood collection device without a discard blood sample.

[0016] 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

[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 in an insertion configuration ready for insertion into a patient, according to some embodiments;

[0019] Figure 1B is an upper perspective view of an example needle hub, with an example introducer needle removed, according to some embodiments;

[0020] Figure 1C is a cross-sectional view of the needle hub of Figure 1B, according to some embodiments;

[0021] Figure 1D is a cross-sectional view of the needle hub of Figure 1B, illustrating the introducer needle press-fit within an example through-hole of the needle hub, according to some embodiments;

[0022] Figure 1E is an upper perspective view of an example plug, according to some embodiments;

[0023] Figure 1F is a cross-sectional view of the plug of Figure 1E coupled to the needle hub of Figure 1B, according to some embodiments;

[0024] Figure 2A is a lower perspective view of the plug of Figure 1E, illustrating an example vent, according to some embodiments;

[0025] Figure 2B is a cross-sectional view of the plug of Figure 2A, according to some embodiments;

[0026] Figure 3A is a lower perspective view of the plug of Figure 1E, illustrating another example vent, according to some embodiments;

[0027] Figure 3B is a cross-sectional view of the plug of Figure 3A, according to some embodiments;

[0028] Figure 4A is an upper perspective view of another example catheter system in the insertion configuration ready for insertion into the patient, according to some embodiments;

[0029] Figure 4B is an upper perspective view of another example needle hub, with an example introducer needle removed, according to some embodiments;

[0030] Figure 4C is a cross-sectional view of the needle hub of Figure 4B, according to some embodiments;

[0031] Figure 4D is a cross-sectional view of the needle hub of Figure 4B, illustrating the introducer needle press-fit within an example through-hole of the needle hub, according to some embodiments;

[0032] Figure 4E is an upper perspective view of another example plug, according to some embodiments;

[0033] Figure 4F is a cross-sectional view of the plug of Figure 4E coupled to the needle hub of Figure 4B, according to some embodiments;

[0034] Figure 5A is a cross-sectional view of an example catheter, according to some embodiments;

[0035] Figure 5B is a top view of the catheter of Figure 5B, according to some embodiments; and

[0036] Figure 6 is a cross-sectional view of an example introducer needle, according to some embodiments.

DESCRIPTION OF EMBODIMENTS

[0037] 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.

[0038] Referring now to Figure 1A, in some embodiments, a catheter system 10 may include a catheter assembly 12, which may include a catheter adapter 14 and a catheter 16. In some embodiments, the catheter adapter 14 may include a distal end 18, a proximal end 20, and a lumen extending through the distal end 18 and the proximal end 20. In some embodiments, the catheter 16 may be secured within the catheter adapter 14 and may extend distally from the distal end 18 of catheter adapter 14.

[0039] In some embodiments, the catheter system 10 may include a needle assembly 22, which may include a needle hub 24. In some embodiments, the needle hub 24 may include a distal end coupled to the proximal end 20 of the catheter adapter 14. In some embodiments, the needle assembly 22 may include an introducer needle 25, which may extend through the catheter 16 when the catheter system 10 is in an insertion configuration, ready for insertion into vasculature of a patient.

[0040] In some embodiments, the introducer needle 25 may include a sharp distal tip, which may aid in piercing the vasculature. In some embodiments, the catheter system 10 may include a plug 26 coupled to the proximal end of the needle hub 24. In some embodiments, the needle assembly 22 may include a grip 28, which may extend outwardly from the needle hub 24 and distal to the distal end of the needle hub 24.

[0041] In some embodiments, the catheter system 10 may include a peripheral intravenous catheter system (“PIVC”), such as, for example, the BD NEXIVA™ Closed IV Catheter system, the BD CATHENA™ Catheter system, the BD VENFLON™ Pro Safely Shielded IV Catheter system, the BD NEOFLON™ IV Cannula system, the BD INSYTE™ AUTOGUARD™ BC Shielded IV Catheter system, or another suitable peripheral intravenous catheter system. In some embodiments, the catheter system 10 may include a peripherally-inserted central catheter (“PICC”) system or a midline catheter system.

[0042] Referring now to Figures 1B-1F, in some embodiments, the needle hub 24 may include a proximal end 30. In some embodiments, the needle hub 24 may include a wall 32, which may be disposed at the distal end 34 of the needle hub 24 or between the distal end 34 of the needle hub 24 and the proximal end 30 of the needle hub 24. In some embodiments, the needle hub 24 may include a through-hole 36. In some embodiments, the needle hub 24 may include a flashback

chamber 38, which may extend through the proximal end 30 of the needle hub 24. In some embodiments, the through-hole 36 may be disposed at a distal end of the flashback chamber 38. In some embodiments, the wall 32 may include the through-hole 36. In some embodiments, flashback chamber 38 may be proximate the wall 32. In some embodiments, the needle hub 24 may be transparent, which may allow visualization of blood within the flashback chamber 38.

[0043] In some embodiments, the introducer needle 25 may be press-fit within the through-hole 36. In further detail, in some embodiments, an outer diameter of a proximal end of the introducer needle 25 may be slightly greater than a diameter of the through-hole 36 such that the introducer needle 25 and the through-hole 36 interfere with each other. In some embodiments, a proximal end of the introducer needle 25 may be disposed within the flashback chamber 38, such that in response to insertion of the introducer needle 25 within the vasculature of the patient, blood may flow through the introducer needle 25 and into the flashback chamber 38, where it may be visible to a user.

[0044] In some embodiments, the plug 26 may plug a proximal opening 40 of the flashback chamber 38 and provide venting of the flashback chamber 38. In some embodiments, the plug 26 may include a distal end 42, a proximal end 44, a lumen 46 extending through the distal end 42 of the plug 26 and the proximal end 44 of the plug 26, and a tubular section 48 disposed between the distal end 42 of the plug 26 and the proximal end 44 of the plug 26. In some embodiments, the distal end 42 of the plug 26 may include a neck portion 50 and/or a skirt 52, which may each extend from the tubular section 48 to define an annular channel 54 between the skirt 52 and the neck portion 50.

[0045] In some embodiments, the neck portion 50 may be inserted into the proximal end 30 of the needle hub 24 and may fit securely within the proximal end 30 of the needle hub 24. In some

embodiments, an outer surface of the neck portion 50 may include one or more air vent channels 56, which may be configured to provide venting of the flashback chamber 38. In some embodiments, the air vent channels 56 may be configured to pass air but not blood.

[0046] In some embodiments, the proximal end 44 of the plug 26 may include a luer adapter 58. In some embodiments, the proximal end 44 of the plug 26 may include a septum 60, which may be disposed within the luer adapter 58. In some embodiments, the air vent channels 56 may facilitate blood flow through the introducer needle and into the flashback chamber and the plug 26. In some embodiments, the plug 26 may facilitate blood collection from the flashback chamber via a blood collection device, which may be connected to the luer adapter 58.

[0047] In some embodiments, a method of blood sampling or collecting blood may include inserting the catheter system 10 into vasculature of a patient. In some embodiments, the method may include coupling the blood collection device to the proximal end 44 of the plug 26. In some embodiments, the method may include collecting blood from the vasculature within the blood collection device. In some embodiments, the method may include priming the catheter system 10 prior to insertion of the catheter system 10 into the vasculature.

[0048] In some embodiments, the septum 60 may include a proximal portion 62, which may be disposed outside the luer adapter 58. In some embodiments, the septum 60 may include a distal portion 64, which may extend across the tubular section 48. In some embodiments, the septum 60 may include an intermediate portion 66, which may be disposed between the proximal portion 62 and the distal portion 64. In some embodiments, the septum 60 may include a slit 68, which may extend longitudinally through the proximal portion 62, the distal portion 64, and the intermediate portion 66. In some embodiments, a cross-section of the proximal portion 62, the distal portion 64, and the intermediate portion 66 may form a general H-shape. In some embodiments, the distal

portion 64 may be pinched within the plug 26 to secure the septum 60 within the plug 26, although it is understood that the septum 60 may be secured within the plug 26 by other means.

[0049] Referring now to Figures 2A-2B, in some embodiments, a portion of a wall of the tubular section 48 may include a hole 70, which may extend through the wall. In some embodiments, a hydrophobic membrane 72 may be disposed within the hole 70 towards an outside of the plug 26. In some embodiments, a hydrophilic membrane 74 may be disposed within the hole 70 towards an inside of the plug 26 and/or proximate the hydrophobic membrane 72. In some embodiments, the hydrophilic membrane 74 may prevent fluid leakage through the hole 70, and the hydrophobic membrane 72 may provide venting of the flashback chamber. In some embodiments, after the hydrophobic membrane 72 is wetted by blood, it loses its capacity to vent air and becomes a barrier to prevent atmospheric air from entering the plug 26. The blood collection device, such as a tube or syringe, may then be used to collect blood when negative pressure is applied.

[0050] In some embodiments, the hole 70 may be distal to the distal portion 64 of the septum 60. In some embodiments, the hole 70 may be elongated and/or arc-shaped along a shape of a flange of the tubular section 48. In some embodiments, the hole 70 may be another suitable shape. In some embodiments, the hydrophobic membrane 72 may facilitate blood flow through the introducer needle and into the flashback chamber and the plug 26.

[0051] Referring now to Figures 3A-3B, in some embodiments, as an alternative to the hydrophobic membrane and the hydrophilic membrane described with respect to Figures 2A-2B, a porous membrane 76 may be disposed within the hole 70. In some embodiments, the porous membrane 76 may be configured to pass air but not blood. In some embodiments, the porous

membrane 76 may facilitate blood flow through the introducer needle 25 and into the flashback chamber and the plug 26.

[0052] Referring now to Figures 4A-4D, a catheter system 78 may be similar or identical to the catheter system 10 described with respect to Figures 1A-3B in terms of one or more included components and/or operation. In some embodiments, the catheter system 78 may include a plug 80. In some embodiments, the plug 80 may be similar or identical to the plug 26 described with respect to Figures 1A-3B in terms of one or more included components and/or operation. In some embodiments, the needle hub 24 may be configured to insert into the catheter adapter 14, as illustrated, for example, in Figures 1B-1D. In other embodiments, the catheter adapter 14 may be configured to insert into a distal cavity 82 of the needle hub 24, as illustrated, for example, in Figures 4B-4D.

[0053] Referring now to Figures 4E-4F, in some embodiments, a septum 60 of the plug 80 may include a resiliently deformable piston element. In some embodiments, the piston element comprises a piston head 84 coupled to one or more bellows 86, which may form an accordion shape. In some embodiments, the piston head 84 may include a slit or bore. In some embodiments, in response to coupling of the blood collection device to the luer adapter 58, the piston head 84 may move distally and the bellows 86 may compress. In some embodiments, in response to compression of the bellows 86, the septum 60 may open to allow blood to flow through the septum 60 and into the blood collection device.

[0054] Referring now to Figures 5A-5B, in some embodiments, a distal end of the catheter 16 may include a hole or notch 88 configured to receive blood in response to insertion of the distal end of the catheter 16 into the vasculature of the patient. In some embodiments, the catheter system 10 and/or the catheter system 78 may include the catheter 16 having the notch 88. In some

embodiments, the notch 88 may be in fluid communication with the flashback chamber. In further detail, in some embodiments, blood may flow into the notch 88 and between an inner surface of the catheter 16 and the introducer needle in a proximal direction. Blood may exit the proximal end of the introducer needle, flow into the flashback chamber, and then flow into the plug 26 described with respect to Figures 1A-3B or the plug 80 described with respect to Figures 4A-4F.

[0055] In some embodiments, the distal end of the catheter 16 may include the notch 88 in fluid communication with the flashback chamber, and the blood from the vasculature may be collected within the blood collection device without a discard blood sample. In some embodiments, the discard blood sample may not be necessary because priming solution may not enter the introducer needle due to the notch 88 being in the catheter 16 as opposed to the introducer needle.

[0056] Referring now to Figure 6, in some embodiments, the introducer needle 25 may include multiple inner diameters. In some embodiments, an inner surface of the introducer needle 25 may include one or more stepped portions 90 at which an inner diameter of the introducer needle 25 may increase. In some embodiments, the stepped portions 90 may facilitate increased blood flow through the introducer needle 25. In some embodiments, the catheter system 10 and/or the catheter system 78 may include the introducer needle 25 having the stepped portions 90.

[0057] The present invention may be embodied in other specific forms without departing from its structures, methods, or other essential characteristics as broadly described herein and claimed hereinafter. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.