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PORTED IV CATHETER HAVING EXTERNAL NEEDLE SHIELD AND INTERNAL BLOOD CONTROL SEPTUM

Abstract

An extravascular system is provided which includes a catheter adapter having a blood control septum configured to control flow of a fluid through the catheter adapter, the catheter adapter further having a catheter configured for intravenous insertion. The extravascular system further includes a septum activator slidably inserted within the catheter adapter and configured for advancement through the blood control septum to provide a fluid pathway through the blood control septum. Further still, the extravascular system includes an external safety mechanism comprising a needle hub and a needle shield interconnected via a tether, wherein the needle shield includes a safety clip that is configured to retain a sharpened end of the introducer needle within the needle shield. Some implementations further comprise an access port forming a portion of the catheter adapter and providing selective access to the lumen of the catheter adapter.

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Background/Summary

RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 17/992,831 filed on Nov. 22, 2022, which is a continuation of U.S. patent application Ser. No. 16/678,650 filed on Nov. 8, 2019 (issued as U.S. Pat. No. 11,534,581 on Dec. 27, 2022), which is a continuation of U.S. patent application Ser. No. 14/295,953 filed on Jun. 4, 2014 (issued as U.S. Pat. No. 10,500,376 on Dec. 10, 2019), which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/832,512, filed Jun. 7, 2013. The disclosures of all of these applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION
[0002] The present invention relates to various intravenous (IV) catheter devices having an integrated external needle safety mechanism, an internal blood control valve or septum, and integrated septum activator. More particularly, the present invention relates to an IV catheter assembly having a catheter adapter comprising a blood control septum, and a needle shield selectively coupled to a proximal end of the catheter adapter. The needle shield is configured to catch and retain the sharpened, distal point of an introducer needle following catheterization of a patient. The septum activator is advanced through the blood control septum to provide a fluid pathway therethrough. In some instances the septum activator is advanced through the blood control septum by inserting a Luer device into the catheter adapter as part of an infusion procedure. Some implementations of the present invention further comprise a needle shield that is tethered to a needle hub such that the needle hub, introducer needle, and needle shield form a unitary structure that is removed from the catheter adapter following a catheterization procedure.
BACKGROUND OF THE INVENTION
[0003] Generally, vascular access devices are used for communicating fluid with the vascular system of patients. For example, catheters are used for infusing fluid, such as normal saline solution, various medicaments, and total parenteral nutrition, into a patient, withdrawing blood from a patient, or monitoring various parameters of the patient's vascular system.
[0004] A common type of intravenous (IV) catheter is an over-the-needle peripheral IV catheter. As its name implies, an over-the-needle catheter is mounted over an introducer needle having a sharp distal tip. At least the inner surface of the distal portion of the catheter tightly engages the outer surface of the needle to prevent peelback of the catheter and thus facilitate insertion of the catheter

into the blood vessel. The catheter and the introducer needle are 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 the patient's skin. The catheter and introducer needle are generally inserted at a shallow angle through the patient's skin into a blood vessel.

[0005] In order to verify proper placement of the needle and/or catheter in the blood vessel, the clinician generally confirms that there is “flashback” of blood in a flashback chamber of the catheter assembly. Once proper placement of the catheter into the blood vessel is confirmed, the clinician may apply pressure to the blood vessel by pressing down on the patient's skin over the blood vessel distal of the introducer needle and the catheter. This finger pressure occludes the vessel, minimizing further blood flow through the introducer needle and the catheter.

[0006] The clinician may then withdraw the introducer needle from the catheter. The introducer needle may be withdrawn into a needle tip shield device that covers the needle tip and prevents accidental needle sticks. In general, a needle shield includes a housing, a sleeve, or other similar device that is designed such that when the needle is withdrawn from the patient, the needle tip will be trapped/captured within the needle tip shield. The purpose of these needle tip shield devices is to house the tip of the needle in a secure location, thereby avoiding the possibility of needle sticks after the needle and needle shield device are separated from the catheter, which is left in place to provide intravenous access to the patient.

[0007] Various systems and methods are available that are designed to shield needle tips and then be separated from the remainder of a catheter assembly following catheterization. Some currently available tip shield systems locate the tip shield within the catheter assembly, thereby exposing various surfaces of the needle shield to blood present within the catheter assembly. Upon removal of the tip shield from the catheter assembly, blood may be flicked or splattered, thereby exposing the clinician to blood and blood borne pathogens. Accordingly, there is a need in the art for a catheter assembly having tip shielding features that overcomes the failings of present devices. Such a catheter assembly is provided herein.

BRIEF SUMMARY OF THE INVENTION

[0008] The present invention has been developed in response to problems and needs in the art that have not yet been fully resolved by currently available vascular access systems and methods. Thus, these systems and methods are developed to provide more efficient vascular access systems and methods capable of ensuring proper needle tip shield function.

[0009] An extravascular system for accessing the vasculature of a patient may include a catheter adapter having a distal end supporting a catheter, and further comprising a proximal opening, wherein the catheter adapter includes a lumen extending therebetween. The extravascular system further includes a blood control septum disposed within the lumen of the catheter adapter and dividing the lumen into a proximal fluid chamber and a distal fluid chamber. In some instances, an extravascular system is provided having a septum activator slidably positioned within the proximal fluid chamber, wherein the septum activator includes a base and a probe end. The system further includes an external safety mechanism removably coupled to the proximal opening of the catheter adapter and comprising a safety clip configured to secure a sharpened tip of an introducer needle.

[0010] Some implementations of the present invention further include an external safety mechanism having a needle shield housing a safety clip that is configured to retain a sharpened tip of the introducer needle within the needle shield. The external safety mechanism may also include a needle hub having a first end for securing a proximal end of the introducer needle, and a second end configured to temporarily house the needle shield, wherein the needle shield is slidably housed within the second end. The needle hub may be temporarily coupled to the catheter adapter and configured to support an introducer needle, the introducer needle extending outwardly from the needle hub and through the catheter adapter, septum activator, blood control septum and catheter.

[0011] In some instances, the present invention includes a safety clip having a pawl or other structural feature configured to prevent the sharpened tip of the introducer needle from exiting a

distal opening of the needle shield. The safety clip may also be configured to selectively interconnect the needle shield and the catheter adapter. In some instances, the external safety mechanism is configured to be removed from the proximal opening of the catheter adapter following removal of the sharpened tip of the introducer needle from the catheter and catheter adapter.

[0012] Some implementations of the present invention further include a tether that is configured to couple the needle shield to the needle hub. The tether includes a first end coupled to the needle hub and a second end coupled to the needle shield, the tether having a length that provides a maximum distance between the needle hub and the needle shield, wherein the maximum distance positions and retains the sharpened tip within the needle shield. Some implementations of the present invention further include a blood control septum having a self-sealing or self-closing opening, such as a slit. The blood control septum is further configured to control a flow of a fluid through the catheter adapter. The blood control septum may be activated or opened to selectively permit passage of fluids through the lumen of the catheter adapter.

[0013] Other implementations of the present invention comprise a catheter adapter having a proximal opening that is configured to receive a Luer adapter. Some embodiments include a proximal opening having a structural feature configured to receive a Luer adapter, such as a set of threads or a detent.

[0014] Some implementations of the present invention further include a septum activator or actuator that is configured to be selectively advanced through the blood control septum, to provide a fluid pathway therethrough. In some instances, the septum activator comprises a base configured to contact a Luer adapter that is inserted within the proximal opening of the catheter adapter. The septum activator is slidably inserted within the catheter adapter and configured for advancement through the blood control septum when contacted and advanced in a distal direction by the Luer adapter. The septum activator further comprises a pathway through which the introducer needle passes, and wherein the pathway provides fluid communication between the proximal and distal fluid chambers when the septum activator is advanced through the blood control septum.

[0015] Some implementations of the present invention further include a safety clip that is moveable between a first position and a second position, wherein the first position permits passage of the sharpened tip through a distal opening of the external safety mechanism, and the second position prevents passage of the sharpened tip through the distal opening of the external safety mechanism.

[0016] Some implementations of the present invention further include an access port that is coupled to, or forms a portion of the catheter adapter. The access port comprises an inner lumen that may be accessed via a needleless connector, such as a syringe or Luer adapter. The catheter adapter further includes a defeatable barrier that is seated within an annular groove formed on the inner surface of the catheter adapter and forms a sealed interface with the inner lumen of the access port. In some instances, the defeatable barrier is placed in the catheter adapter an immobilized solely via a friction fit. The defeatable barrier is defeated by inserted an external device into the inner lumen of the access port, whereby the external device contacts and temporarily defeats the barrier. In other instances, fluid pressure from the external device builds up within the access port until the barrier is defeated and the fluid is allowed to bypass the barrier and flow into the lumen of the catheter adapter. Once defeated, fluid communication is provided between the inner lumen of the access port and the lumen or fluid pathway of the catheter adapter. Upon removal of the external device, the resilient nature of the defeatable barrier causes the barrier to resume its tubular shape, thereby reestablishing its sealed interface with the inner lumen of the access port. The sealed interface prevents active fluid communication between the inner lumen and the lumen of the catheter adapter. In some instances, the defeatable barrier comprises a non-tubular shape or configuration.

[0017] Some implementations of the present invention include a method for manufacturing an extravascular system, wherein the method includes steps for: 1) providing a catheter adapter having a distal end supporting a catheter, and further comprising a proximal opening, the catheter adapter

having a lumen; 2) disposing a blood control septum within the lumen of the catheter adapter, the blood control septum dividing the lumen into a proximal fluid chamber and a distal fluid chamber; 3) slidably positioning a septum activator within the proximal fluid chamber, the septum activator having a base and a probe end; and 4) removably coupling an external safety mechanism to the proximal opening of the catheter adapter, the external safety mechanism having a safety clip that is configured to secure a sharpened tip of an introducer needle.

[0018] These and other features and advantages of the present invention may be incorporated into certain embodiments of the invention and will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter. The present invention does not require that all the advantageous features and all the advantages described herein be incorporated into every embodiment of the invention.

Description

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0019] In order that the manner in which the above-recited and other features and advantages of the invention are obtained will be readily understood, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. These drawings depict only typical embodiments of the invention and are not therefore to be considered to limit the scope of the invention.

[0020] FIG. **1** is a perspective view of a catheter assembly in accordance with a representative embodiment of the present invention.

[0021] FIG. **2** is a cross-section view of a catheter assembly in accordance with a representative embodiment of the present invention.

[0022] FIG. **3** is an exploded view of the catheter assembly of FIG. **1** in accordance with a representative embodiment of the present invention.

[0023] FIG. **4** is a cross-section view of a catheter assembly following separation of the needle shield assembly from the catheter adapter in accordance with a representative embodiment of the present invention.

[0024] FIG. **5** is a cross-section view of a catheter assembly coupled to a Luer device, wherein the septum activator is advanced through the blood control septum in accordance with a representative embodiment of the present invention.

[0025] FIG. **6**, shown in parts A-H, provides various plan and cross-section views of an extravascular access device in accordance with a representative embodiment of the present invention.

[0026] FIG. **7**, shown in parts A-E, provides various views of an extravascular access device in accordance with a representative embodiment of the present invention.

[0027] FIG. **8**, shown in parts A-F, provides various views of an extravascular access device in accordance with a representative embodiment of the present invention.

[0028] FIG. **9**, shown in parts A and B, provides a cross-section view of an extravascular access device in accordance with a representative embodiment of the present invention.

[0029] FIG. **10**, shown in parts A-D, provides various plan and cross-section views of an extravascular access device in accordance with a representative embodiment of the present invention.

[0030] FIG. **11**, shown in parts A-D, provides various plan and cross-section views of an extravascular access device in accordance with a representative embodiment of the present invention.

[0031] FIGS. **12**A-**17**B provide various views of acceptable combinations of the features disclosed herein to provide an extravascular access device in accordance with a representative embodiment

of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0032] The presently preferred embodiments of the present invention will be best understood by reference to the drawings, wherein like reference numbers indicate identical or functionally similar elements. It will be readily understood that the components of the present invention, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description, as represented in the figures, is not intended to limit the scope of the invention as claimed, but is merely representative of presently preferred embodiments of the invention.

[0033] Referring to FIG. **1**, a perspective view illustrates an example of an extravascular system **10** incorporating an external safety mechanism. In this example the extravascular system **10** includes a catheter assembly **11** and an external safety mechanism comprising a needle assembly **20**. The catheter assembly **11** includes a catheter adapter **13** having a distal end **14** configured to support an intravenous catheter **15**. Intravenous catheter **15** is configured for insertion into the vasculature of a patient, and therefore may comprise any length and diameter sufficient to access a desired vein or artery of the patient. Catheter **15** may further comprise any material or combination of materials compatible for use with the vasculature of a patient. For example, in some embodiments catheter **15** comprises a polymer material, such as polyvinyl chloride, polypropylene, silicone, Teflon, nylon, and/or latex rubber.

[0034] Catheter adapter **13** further comprises a proximal end **16** having an opening whereby to access an interior lumen of catheter adapter **13**. In some embodiments, proximal end **16** further comprises structural features to accommodate attachment of various Luer devices to catheter adapter **13**. For example, in some embodiments proximal end **16** comprises a set of threads. Proximal end **16** is further configured to compatibly and selectively receive needle assembly **20**.

[0035] Needle assembly **20** comprises a needle hub **21** having a distal opening **22** that is configured to compatibly and selectively receive proximal end **16** of catheter adapter **13**. Needle hub **21** further comprises a distal end **23** that is configured to support and permanently retain a proximal end of an introducer needle **40**. Introducer needle **40** further comprises a sharpened distal end **41** that is threaded through catheter adapter **13** and catheter **15** to provide extravascular system **10**. Once fully assembled, sharpened distal end **41** of needle **40** extends distally beyond the tip **17** of catheter **15**. As thus configured, sharpened distal end **41** is exposed and may be used to provide an opening through the skin and soft tissues of the patient, thus providing an opening through which tip **17** of catheter **15** may be inserted into the vasculature of the patient.

[0036] Referring now to FIG. **2**, catheter adapter **13** further comprises a blood control septum **18** that is positioned within an inner lumen of catheter adapter **13**. Blood control septum **18** divides the inner lumen of catheter adapter **13** into proximal and distal fluid chambers, wherein blood control septum **18** prevents fluid communication between the fluid chambers. In some instances, blood control septum **18** comprises a self-sealing slit **19** or small opening through which introducer needle **40** is inserted when assembled. Upon removal of needle **40** from catheter adapter **13**, slit **19** automatically closes, thereby preventing fluid communication between the fluid chambers. Thus, blood control septum **18** prevents fluid within the catheter **15** and the distal fluid chamber from entering the proximal fluid chamber and leaking out of catheter adapter **13** via the opening in proximal end **16**.

[0037] Catheter adapter **13** further comprises a septum activator **50** that is configured to be slidably advanced through blood control septum **18**, thereby providing a fluid pathway through septum **18**. Septum activator **50** is slidably positioned within the proximal fluid chamber. Septum activator **50** comprises a base **51** that is oriented towards proximal end **16** and is accessible via proximal end **16**. Septum activator **50** further comprises a probe end **52** that is oriented towards, and proximal to blood control septum **18**. Septum activator **50** is advanced through blood control septum **18** by inserting a Luer device through the opening of proximal end **16**, as will be discussed in greater

detail below.
[0038] Septum activator **50** may comprise any material or combination of materials that are compatible for use in an intravenous device. Generally, septum activator **50** comprises a rigid material. For example, in some embodiments septum activator **50** comprises a nylon material. Septum activator **50** may further comprise an antibacterial coating or anticoagulant coating to provide further benefits to the extravascular assembly **10**.
[0039] With continued reference to FIG. **2**, needle assembly **20** further comprises a needle shield **30** that is slidably stored in a distal opening of needle hub **21**. Needle shield **30** comprises a proximal aperture **31** through which introducer needle **40** is threaded. Needle shield **30** further comprises a needle clip **32** that is configured to block distal movement of sharpened tip **41** when positioned within needle shield **30**.
[0040] In some embodiments, needle shield **30** is coupled to needle hub **21** via a tether **25**. Tether **25** is configured to permit needle shield **30** to be slid distally along introducer needle **40**, but prevents needle shield **30** from being completely removed from needle **40**, as shown in FIG. **3**.
[0041] Referring now to FIGS. **3** and **4**, extravascular system **10** is shown in an expanded configuration, which represents the configuration of the various components following a catheterization procedure. The catheterization procedure results in catheter **15** being inserted into the vasculature of a patient. Once catheter **15** is properly inserted into the patient's vasculature, needle hub **21** is moved in proximal direction **100** thereby removing needle shield **30** from the distal opening of needle hub **21**. Introducer needle **40** and sharpened tip **41** are withdrawn from catheter **15** and catheter adapter **13** as needle hub **21** is moved in proximal direction **100**.
[0042] Tether **25** is unraveled from the distal opening of needle hub **21** as needle hub **21** moves in proximal direction **100**, as shown in FIG. **4**. When a maximum distance **102** between needle hub **21** and needle shield **30** is achieved, tether **25** prevents further separation or distance between the two components. Sharpened tip **41** is entirely withdrawn from catheter adapter **13** and into needle shield **30** at a distance that is less than maximum distance **102**.
[0043] In some embodiments, safety clip **32** is repositioned within needle shield **30** to block and prevent sharpened tip **41** from exiting needle shield **30** once tip **41** has been drawn proximally past safety clip **32**, as shown in FIG. **4**. Thus, sharpened tip **41** is trapped within needle shield **30**. In particular, needle shield **30** prevents sharpened tip **41** from exiting the distal end of needle shield **30**, and tether **25** prevents sharpened tip **41** from exiting the proximal end of needle shield **30** by preventing separation of needle shield **30** and needle hub **21** in excess of maximum distance **102**.
[0044] In some embodiments, safety clip **32** is further configured to securely retain the connection between needle shield **30** and catheter proximal end **16** of catheter adapter **13**. In some instances, safety clip **32** further comprises a pawl or other feature that selectively and/or temporarily interconnects with a surface of proximal end **16** when safety clip **32** is held in a first position. The first position of safety clip **32** is maintained by contact between introducer needle **40** and safety clip **32**. When introducer needle **40** is withdrawn past safety clip **32** in proximal direction **100**, safety clip **32** is released from the first position and is repositioned to block sharpened tip **41** from exiting needle shield distally. When safety clip **32** is repositioned, the pawl or other feature releases the surface of proximal end **16**, thereby permitting physical separation of catheter adapter **13** from needle shield **30**, as shown.
[0045] Referring now to FIG. **5**, catheter adapter **13** is shown following separation from needle shield **30**. In some embodiments, the vasculature of a patient is accessed via catheter assembly **11** by inserting a Luer adapter **110** or other device into the proximal end or opening **16** of catheter adapter **13**. In some instances, Luer adapter **110** comprises a probe **112** that is inserted within opening **16** and contacts base **51** of septum activator **50**. Upon insertion of probe **112** into opening **16**, probe **112** contacts septum activator **50** and advances septum activator **50** within the proximal fluid chamber in distal direction **200**. Upon further insertion of probe **112** into opening **16**, probe end **52** of septum activator is advanced through slit **19** of blood control septum **18**, thereby

providing fluid communication between Luer adapter **110** and catheter **15** via the distal fluid chamber.

[0046] Some embodiments of the present invention provide a single use septum activator, wherein the septum activator maintains a pathway through the blood control septum following removal of a Luer device from the catheter adapter. In other embodiments, the present invention provides a multiple use septum activator, wherein the septum activator is automatically removed from the blood control septum following removal of a Luer device from the catheter adapter, thereby closing a pathway through the blood control septum.

[0047] For example, in some embodiments upon removal of Luer adapter **110** from proximal end **16**, septum activator **50** is moved in proximal direction **100** as slit **19** of septum **18** resumes its closed position. Thus, fluid in the distal fluid chamber and catheter **15** are prevented from bypassing septum **18** when Luer adapter **110** is disconnected. In other embodiments, upon removal of Luer adapter **110** from proximal end **16**, septum activator **50** remains positioned within slit **19** of septum **18**, thereby maintaining a fluid pathway through septum **18**.

[0048] The various components and parts disclosed herein may comprise any shape or configuration that may be desired or necessary to achieve the benefits of the present invention. For example, needle shield **30** may achieve integrated tip protection using a transverse barrier containing a washer-like hole in the proximal end of safety clip **32** to catch a feature on the exterior surface of introducer needle **40**, such as a crimp or a ferrule. Safety clip **32** may alternatively be divided into two or more pieces. For example, a first piece of clip **32** may provide the interlocking action between the needle shield **30** and catheter adapter **13**. The second piece of clip **32** may provide the function of blocking sharpened tip **41** from exiting needle shield **40** in distal direction **200**. Alternatively, the second piece of clip **32** may comprise a hole having a diameter that is greater than an outer diameter of needle **40**, yet less than an outer diameter of a feature on the outer surface of the needle **40**. As such, the second piece of clip **32** may prevent complete separation of needle shield **30** from needle **40**, thereby trapping sharpened tip **41** within needle shield **30**. Clip **32** may further include a non-friction coating to reduce drag forces on needle **40** when withdrawing needle **40** from catheter adapter **13** in proximal direction **100**.

[0049] In some instances, blood control septum **18** further comprises various air vents and other features to permit controlled flashback in catheter **15** during catheterization. For example, in some embodiments catheter adapter **13** comprises a recessed surface configured to receive and retain septum **18**. In some instances, the recessed surface further comprises a plurality of grooves that form air channels between the outer, circumferential surface of septum **18** and the recessed surface. Further, in some instances the plurality of grooves interconnect the distal and proximal fluid chambers, thereby permitting air pressure in the distal fluid chamber to be released into the proximal fluid chamber by passing through the plurality of grooves. As such, excess buildup of air pressure in the distal fluid chamber is prevented, thereby allowing blood to enter into the distal fluid chamber as flashback during catheterization. Alternatively, the outer, circumferential surface of septum **18** may comprises a plurality of grooves, thereby forming a plurality of air channels between the outer surface of the septum and the recessed surface of catheter adapter **13**.

[0050] Referring now generally to FIGS. **6**A-**9**B, various alternative and representative embodiments of the present invention are shown. In particular, FIGS. **6**A-**9**B demonstrate various alternative configurations of extravascular system **10**. FIGS. **6**A-**9**B further demonstrate various alternative components and structures for extravascular system **10**.

[0051] Referring now to FIGS. **6**A-**6**H, an assembled extravascular system **10** is shown in various plan and cross-section views, prior to catheterization. In some instances catheter adapter **13** further comprises a needle cap **102** that is configured to receive and shield needle tip **41** and catheter **15** prior to use. Needle cap **102** comprises a proximal end that is friction fit over the distal end of catheter adapter **13**. Prior to catheterization, needle cap **102** is removed from catheter adapter **13** and disposed.

[0052] In some instances, system **10** further comprises a flashback chamber **110** that is in fluid communication with the proximal end of introducer needle **40**. Flashback chamber **110** comprises a clear material that is capable of being used with biological fluids, such as blood. Introducer needle **40** further comprises a window **43** that is positioned near sharpened distal tip **41**. When sharpened tip **41** is inserted into the vasculature of the patient, blood flows through window **43** and into the space between the outer surface of needle **40** and the inner wall surface of catheter **15**. This blood may be seen through the clear wall of the catheter, thereby providing a visual signal to the caregiver that the sharpened tip **41** is in the patient's vein. Excess blood travels through the hollow interior of introducer needle **40** and into flashback chamber **110**. Flashback chamber **110** collects the excess blood, providing further confirmation of accurate needle and catheter placement into the vessel, and preventing undesired exposure to the caregiver. In some instances, flashback chamber **110** is coupled to needle hub **21** via a vented fitting whereby gas or air within flashback chamber **110** is vented as liquid enters from the proximal end and opening of needle **40**.
[0053] In some instances, excess blood collected in flashback chamber **110** is preserved for clinical testing or other types of diagnostic procedures. For these instances, flashback chamber **110** may be selectively removed from needle hub **23** prior to disposal of needle **40** and the remaining disposable components of system **10**.
[0054] In some embodiments, needle shield **30** comprises a washer **33** that forms the proximal aperture through which needle **40** is threaded. Needle **40** may further comprise a crimp or ferrule proximate to sharpened distal tip **41** that has a diameter that is greater than the diameter of the opening in washer **33**. As such, the crimp or ferrule is prevented from passing through washer **33** in proximal direction **100**. In some embodiments, the distance between sharpened tip **41** and the crimp or ferrule is configured so that sharpened tip **41** is entirely positioned within needle shield **30** when the crimp or ferrule contacts washer **33**.
[0055] Referring now to FIGS. **7**A-**7**E, various cross-section views of an extravascular system **10** is shown. In some embodiments, needle shield **30** comprises a clip **32** that is held in a compressed configuration by needle **40** prior to catheterization. When needle **40** is withdrawn from catheter **15** and tip **41** is drawn proximately past clip **32**, clip **32** is released and flap or flag **37** covers and blocks aperture **39**, thereby preventing sharpened distal tip **41** from exiting needle shield **30** via aperture **39**. In some embodiments, clip **32** comprises a v-clip.
[0056] In some instances, a pawl **45** or other structure of clip **32** intersects and securely retains a portion of catheter adapter **13** when in the compressed configuration. For example, in some instances pawl **45** intersects the proximal rim of catheter adapter **13**. When clip **32** is released following withdrawal of tip **41** into needle shield **30**, pawl **45** of clip **32** releases catheter adapter **13**, thereby permitting separation of the two components. Thus, needle shield **30** and catheter adapter **13** are securely interconnected prior to withdrawing distal tip **41**, and capable of being separated once distal tip **41** is securely shielded within needle shield **30**.
[0057] As discussed previously, in some embodiments blood control septum **18** comprises one or more air vents **181** which are formed in the outer circumferential surface of septum **18**. Vents **181** provide a fluid and/or an air pathway between the inner surface of catheter adapter **13** and the outer surface of septum **18**. Alternatively, air vents may be provided by grooving the inner surface of catheter adapter **13** at the position where septum **18** is seated.
[0058] Blood control septum **18** may further comprise blood wicking apertures **183** formed on distal face of the septum. Apertures **183** are positioned and configured to wick excess blood from the outer surface of introducer needle **40** when needle **40** is being withdrawn from catheter adapter **13**. Apertures **183** may also wick excess blood that leaks into catheter adapter **13** as flashback during catheterization.
[0059] Septum activator **50** comprises a proximal end **51** that is configured to be contacted and advanced though slit or opening **19** of septum **18** when an external object is inserted into the proximal opening of catheter adapter **13**. Septum activator **50** comprises a distal end **53** that is

positioned proximate to septum **18**, and is sized to permit partial or complete penetration of slit **19**. In some instances, distal end **53** merely contacts and deforms septum **18**, which thereby causes slit **19** to be biased into an open conformation.

[0060] In some instances, septum activator **50** is incapable of being removed from septum **18** following insertion through slit **19**. Once inserted, septum activator **50** provides and/or opens a permanent pathway through septum **18**. Thus, septum activator **50** may be configured for one-time use. In other instances, septum activator **50** is configured automatically be removed from or backed out of slit **19** when septum activator **50** is not actively advanced in distal direction **200**, or held in place via an external device. For example, in some instances septum activator **50** is prevented from fully penetrating slit **19**. Thus, when the external device is removed from catheter adapter **13**, the elastic properties of septum **18** self-closes slit **19** thereby backing distal end **53** out of slit **19**. Thus, septum activator **50** may be configured for multiple-time usage.

[0061] Septum activator **50** may further comprise one or more flow disrupting features **55**. Features **55** are configured to provide disruption to fluid passing though catheter adapter **13** in proximity to septum activator **50**. In some instances, septum activator **50** comprises one or more fins and/or windows **55** that divert fluid between the interior and exterior surfaces or surroundings of septum activator **50**. Fins **55** may further be configured to slidably seat within an annular groove **57** on the inner surface of catheter adapter **13**. The interaction between fins **55** and annular groove **57** prevents septum activator **50** from being removed from the proximal opening of catheter adapter **13**. Annular groove **57** may also be configured to prevent over-insertion of distal end **53** through septum **18**.

[0062] In some instances, needle shield **30** comprises a clip **32** having a distal end configured to block a distal aperture of shield **30**, and further comprises a proximal end forming washer **33**, as shown in FIGS. **8**A-**8**C. The distal end of clip **32** is biased away from the distal aperture by the presence of needle **40** in the distal aperture. Following catheterization and withdrawal of distal tip **41** into needle shield **30**, the distal end of clip **32** is released from its biased position and blocks the distal aperture, thereby preventing distal tip **41** from exiting safety shield **30**. The aperture of washer **33** comprises a diameter that permits needle **40** to slide therethrough, but prevents passage of a crimp **47** or ferrule that is located on needle **40** proximate to distal tip **41**. Thus the distal and proximal ends of clip **32** trap distal tip **41** within needle shield **30**, as shown in FIG. **8**C. Needle shield **30** may further comprise an extended distal nose **35** that securely and selectively interlocks needle shield **30** and catheter adapter **13** via a friction fit.

[0063] In some instances, clip **32** may be divided into two or more pieces. For example, a first piece may be configured to providing an interlocking action to release catheter adapter **13**, and a second piece may be configured to trap a ferrule or crimp on needle **40**, thereby preventing proximal of distal movement of needle **40**. Referring now to FIGS. **9**A and **9**B, needle shield **30** may further include a first clip **32***a* and a second clip **32***b*, wherein first and second clips **32***a* and **32***b* are configured to retain distal tip **41** of needle **40** within needle shield **30**. In some instances, first clip **32***a* is further configured to temporarily interconnect needle shield **30** and catheter adapter **13**, as discussed previously.

[0064] In some instances, clip **32** is used with a second member as a housing. Clip **32** may also be used as only a safety mechanism, while the second member provides an interlocking feature. For example, in some embodiments a second member comprises a plurality of fingers that are configured to overlap the Luer connector of catheter adapter **13** to interlock catheter adapter **13** and needle shield **30** via a friction interface.

[0065] Any of the embodiments of the present invention may further comprise an access port **302**, as shown in FIGS. **10**A-**17**B. Port **302** generally comprises a portion of catheter adapter **313**. In some instances, access port **302** comprises a cylinder coupled to the outer surface of catheter adapter **313**, the cylinder having an inner lumen **304** that is in fluid communication with an inner lumen or fluid pathway of catheter adapter **313**. Access port **302** further comprises an inner

diameter that is configured to receive an external device, such as a needleless connector. In some instances, access port **302** comprises a removable cap or lid **306** that protects port **302** from contamination. In some instances, lid **306** is hingedly coupled to the base of access port **302**.
[0066] In some embodiments, system **300** further comprises a defeatable barrier **310** that is seated into an annular groove formed on the inner surface of catheter adapter **313** and interposed between inner lumen **304** and the fluid pathway of catheter adapter **313**. In some instances, barrier **310** comprises a tubular valve having an outer surface that forms an interface with inner lumen **304**. Barrier **310** is defeated when an external device is inserted into inner lumen **304** and contacts the outer, exposed surface of barrier **310**. When contacted by the external device, the tubular structure of barrier **310** slightly collapses thereby breaking the interface between the outer surface of barrier **310** and inner lumen **304**. A fluid may then be added to the fluid pathway or lumen of catheter adapter **313**. Alternatively, in some instances fluid pressure from the external device builds up within access port **302** until the interface between the outer surface of barrier **310** and inner lumen **304** is defeated. The fluid within access port **302** is then added to the fluid pathway or lumen of catheter adapter **313** via the temporarily defeated barrier **310**. Upon removal of the external device, the resilient defeatable barrier **310** resumes its original shape thereby reestablishing the sealed interface with inner lumen **304**.
[0067] Referring now to FIGS. **10**A-**10**D, an assembly extravascular system **300** is shown in various plan and cross-section views, prior to catheterization. In some embodiments, system **300** comprises a blood control septum **18** that is placed within catheter adapter **313** at a position that is downstream or distal from access port **302**. Thus, system **300** further comprises an elongated septum activator **350**. Elongated septum activator **350** comprises an extended distal end **353** that is configured to pass through defeatable barrier **310** and reside in proximity to septum **18**. This type of stacked or parallel configuration allows the overall length of catheter adapter **313** to be shortened.
[0068] In other embodiments, system **300** comprises a blood control septum **18** that is placed within catheter adapter **313** at a position that is upstream from access port **302**, as shown in FIGS. **11**A-**11**D. In these embodiments, system **300** includes a normal length septum activator **50**. Unlike the shortened length of the catheter adapter **313**, the linear or serial configuration of these embodiments may require that the overall length of catheter adapter **313** be extended.
[0069] System **300** may include any combination of external needle shield, internal blood control septum, and septum activator as disclosed herein. Examples of various acceptable combinations are shown in FIGS. **12**A-**17**B. As previously mentioned, any of the embodiments described in FIGS. **1**-**9**B may be modified to include any of the features of the embodiments shown in FIGS. **10**A-**17**B, and in particular these embodiments may be modified to include an access port **302** and defeatable barrier **310**.
[0070] In some instances, system **300** may include a crimp or ferrule retention washer **33**, as shown in FIG. **14**B and **14**C. Access port **302** may further include one or more bumps or outward protrusions configured to retain cap **306** on the outer surface of port **302**.
[0071] 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.

Claims

1. A catheter assembly, comprising: a catheter configured to carry a needle; and a catheter adapter connected to the catheter, the catheter adapter including: a push tab disposed on an upper surface of

the catheter adapter; and wings disposed below a majority of the push tab with respect to a vertical axis perpendicular to a longitudinal axis of the catheter assembly; and a needle assembly engaged to the catheter adapter and carrying a clip that is configured to shield the needle.

2. The catheter assembly of claim 1, wherein the wings including a proximal end surface and a distal end surface; and the distal end surface of the wings is proximal to the push tab in relation to the longitudinal axis.

3. The catheter assembly of claim 1, wherein the push tab includes a cavity configured to engage a finger of a clinician.

4. The catheter assembly of claim 3, wherein the cavity is proximal to the push tab.

5. The catheter assembly of claim 3, wherein the cavity and the push tab are integral to the catheter adapter.

6. The catheter assembly of claim 3, wherein the wings including a proximal end surface and a distal end surface; and the proximal end surface of the wings is proximal to the cavity of the push tab with respect to the vertical axis perpendicular to the longitudinal axis of the catheter assembly.

7. The catheter assembly of claim 3, wherein the wings including a proximal end surface and a distal end surface; and a proximal end of the cavity is disposed above a central portion of the wings with respect to the vertical axis perpendicular to the longitudinal axis of the catheter assembly.

8. The catheter assembly of claim 1, wherein the catheter adapter does not include a side port.

9. The catheter assembly of claim 1, wherein the needle assembly includes ribs.

10. The catheter assembly of claim 1, wherein the needle assembly does not include a tab.

11. The catheter assembly of claim 1, wherein the clip is configured to engage and disengage a proximal end of the catheter adapter.