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VASCULAR ACCESS SITE MANAGEMENT SYSTEM

Abstract

A vascular access site management system includes a stabilization body and a flow housing that is rotatable relative to the stabilization body. The flow housing may have a flow path extending through it to allow fluids to be introduced into or extracted from a patient via a catheter connected to the vascular access site management system. The vascular access site management system may also include a needle free connector fluidly connected to the flow housing via a section of tubing.

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Background/Summary

PRIORITY [0001] This application is a continuation of and claims priority from co-pending U.S. application Ser. No. 17/395,825, filed Aug. 6, 2021, entitled “Vascular Access Site Management System,” assigned attorney docket number 130974-04504, and naming Todd Chelak, John Damarati, Nicholas Dennis and Nicholas Illsley as inventors, the disclosure of which is incorporated herein, in its entirety, by reference. [0002] U.S. application Ser. No. 17/395,825, in turn, claims priority from U.S. application Ser. No. 16/298,175, filed Mar. 11, 2019, entitled “Vascular Access Site Management System,” assigned attorney docket number 130974-04503, and naming Todd Chelak, John Damarati, Nicholas Dennis and Nicholas Illsley as inventors, the disclosure of which is incorporated herein, in its entirety, by reference. [0003] U.S. application Ser. No. 16/298,175, in turn, claims priority from U.S. Provisional Application No. 62/641,649 filed Mar. 12, 2018, entitled “Vascular Access Site Management System,” assigned attorney docket number 130974-04501 (formerly 1600/A45), and naming Todd Chelak, John Damarati, Nicholas Dennis and Nicholas Illsley as inventors, the disclosure of which is incorporated herein, in its entirety, by reference. RELATED UNITED STATES APPLICATIONS [0004] This patent application is related to U.S. patent application Ser. No. 16/298,501 entitled “Vascular Access Site Management System,” filed on Mar. 11, 2019, assigned attorney docket number 130974-04502, now U.S. Pat. No. 11,013,902, and naming Todd Chelak, John Damarati, Nicholas Dennis and Nicholas Illsley as inventors, the disclosure of which is incorporated herein, in its entirety, by reference.

TECHNICAL FIELD
[0005] The present invention relates to vascular access sites, and more particularly to devices and systems that manage a vascular access site inclusive of an associated indwelling catheter such as a peripheral intravenous (IV) catheter.
BACKGROUND ART
[0006] In instances in which a patient will need regular administration of fluid or medications (or regular withdrawal of fluids/blood), catheters are often inserted into the patient and used to administer the fluids/medications. The catheter may remain in the patient for extended periods of time (several hours to several days or longer). Additionally, an extension tube may be connected to the catheter to facilitate use of the catheter and connection of a medical implement (e.g., a syringe). To ensure that the catheter and/or extension tube remain in place and are not accidentally removed, some prior art systems secure the catheter and/or extension tube to the patient using tape or similar adhesive materials (e.g., a film dressing).
[0007] Tapes and adhesive film dressings can be problematic in that they may not firmly secure the catheter in place, which can lead to local trauma to the vein and a medical condition referred to as phlebitis requiring removal of the catheter. Additionally, in some instances, the manner in which the tape is applied and the positioning/location of the catheter and/or extension tube may cause the catheter and/or extension tube to be bent. This, in turn, increases the risk of kinking (which can reduce/stop flow through the catheter and/or extension tube) and makes it more difficult to connect the medical implement required to introduce the fluid/medication.
[0008] Other prior art systems attempt to manage the extension set tubing and include various ways to secure the indwelling IV catheter during the final stages of placement. However, these systems either require cumbersome manipulation of the tubing to fit a desired “J-loop” configuration or present a “hard-wired” configuration that may not adapt to the available space surrounding the

insertion site. Additionally, the structure used to secure the catheter to the patient is often a separate component that requires maneuvering of several pieces to reach a final state of deployment. This further burdens the clinician's time and skill level.

SUMMARY OF THE INVENTION

[0009] In accordance with one embodiment of the invention, a vascular access site management system for transfer of fluid to and/or from a patient has a stabilization body and a flow housing. The stabilization body may have an inlet, an outlet (e.g., a male luer that may connect to a catheter) configured to be connected to a vascular access device, and an internal fluid path extending through at least a portion the stabilization body and between the inlet and outlet. The stabilization body may also have a stabilization surface located on an underside of the stabilization body to stabilize the vascular access site when on the patient. The flow housing may have a sleeve portion and a pathway portion extending from the sleeve portion. The pathway portion may have a flow path extending through at least a portion of it. The sleeve portion may be rotatably coupled to the stabilization body such that the flow housing is rotatable with respect to the stabilization body. The stabilization base may be oriented at an angle (e.g., between 5 and 10 degrees) with respect to a longitudinal axis of the outlet.

[0010] In some embodiments, the flow housing may be able to rotate relative to the stabilization body between a first position and at least a second position. The flow path may be fluidly disconnected from the inlet of the stabilization body when in the first portion, and fluidly connected to the inlet of the stabilization body when in the second position. The system may also include an o-ring located between a portion of the stabilization body and a portion of the flow housing.

[0011] On the underside of the stabilization surface, the system may have a first securement portion that secures the vascular access site management system to the patient. The system may also have a second securement portion located on a portion of the underside of the stabilization surface. The second securement portion may further secure the vascular access site management system to the patient. The first securement portion may have a first tack adhesive and the second securement portion may have a second tack adhesive. The second tack adhesive may be stronger than the first tack adhesive. The first securement portion may have a first liner covering the first tack adhesive and the second securement portion may have a second liner covering the second tack adhesive. The liners may be removed prior to securing the vascular access site management system to the patient. Additionally or alternatively the first securement portion may include a gripping and/or conforming structure.

[0012] In further embodiments, the system may have a valve mechanism located in the fluid path. The valve mechanism selectively prevents and allows fluid flow through the internal fluid path. The stabilization body may have an inlet body and an outlet body and the valve mechanism may be positioned between the inlet body and outlet body. The valve mechanism may be a two way pressure activated valve that deforms in the presence of a forward pressure within the internal fluid path (e.g., to allow fluid flow around the valve mechanism from the inlet to the outlet). To help support the valve mechanism within the stabilization body, the outlet body may have a plurality of support arms. The valve mechanism may deform over the support arms in the presence of the forward pressure. Additionally or alternatively, the valve mechanism may include a slit extending through it. The slit may open in the presence of a back pressure within the internal fluid path to allow fluid flow through the slit and from the outlet to the inlet. Additionally or alternatively, the pressure required to open the slit may be above the venous pressure of the patient.

[0013] In additional embodiments, the system may have a tube with a first end that is fluidly connected to the flow path of the pathway portion and a second end. The device may also have a female luer connector located at the second end of the tube. Alternatively, the inlet of the flow path within the pathway portion may fluidly connect to a medical implement.

[0014] To reduce pressure over a vein of the patient, the stabilization body may include a vein relief zone. The vein relief zone may have an adhesive portion that lifts the patient's skin when the

vascular access site management system is on the patient. The relief zone may be axially aligned with the outlet of the stabilization body. In some embodiments, the stabilization body may have a protrusion extending from a surface of the stabilization body, and the flow housing may have a recess. The recess may snap over the protrusion such that the protrusion enters the recess to axially secure the flow housing to the stabilization base.

[0015] In accordance with further embodiments, a method for managing a vascular access site for transfer of fluid to and/or from a patient includes providing a vascular access site management system. The system may include a stabilization body and a flow housing. The stabilization body may include an inlet, an outlet, and an internal fluid path extending through a portion the stabilization body and between the inlet and outlet. The stabilization body may also have a stabilization surface located on an underside of the stabilization body. The flow housing may have a sleeve portion and a pathway portion extending from the sleeve portion. The pathway portion has a flow path extending through a portion it. The sleeve portion may be rotatably coupled to the stabilization body such that the flow housing is rotatable with respect to the stabilization body.

[0016] The method may also include connecting the outlet of the stabilization body to a vascular access device, and placing the stabilization body on the patient. The stabilization surface may stabilize the vascular access site management system on the patient. Once on the patient, the method may then rotate the sleeve portion of the flow housing relative to the stabilization body to a second position. The flow path in the pathway portion may be fluidly disconnected from the inlet of the stabilization body when in the first portion, and fluidly connected to the inlet of the stabilization body when in the second position.

[0017] In some embodiments, the system may include a valve mechanism located in the fluid path. The valve mechanism may have a slit through it and may selectively prevent and allow fluid flow through the internal fluid path. For example, the valve mechanism may deform in the presence of a forward pressure within the internal fluid path to allow fluid flow around the valve mechanism from the inlet to the outlet. Additionally or alternatively, the slit may open in the presence of a back pressure within the internal fluid path to allow fluid flow through the slit and from the outlet to the inlet. The vascular access site management system may have a first and second securement portion located on the underside of the stabilization surface. The first and second securement portions may secure the vascular access site management system to the patient.

[0018] In accordance with further embodiments, a vascular access site management system includes a stabilization body having a base, and an upper portion having a first end configured to be connected to a vascular access device and a second end configured to receive a medical implement. The stabilization body may also have a flow path connecting the first end and the second end along a substantially linear pathway. At the second end, the device may have a port that may connect with the medical implement. The medical implement may have a distal tip and a passage extending through a portion of the medical implement to the distal tip. The passage allows a medical article to pass through the medical implement. A valve mechanism may be located within the flow path to selectively prevent and allow fluid flow through the flow path. The base may be oriented at an angle (e.g., between 5 and 10 degrees) with respect to an outlet of the system.

[0019] The device may also have a first engagement element located on a surface of the vascular access site management system. The first engagement element may engage with a second engagement element located on the medical implement to couple the medical implement with the vascular access site management system and position the distal tip at a predetermined longitudinal position in the flow path (e.g., when coupled to the vascular access site management system). The distal tip may interact with the valve mechanism when in the predetermined longitudinal position to allow passage of the medical article into the vascular access site management system. For example, the distal tip of the medical implement may at least partially open the valve mechanism when in the predetermined longitudinal position. In some embodiments, the valve mechanism may be supported in the vascular access site management system such that the longitudinal movement

of an outer portion of the slit toward the first end is minimized.
[0020] In some embodiments, the valve mechanism may be a two way pressure activated valve. In such embodiments, the valve mechanism may deform in the presence of a forward pressure within the flow path to allow fluid flow around the valve mechanism from the inlet to the outlet. The upper portion may have a plurality of support arms that support the valve mechanism within the flow housing and the valve mechanism may deform over the support arms in the presence of the forward pressure.
[0021] The valve mechanism may have a slit extending through it. The slit may open in the presence of a back pressure within the flow path to allow fluid flow through the slit and toward the second end. The back pressure required to open the slit may be above a venous pressure of the patient, and/or the distal tip of the medical implement may partially open the slit when in the predetermined longitudinal position.
[0022] The first engagement element may include at least one protrusion and the second engagement element may include at least one recess. The protrusion(s) may enter the recess(es) when the medical implement is connected to the vascular access site management system. Additionally or alternatively, the first engagement element may include at least one recess and the second engagement element may include at least one protrusion. Similarly, the at least one protrusion may enter the at least one recess when the medical implement is connected to the vascular access site management system. The medical implement may have at least one flexible arm, and the second engagement element may be on the at least one flexible arm.
[0023] In further embodiments, the vascular access site management system may include a septum located within the port. The septum normally obstructs the port, and at least a portion of the medical implement may extend through the septum when connected to the vascular access site management system. For example, the septum may include a slit extending through it, and the distal tip of the medical implement may open and extend through the slit when the medical implement is connected to the vascular access site management system.
[0024] Additional embodiments of the vascular access site management system may have a flow housing with a sleeve portion and a pathway portion extending from the sleeve portion. The pathway portion may have a fluid path extending through at least a portion of the pathway portion, and the sleeve portion may be rotatably coupled to the upper portion of the stabilization body such that the flow housing is rotatable with respect to the stabilization body. The flow housing may rotate with respect to the stabilization body between a first position, a second position and, perhaps, a third position. The fluid path may be in fluid communication with the flow path of the upper portion when the sleeve portion is in the first position and/or the third position, and fluidly disconnected when in the second position. The upper portion may have a first and second hole extending through a wall of the upper portion. The first hole may fluidly connect the fluid path and the flow path when the sleeve portion is in the first position, and the second hole may fluidly connect the fluid path and the flow path when the sleeve portion is in the third position.
[0025] Further embodiments may include a tube having a first end and a second end. The first end may be fluidly connected to an inlet of the vascular access site management system and/or there may be a needle free connector located at the second end of the tube. The upper portion may include a male luer lock connector that may be connected to a catheter/or alternatively an access device such as a needleless connector. Additionally or alternatively, the upper portion may have a contact surface within the flow path. The contact surface may contact an outer surface of the medical implement during connection of the medical implement to prevent further longitudinal movement of the distal tip within the flow path and/or radially align the distal tip with the flow path. The upper portion may also have a crushable or deformable guide rib within the flow path to keep the distal tip concentric within the flow path during connection of the medical implement.
[0026] In accordance with additional embodiments, a method for managing a vascular access site and introducing a medical article includes providing a vascular access site management system

with a stabilization body having a base, an upper portion with a first end and a second end, and a flow path connecting the first end and the second end along a substantially linear pathway. The system may also include (1) a port located at the second end of the upper portion of the stabilization body, (2) a valve mechanism located within the flow path that selectively prevents and allows fluid flow through the flow path, and (3) a first engagement element located on a surface of the vascular access site management system. The method may also include connecting a vascular access device to the first end of the upper portion and connecting a medical implement to the port at the second end of the upper portion. During connection, the first engagement element may engage with a second engagement element located on the medical implement. The medical implement may have distal tip and a passage extending through a portion of the medical implement to the distal tip. The distal tip may be positioned at a predetermined longitudinal position in the flow path and may interact with the valve mechanism when the first engagement element is engaged with the second engagement element. The method may then pass a medical article through the passage of the medical implement and into the vascular access site management system. The distal tip of the medical implement may partially open the valve mechanism (e.g., a slit within the valve mechanism) when in the predetermined longitudinal position.

[0027] In some embodiments, the method may also include fluidly connecting a second medical implement to an inlet of the system, and transferring fluid through the vascular access site management system, The pressure applied to the valve mechanism by the fluid may deform the valve mechanism to allow fluid flow around the valve mechanism from the inlet to the outlet. Additionally or alternatively, the vascular access site management system may also include a flow housing having a sleeve portion and a pathway portion extending from the sleeve portion. The pathway portion may have a fluid path extending through at least a portion of the pathway portion, and the sleeve portion may be rotatably coupled to the upper portion of the stabilization body. In such embodiments, the method may also include rotating the flow housing from a first position to a second position. The fluid path may be in fluid communication with the flow path of the upper portion when the flow housing is in the second position, and fluidly disconnected when in the first position.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] The foregoing features of embodiments will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

[0029] FIGS. **1**A-**1**B schematically show various views of a vascular access site management system in an undeployed state, in accordance with various embodiments of the present invention.

[0030] FIGS. **1**C-**1**D schematically show various views of a vascular access site management system in a deployed state, in accordance with various embodiments of the present invention.

[0031] FIG. **2** schematically shows an exploded view of the vascular access site management system shown in FIGS. **1**A-**1**D, in accordance with some embodiments of the present invention.

[0032] FIG. **3** schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **1**A-**1**D, in accordance with some embodiments of the present invention.

[0033] FIG. **4**A-**4**D schematically show a camming mechanism within the vascular access site management system shown in FIGS. **1**A-**1**D, in accordance with some embodiments of the present invention.

[0034] FIG. **5**A schematically shows an alternative embodiment of a vascular access site management system in a closed mode, in accordance with some embodiments of the present invention.

[0035] FIG. **5**B schematically shows the alternative embodiment of a vascular access site

management system shown in FIG. **5**A in an open mode, in accordance with some embodiments of the present invention.
[0036] FIG. **5**C schematically shows an exploded view of the alternative embodiment of a vascular access site management system shown in FIG. **5**A, in accordance with some embodiments of the present invention.
[0037] FIG. **5**D schematically shows a cross-sectional view of the alternative embodiment of a vascular access site management system shown in FIG. **5**A in the closed mode, in accordance with some embodiments of the present invention.
[0038] FIG. **5**E schematically shows a cross-sectional view of the alternative embodiment of a vascular access site management system shown in FIG. **5**A in the open mode, in accordance with some embodiments of the present invention.
[0039] FIG. **6**A schematically shows a further alternative embodiment of a vascular access site management system, in accordance with some embodiments of the present invention.
[0040] FIG. **6**B schematically shows the alternative embodiment of a vascular access site management system shown in FIG. **6**A in a first deployed position, in accordance with some embodiments of the present invention.
[0041] FIG. **6**C schematically shows the alternative embodiment of a vascular access site management system shown in FIG. **6**A in a second deployed position, in accordance with some embodiments of the present invention.
[0042] FIG. **6**D schematically shows a cross-sectional view of the flow housing of the alternative embodiment of a vascular access site management system shown in FIG. **6**A, in accordance with some embodiments of the present invention.
[0043] FIG. **6**E schematically shows a cross-sectional view of the alternative embodiment of a vascular access site management system shown in FIG. **6**A, in accordance with some embodiments of the present invention.
[0044] FIGS. **7**A-**7**D schematically show an additional embodiment of a vascular access site management system in a first position, in accordance with further embodiments of the present invention.
[0045] FIGS. **8**A-**8**C schematically show the vascular access site management system of FIGS. **7**A-**7**D in a second position, in accordance with further embodiments of the present invention.
[0046] FIGS. **9**A-**9**C schematically show the vascular access site management system of FIGS. **7**A-**7**D in a third position, in accordance with further embodiments of the present invention.
[0047] FIG. **10**A schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **7**A-**7**D with a valve mechanism in the closed mode, in accordance with additional embodiments of the present inventions.
[0048] FIG. **10**B schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **7**A-**7**D with a valve mechanism in an open mode for retrograde flow, in accordance with additional embodiments of the present inventions.
[0049] FIG. **11** schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **7**A-**7**D with a medical implement connected to the vascular access site management system, in accordance with additional embodiments of the present inventions.
[0050] FIGS. **12**A-**12**D schematically show an additional embodiment of a vascular access site management system in a first position, in accordance with further embodiments of the present invention.
[0051] FIGS. **13**A-**13**D schematically show the vascular access site management system of FIGS. **12**A-**12**D in a second position, in accordance with further embodiments of the present invention.
[0052] FIGS. **14**A-**14**D schematically show the vascular access site management system of FIGS. **12**A-**12**D in a third position, in accordance with further embodiments of the present invention.
[0053] FIG. **15** schematically shows an exploded view of the vascular access site management system of FIGS. **12**A-**12**D, in accordance with some embodiments of the present invention.

[0054] FIG. **16**A schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **12**A-**12**D with a valve mechanism in the closed mode, in accordance with additional embodiments of the present inventions.
[0055] FIG. **16**B schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **12**A-**12**D with a valve mechanism in an open mode for retrograde flow, in accordance with additional embodiments of the present inventions.
[0056] FIG. **16**C schematically shows a cross-sectional view of the vascular access site management system shown in FIGS. **12**A-**12**D with a valve mechanism in an open mode for forward flow, in accordance with additional embodiments of the present inventions.
[0057] FIGS. **17**A-**17**C schematically show the vascular access site management system of FIGS. **12**A-**12**D with a vein relief area, in accordance with some embodiments of the present invention.
[0058] FIG. **18** schematically shows an additional embodiment of a vascular access site management system with an alternate base direction, in accordance with further embodiments of the present invention.
[0059] FIGS. **19**A-**19**D schematically show an alternative embodiment of a locking mechanism for locking the vascular access site management system to the catheter, in accordance with some embodiments of the present invention.
[0060] FIGS. **20**A-**20**D schematically show an additional alternative embodiment of a locking mechanism for locking the vascular access site management system to the catheter, in accordance with some embodiments of the present invention.
[0061] FIGS. **21**A-**21**D schematically show a further alternative embodiment of a locking mechanism for locking the vascular access site management system to the catheter, in accordance with some embodiments of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0062] In illustrative embodiments, a vascular access site management system includes a stabilization body and a flow housing that is rotatable relative to the stabilization body. The flow housing may have a flow path extending through it to allow fluids to be introduced to or extracted from a patient via a catheter connected to the vascular access site management system. Additionally, in some embodiments, the vascular access site management system may include a needle free connector or other medical connector fluidly connected to the flow housing via a section of tubing. Details of illustrative embodiments are discussed below.
[0063] FIGS. **1**A-**1**D schematically show a vascular access site management system **100** in both an undeployed state (FIGS. **1**A and **1**B) and a deployed state (FIGS. **1**C and **1**D), in accordance with some embodiments of the present invention. FIG. **2** shows an exploded view of the vascular access site management system **100**. The management system **100** may include a stabilization base **110** (e.g., an adherent substrate) that may be secured to the patient to hold the management system **100** in place during use. More specifically, the stabilization base **110** may include one or more adhesive layers on its underside to secure the management system **100** to the patient. For example, as discussed in greater detail below, the stabilization base may include two sections of adhesive (FIG. **2**). The first section **112** may be a light tack adhesive that allows the user to position and re-position the management system **100** as needed. The second section of adhesive **114** may be stronger adhesive that allows the user to firmly secure management system **100** once the system **100** is in place.
[0064] The locations of the adhesive sections **112**/**114** may vary depending on the application. For example, in some embodiments, the first section adhesive **112** may be located at the leading end (e.g., the end closed to the catheter) of the stabilization base **110** (see FIG. **2**), and the second section **114** of adhesive may be located on the remainder of the underside of the stabilization base **110**. However, in other embodiments, the first section of adhesive **112** may be located at the trailing end of the stabilization base **110** (e.g., the end farthest from the catheter). Additionally or alternatively, the stronger adhesive (e.g., the second section of adhesive **114**) may be located on the

entire underside of the stabilization base **110** and the first section of adhesive **112** may be located on top of a portion of the stronger adhesive (e.g., one or more areas on the underside of the stabilization base **110** will have multiple layers of adhesive—a layer of stronger adhesive and a layer of lighter tack adhesive on top of the stronger adhesive).

[0065] To prevent the sections of adhesive **112**/**114** from inadvertently sticking to the wrong surface and/or to prevent bacteria and other contamination from sticking to the adhesive, the stabilization base **110** may include one or more liners covering the adhesive. Each of the liners may include a tab so that the liner can be easily removed. For example, the stabilization base **110** can include a first liner **111** for the first section of adhesive **112** and a second liner **113** for the second section of adhesive **114**. Alternatively, a single liner may be used for both sections of adhesive **112**/**114** or each section **112**/**114** may have multiple liners.

[0066] Although any number of adhesives may be used to secure the management system **100** to the patient, the adhesive used for the first section **112** should be easily peelable (e.g., to allow the user to reposition the device **100**), but be able to resist shear loads so that the weight of the device **100** and any attached medical implements (e.g., a syringe) do not cause the device **100** to inadvertently move or fall off. The adhesive used for the second section **114** should be strong enough such that the stabilization base **110** and the management system **100** do not peel off the patient's skin during regular movement by the patient (e.g., manipulation of the hand, arm etc.).

[0067] In some instances, it may be beneficial for the stabilization base **110** to be folded up prior to use/deployment (see FIGS. **1**A and **1**B) such that a portion of the stabilization base **110** interfaces with the stabilization body **120** (or flow housing **140**). For example, the stabilization base **110** (or the liners **111**/**113**) may be bi-stable such that it is stable in either the folded up position or in the folded down position (e.g., it will not revert to the folded down position when it is folded up and vice versus). Alternatively, the system **100** may include a mechanism that holds that stabilization base **110** in the folded up position (e.g., the body **120** may include a protrusion that extends through the base **110** when in the folded up configuration and prevents the base **110** from returning to the folded down position).

[0068] As discussed in greater detail below, when the stabilization base **110** is in the folded up position, the underside of the base **110** provides a surface on each side of the management system **100** where the user may grab and manipulate the device. To further improve the user's ability to grip and manipulate the device **100**, the release liners **111**/**113**, the adhesive **112**/**114**, or the stabilization base **110** may be a material that deforms in the presence of a pressure such that it conforms to the user's fingers, the shape of the stabilization body **120** and/or flow housing **140**.

[0069] Located on and secured to the stabilization base **110**, the management system **100** has a stabilization body **120** with an opening **122** extending through it. For example, the stabilization body **120** may have a bottom portion **124** that is secured to the stabilization base **110** and a proximally extending portion **126** that extends upward from the bottom portion **124** and through which the opening **122** extends. The bottom portion **124** may be secured to the stabilization base **110** in any number ways (e.g., via adhesive, ultrasonic welding, bonding, etc.). In some embodiments, it may be beneficial for the stabilization body **120** to conform to the patient. To that end, the stabilization body **120** may include living hinges **121** (FIGS. **4**A and **4**B) that allow the bottom portion **124** of the stabilization body **120** to flex (e.g., with respect to portion **126**).

[0070] As mentioned above, the management system **100** may be connected to a catheter **210** that has been inserted into the patient. To that end, the stabilization body **120** may include a pair of locking arms **130**A/**130**B that extend from the body **120** and toward the catheter **210**. Each of the locking arms **130**A/**130**B may have an inwardly projection protrusion **132**A/**132**B that engages with a luer thread **212** on the catheter **210** to lock the catheter **210** in place. For example, during connection of the catheter **210**, the user may push the management system **100** against the catheter **210** (while holding the catheter **210** to ensure that it does not move) such that the end of the catheter **210** and the luer thread **212** contact the locking arms **130**A/B. As additional force is

applied by the user, the locking arms **130**A/B will begin to flex outward until the luer thread **212** is located between the arms **130**A/B, at which point the arms **130**A/B will snap back to their original position. Once the arms **130**A/B have "snapped" back, the protrusions **132**A/B will engage the luer thread **212** and lock the catheter **210** to the management system **100**.

[0071] As best shown in FIGS. **2** and **3**, the management system **100** may also include a flow housing **140** that essentially acts as the hub of the management system **100**, and through which fluid being transferred to/from the patient flows. The flow housing **140** includes a main housing **150** and a housing extension **160** that extends outward from the main housing **150** and through the opening **122** in the stabilization body **120**. At least a portion of the housing extension **160** may be a male luer (e.g., male luer portion **164**) that connects with the catheter **210** during use. The extension **160** and/or the opening **122** may be sized such that the extension **160** and, thus the flow housing **140** is free to rotate with respect to stabilization body **120**. Additionally, as discussed in greater detail below, the extension **160** may have one or more protrusions **162** that interact with a camming surface on the stabilization body **120** to further secure the extension **160** (e.g., the male luer portion **164**) to the catheter **210**.

[0072] The main housing **150** of the flow housing **140** may have a port **152** (e.g., an inlet) that fluidly connects to tubing **170** leading to a needle free connector **180** (discussed in greater detail below). Within the interior of the main housing **150**, the flow housing **140** may have an internal fluid path **154** that extends through the body of main housing **150**/flow housing **140** and the extension **160**. As discussed in greater detail below, during use, fluid may flow through the flow housing **140** as fluid is transferred to the patient. It should be noted that, although much of the discussion herein refers to the port **152** as an inlet, the port **152** also may be used as an outlet. In other words, if fluid is to be drawn from the patient (as opposed to transferred to the patient), the fluid may flow into fluid path **154** via the extension **160** and male luer connector **164**, through the internal fluid path **154**, and out of the port **152**.

[0073] In some instances the catheter **210** may extend out of the patient at an angle (e.g., at a 7 degree angle with respect to the patient). To reduce the forces/pressure on the catheter **210**, make it easier for the user to connect the catheter **210** to the device **100** and keep the fluid path **154** in line with the catheter **210**, the fluid path **154** (e.g., the portion extending through the housing extension **160**/male luer) may also be at an acute angle with respect to the surface of the patient. To that end, as shown in FIG. **3**, the proximally extending portion **126** may not be perpendicular with respect to the bottom portion **124** of the stabilization base. Rather, it may be angled back slightly to create the acute angle between the fluid path **154** and the surface of the patient's skin. Additionally or alternatively, the portion of the fluid path **154** extending upward through the fluid housing **140** may be not be at a right angle with respect to the portion that extends through the extension **160**.

[0074] To control fluid flow through the management system **100** and the flow housing **140**, the interior of the flow housing **140** may include a valve mechanism **142** within the internal fluid path **154**. For example, the flow housing **140** may include a two-way pressure activated valve **142** (PAV) that includes a flat diaphragm **143** with a slit **144**. Alternatively, at least a portion of the diaphragm **143** may have a curvature with the slit **144** positioned within the curved portion. The valve mechanism **142** prevents fluid flow through the flow housing **140** (e.g., through the internal fluid path **154**) until it is exposed to a large enough pressure to open the slit through the diaphragm **143** (e.g., a cracking pressure). It is important to note that a diaphragm **143** and slit **144** configuration should be chosen such that the patient's venous pressure is below the backward (i.e. proximally-directed) cracking pressure of the valve mechanism **142** to prevent the venous pressure from opening the slit **144**/pressure activated valve **142**. Additionally, the distally-directed cracking pressure may be different than the proximally-directed cracking pressure.

[0075] Although a diaphragm **143** with a slit **144** may achieve the functionality of a two-way pressure activated valve, other two-way PAVs known in the art may also be used within the flow housing **140**. Additionally or alternatively, the flow housing **140** may include a one-way PAV valve

that only allows a one directional flow through the flow housing **140** (e.g., from the port **152** and towards the catheter **210**). For example, in some embodiments, the diaphragm **143** may not have a slit **144** (e.g., it may be a solid diaphragm). In such embodiments, the diaphragm may deform (e.g., it may deform over a protrusion within the flow housing **140**) in the presence of a pressure within the flow housing **140** to open the internal fluid path **154** and allow the fluid to flow past the diaphragm and through the flow housing **140**.

[0076] To secure the valve **142** within the flow housing, the device **100** may include a cap **145** that may be inserted to an open end of the flow housing **140**. The cap **145** may have a skirt **146** that extends inward into the interior of the flow housing **140** and traps the valve **142** between the skirt **146** and an inner wall of the flow housing **140**. To ensure that the fluid path **154** through the flow housing **140** is not blocked, the cap **145** may include an opening **147** through the skirt **146**. In some instances, connection and disconnection of a medical implement to the needle-free connector **180** may cause a pressure increase and/or decrease within the flow housing **140** (e.g., within the fluid path **154**). To compensate for these pressure changes and to help prevent blood from being pulled into the fluid path **154** (e.g., past the valve **142**), the cap **145** may include a diaphragm or bellows (not shown) that deforms with the changes in pressure. For example, if the pressure within the fluid path **154** increases (e.g., due to connection of the medical implement), the diaphragm or bellows may deform outward with respect to the fluid path **154**. Conversely, if the pressure within the fluid path **154** decreases (e.g., upon disconnection of the medical implement) the diaphragm or bellows may deform inward with respect to the fluid path **154** (e.g., into the interior of the flow housing **140**).

[0077] As noted above, the extension **160** may have one or more protrusions **162** that interact with a camming surface on the stabilization body **120** to further secure the extension **160** (e.g., the male luer portion **164**) to the catheter **210**. For example, as shown in FIGS. **4**A-**4**D, the stabilization base **120** (e.g., in the proximally extending portion **126**) may have slots **310** that allow the protrusions **162** on the extension **160** to pass through the stabilization base **120** (e.g., when the flow housing **140** is in the upright position shown in FIG. **2**). The slots **310** provide a diametric interference with the effective diameter of the protrusions **162** such that they provide a one-way, snap-style insertion of the flow housing **140** into the stabilization body **120**. This allows for proper initial positioning and capturing of the protrusions **162** relative to the camming surfaces **128** on the stabilization body **120**.

[0078] Once in place, a camming surface **163** on the protrusions **162** will contact a camming surface **128** on the stabilization body **120**. Upon rotation of the flow housing **140** toward the deployed position (see FIGS. **1**C and **1**B), the camming surface **163** on the protrusions **162** will slide along and advance up the camming surface **128** on the stabilization body **120**. This, in turn, will cause the flow housing **140** and extension **160** to move towards the catheter **210** such that the male luer portion **164** of the extension **160** moves further into the female luer of the catheter hub **214**. In some embodiments, the protrusions **162**/lugs may travel into a detent within the stabilization body **120** to lock the flow housing **140** in the cammed/fully connected position. It is important note that, as discussed above, the catheter **210** is restrained by the pair of locking arms **130**A/B and therefore is held in place as the male luer portion **164** is connected.

[0079] As mentioned above, the vascular access site management system **100** also includes a needle-free connector **180** that is fluidly connected to the flow housing **140** via a tube **170**. The needle-free connector **180** (e.g., a medical valve) is connectable to a medical implement and is used to control fluid flow to and from the patient. Although any number of needle-free connectors **180** or medical valves can be used (e.g., positive displacement valves, negative displacement valves, neutral displacement valves, etc.), some embodiments may use a simple split septum valve. As is known in the art, a split septum valve includes a septum **182** obstructing the inlet **184** of the valve **180**. To allow flow through the valve **180**, the septum **182** may include an aperture or a slit extending through it. To that end, connection of the medical implement (e.g., a needleless syringe)

to the valve **180** deforms the septum, thus opening the aperture/slit. Once connected, the medical implement may transfer fluid to/from the patient. In order to help reduce potential kinking, the tube **170** may be pre-formed with the arcuate/curved shape shown in the figures. For example, the tube **170** may be initially formed in this shape (e.g., prior to assembly) or the tube **170** may take that curved shape during the sterilization process after assembly.

[0080] During use, the user (e.g., the medical personnel) may first connect a medical implement to the needle-free connector **180** and flush (e.g., prime) the device **100**, for example, with saline. Once the device **100** is flushed/primed, the user may insert the catheter **210** into the patient (e.g., into the patient's arm). It is important to note that prior to inserting the catheter **210**, the insertion site should be properly cleaned per acceptable medical practice. Additionally, to preserve the injection site after insertion of the catheter **210**, the user may place gauze over the injection site and the location where the management device **100** will be placed.

[0081] The user may then connect the catheter **210** to the management device **100**. When attaching the catheter **210** and securing the stabilization device **100**, the user may grab the stabilization body **120** (or the underside of the stabilization base **110** if it is folded up) and press the device **100** against the catheter **120**. As the user presses the device **100** against the catheter **120**, the locking arms **130**A/B will begin to deform until the catheter **210** (e.g., the thread **212** on the catheter hub **214**) snaps into place. At this point, the catheter **210** is, at least partially connected to the male luer connector portion **164** on the extension **160**. Once the catheter **210** is attached, the user may then remove the liner **111** on the first section **112** of adhesive and stick the stabilization base **110** to the patient.

[0082] Once the first section **112** of adhesive is adhered to the patient, it is desirable to check that the fluid flow through the system **100** and in the vein is acceptable/adequate. To that end, the user may gently inject 1-2 ml of saline into the vein to confirm adequate fluid flow. If the fluid flow is not adequate, the user may adjust the positioning of the catheter **210** within the vein by gently lifting the first section **112** of adhesive to release the system **100** from the patient's skin, and move the catheter **210** forward into the vein while gently injecting another 1-2 ml of saline solution. Once the flow is adequate, the user may, once again, secure the system **100** to the patient's skin using the first section **112** of adhesive. Additionally, if the user is satisfied with the placement, the user may remove the liner **113** for the second section **114** of adhesive to further secure the system **100** to the patient.

[0083] After the vascular access site management system **100** is secured (or re-secured) and there is adequate flow within the vein, the user rotate the flow housing **140**, tube **170** and needle-free connector **180** to either the right or the left (e.g., from the upright position to the position shown in FIG. **1**C or **1**D). As the flow housing **140** is rotated, the camming action of the lug **162** camming surface **128** on the stabilization body **120** will cause the flow housing **140** (including the extension **160** and male luer connector portion **164**) to move towards the catheter **210** and further secure the male luer connector portion **164** and the catheter **210**. The user may then place a dressing over the connection site to maintain the cleanliness and sterility of the connection and connection site. It should be noted that, by allowing the user to choose either a left or right configuration, embodiments of the present invention allow the user to choose the best configuration for the given application based, for example, the user's preference, the amount of available space on either side of the catheter **210**, the location of the catheter **210**, etc.

[0084] Once the system **100** is fully secured to the patient, the catheter **210** cannot be inadvertently moved. Additionally, the medical implement (e.g., the syringe) may be connected and disconnected as needed without impacting the placement/location of the catheter **210**. This, in turn, helps to prevent injury to the patient and ensures that adequate fluid flow through the device **100**, catheter **210**, and vein is maintained. Furthermore, because the device **100** includes a needle-free connector **180**, the medical implement can be easily re-attached to the device **100** at a later time to introduce fluids into the patient and/or withdraw fluids from the patient.

[0085] It should be noted that, some embodiments of the present invention may have various features that help the user know/determine the distance from the system **100** to the tip of the catheter **210** so that the user can determine when the tip of the catheter **210** is located within the vein. For example, returning to FIGS. **1**C and **1**D, the stabilization body **120** and/or the flow housing **140** may have a dressing deployment surface **220** on which the dressing may be placed/secured and the edge of the dressing (not shown) may be aligned with a line or a marking on the stabilization body **120** or flow housing. Additionally, in such embodiments, the dressing may have a series of graduations or a grid pattern that corresponds to the length of the catheter **210**. In this manner, when the user applies the dressing such that it is aligned with the line/marking, the user will be able to tell where in the vein the end of the catheter **210** is by the graduations on the dressing. To accommodate multiple types of catheters **210**, the dressing may have multiple sets of graduations that correspond to different types and lengths of catheters **210**.

[0086] Although the embodiments described above have a flow housing **140** with a main housing **150** and a housing extension **160** (with male luer portion **164**) that all rotate relative to the stabilization body **120**, other embodiments may have different rotational configurations. For example, as shown in FIGS. **5**A-**5**E, in some embodiments, the vascular access site management system **400** may have stabilization body **410** with a male luer connector **420** extending from one side of the stabilization body **410** (e.g., the side facing the catheter **210**) and a stabilization body extension **430** extending from the other side. Like the male luer portion **164** discussed above, the male luer connector **420** extending from the stabilization body **410** connects to the catheter **210** during use. Additionally, although not shown, the stabilization device can also include a locking mechanism, for example, locking arms like those described above to lock the catheter **210** to the device **400**.

[0087] The stabilization body extension **430** may have one or more holes **440** (e.g., opposing side holes) (FIG. **5**C) that extend through the wall of the stabilization body extension **430** and to the fluid path **450** (FIG. **5**D) extending through the stabilization body **410** (e.g., through both the stabilization body extension **430** and the male luer connector **420**). In some embodiments, the end of the stabilization body extension **430** may be a female luer lock **460**. However, in other embodiments, the stabilization body extension **430** may have any other type of medical port or it may simply have a closed end or a capped port. In embodiments having a closed end or capped port, the stabilization body extension **430** may have a diaphragm or bellows that flexes/deforms with changes in the pressure, in a manner similar to that described above.

[0088] Located on the stabilization body extension **430**, the device **400** may have a flow sleeve **470** having a flow portion **472** with a fluid path **480** extending (FIG. **5**D) through it, and a ring portion **474** that may snapped over (or otherwise secured) to the stabilization body extension **430**. The flow sleeve **470** is rotatable with respect to the stabilization body extension **430** between a closed mode and one of two open modes. For example, in the closed mode, the flow portion may be in the vertical orientation (FIGS. **5**A and **5**D) and the fluid path **480** within the flow portion **472** may be fluidly disconnected from the holes **440** and the fluid path **450** extending through the stabilization body **410**. During use, to transition the flow sleeve **470** to the one of the open modes (FIGS. **5**B and **5**D), the user may rotate the flow sleeve **470** to the left or right (depending on the user's preference and the configuration of the catheter **210**) until it reaches the horizontal orientation (FIGS. **5**B and **5**E). To prevent leakage between the flow sleeve **470** and the stabilization body extension **430**, the flow sleeve **470** (or the stabilization body extension **430**) may include a seal **485**.

[0089] When in the open mode, the fluid path **480** extending through the flow portion **472** is fluidly connected to the holes **440** and the fluid path **450** extending through the stabilization body **410**. Although not shown, like the embodiments described above, the device **400** may also have a tube and a needle-free connector that are fluidly connected to the flow portion **472** and, in particular, the fluid path **480** (e.g., via port **482**). Therefore, in a manner similar to that described above, when the

flow sleeve **470** is in the open mode, the user may transfer fluid to and from the patient.
[0090] To ensure that the flow sleeve **470** does not inadvertently rotate back to the closed mode, some embodiments may have a locking mechanism that holds the flow sleeve **470** in the open position. For example, in some embodiments, the flow sleeve **470** may have a protrusion that enters a detent within the stabilization body extension **430**. Additionally or alternatively, the stabilization body extension **430** may have protrusion that enters a detent in the flow sleeve **470** when in the open mode.
[0091] Additionally, although the embodiment described above and shown in FIGS. **5**A-**5**E has opposing holes **440** that create discreet open modes, other embodiments may allow for fluid communication between the fluid path **480** in the flow sleeve **470** and the fluid path **450** extending through the stabilization body **410** in any orientation of the flow sleeve **470**. For example, rather than opposing holes **440**, some embodiments may have a channel within stabilization body extension **430** that connects the two holes **440**. Therefore, the fluid path **480** in the flow sleeve **470** is fluidly connected to the fluid path **450** in the stabilization body **410** when the flow sleeve **470** is in the vertical orientation, horizontal orientation or anywhere in between.
[0092] It should be noted that in the embodiment shown in FIGS. **5**A-**5**E, the catheter and the male luer connector **420** are rotationally decoupled from the rotation of the flow sleeve **470**. Therefore, any rotation of the flow sleeve **470** does not rotate the male luer connector **420** and/or the catheter.
[0093] FIGS. **6**A-**6**E show an additional embodiment of a vascular access site management system **500**. Like the management systems **100**/**400** described above, the management system **500** shown in FIGS. **6**A-**6**E may have a needle-free connector **180** that is fluidly connected to a flow housing **540** via a tube **170**. The needle-free connector **180** can be any number of needle-free connectors and/or medical valves. For example, in some embodiments, the needle-free connector may be a swabbable luer activated such that those described in U.S. Pat. Nos. 6,755,391, 7,014,169, 6,039,302, 7,100,890, and 7,789,864, the disclosures of which are incorporated herein by reference.
[0094] The management system **500** also includes a rotatable stabilization pad **520** that is rotatable about the flow housing **540** that is secured/retained within the stabilization pad **520**. The stabilization pad **520** may have base **522** that may be placed on the patient during use and may support the flow housing **540**. To retain the flow housing **540**, the stabilization pad **520** may also include a proximally extending portion **524** that extends upward from the base **522**, and an opening **526** extending through the proximally extending portion **524**. The flow housing **540** may be pushed through the opening **526** such that the portion of the proximally extending portion **524** surrounding the opening **526** snaps into a recess **541** within the flow housing **540**. As noted above, the stabilization pad **520** should be able to rotate about the flow housing **540**. Therefore, the opening **526** should be sized such that the connection between the pad **520** and flow housing **540** does not interfere with the rotation. In some embodiments, the stabilization pad **520** may be elastomeric.
[0095] At one end, the flow housing **540** may include a male luer lock connector **550** that connects to the catheter **210** within the patient. To help the user during connection of the catheter **210**, the stabilization pad **520** may include a retention feature **528** (FIG. **6**E) that holds the collar/ring **552** of the male luer lock connector **550** back during initial connection with the catheter **210**. For example, the retention feature **528** may be a ridge or protrusion that contacts the ring **552** and essentially interferes with the forward and backward movement of the ring **552**. Once the initial connection has been made (e.g., the male luer portion has been inserted into the female luer on the catheter **210**), the user may rotate the ring **552** to release it from the retention feature **528** and allow the user to screw the ring **552** onto the catheter **210**.
[0096] Like the flow housings described above, the flow housing **540** shown in FIGS. **6**A-**6**E has a flow path **542** extending through it to allow fluid to be transferred to and/or from the patient during use. The tube **170** may be fluidly connected to the flow path **542** via port **543**. To control fluid flow through the management system **500** and the flow housing **540**, the interior of the flow housing **540** may include a valve mechanism **544** within the internal fluid path **542** (FIGS. **6**D and **6**E). For

example, the flow housing **540** may include a two-way pressure activated valve **544** (PAV) like that described above. The valve mechanism **544** prevents fluid flow through the flow housing **540** (e.g., through the internal fluid path **154**) until it is exposed to a large enough pressure to open the slit through the diaphragm (e.g., a cracking pressure).

[0097] In some applications, it may be necessary to introduce a medical article into the catheter **210**. For example, the user may need to access to a peripheral vein through the indwelling catheter **210** to introduce sensors for detecting a patient condition, introduce delivery lines for certain medicaments/agents, and/or introduce tubing for direct blood withdrawal. To that end, the flow housing **540** may have a split septum port **560** for receiving a medical implement **610** (e.g., a blunt cannula or other medical device or connector). As the name suggests, the split septum port **560** includes a septum **562** that obstructs the port **560** and normally seals off the interior of the flow housing **540** (e.g., it seals off the flow path **542** from the environment/exterior of the flow housing **540**. To allow for connection of the medical implement **610**, the septum **562** may include an aperture or a slit extending through it. To that end, during connection of the medical implement **610** to the flow housing **540**, the end **612** (e.g., the distal tip) of the medical implement **610** deforms the septum **562**, thus opening the aperture/slit to allow the medical implement **610** to extend through the septum **562**.

[0098] As shown in FIG. **6**E, the medical implement **610** may have a channel **614** extending through it to allow the medical article (not shown) to be introduced into the catheter **210** and/or vein through the system **500**. However, it should be noted that any obstructions, bends, turns, etc. within the path between the channel **614** and the catheter **210**/vein may make it difficult to introduce the medical article. For example, if the valve mechanism **544** is closed, it will obstruct the pathway and, potentially prevent the medical article from being introduced. In view of the above, some embodiments may have various features that help to provide a clear path for the introduction of the medical article by positioning the medical implement **610** such that the end **612** of the medical implement **610** is near the valve mechanism **544** and, in some cases, partially opens or fully opens the valve mechanism.

[0099] For example, the flow housing **540** can include one or more protrusions **546** that extend out from the flow housing **540** and enter a recess **617** within the arms **616** of the medical implement **610** when it is connected to the flow housing **540**. The location of both the protrusions **546** and the recesses **617** may be such that the end **612** of the medical implement **610** is located at the valve mechanism **544** or, as shown in FIG. **6**E opens the valve mechanism **544**. Additionally or alternatively, to help appropriately position the medical implement **610**, the flow path **542** may include a contact surface **543** that contacts the outer surface of the medical implement **610** and acts as a stop for the medical implement **610** (e.g., the outer diameter of the medical implement **610** may contact the inner diameter of the flow path **542** so that the medical implement **610** stops in the desired position). In addition to acting as a stop for the medical implement **610**, the contact surface **543** may also keep the tip/end **612** of the medical implement **610** (and therefore the channel **614**) concentric with the opening through the valve mechanism **544** and the male luer connector **550**.

[0100] In other embodiments, the medical implement **610** and/or the flow path **542** may also have a guide ribs extending along at least a portion of its length (e.g., along the outer diameter of the medical implement **610** and/or the inner diameter of the flow housing **540**). The guide ribs guide the medical implement **610** into the flow housing **540** and keep it concentric within the flow path **542** and, perhaps help position the medical implement **610** longitudinally within the flow housing **540**. The ribs may be deformable or crushable.

[0101] Although the vascular access site management system shown in FIGS. **6**A-**6**E includes a stabilization pad **520** that rotates with respect to the flow housing **540**, other embodiments may have different configurations. For example, as shown in FIGS. **7**-**11**, some embodiments may include a stabilization body **1010** and a flow housing **1090** that is rotatable about the stabilization body **1010** (and not just a stabilization pad **520**). It should be noted that, like the management

systems described above, the management system **1000** shown in FIGS. **7**-**11** may have a needle-free connector that is fluidly connected to the flow housing **1090** via a tube. The needle-free connector can be any number of needle-free connectors and/or medical valves.

[0102] The stabilization body **1010** has a base **1020** and an upper portion **1030** extending from the base **1020**. During use, the base **1020** may be placed on the patient to support and stabilize the device **1000** on the patient. At one end, the upper portion **1030** may include a male luer lock connector **1032** that connects to the catheter **210** within the patient. Like the other embodiments described herein, the base **1020** may be oriented at an angle (e.g., between 5 and 10 degrees) with respect to a longitudinal axis of the outlet **1031** (e.g., the outlet of the male luer lock connector). To help the user during connection of the catheter **210**, the base **1020** may include a retention feature **1022** (FIGS. **10**A and **10**B) that holds the collar/ring **1033** of the male luer lock connector **1032** back during initial connection with the catheter **210**. For example, like the retention feature described above, the retention feature **1022** may be a ridge or protrusion that contacts the ring **1033** and essentially interferes with the forward and backward movement of the ring **1033**.

[0103] As shown in FIG. **10**A, the upper portion **1030** has a flow path **1040** extending through it (e.g., to outlet **1031**) to allow fluid to be transferred to and/or from the patient during use. To control fluid flow through the management system **1000** and the upper portion **1030**, the interior of the upper portion **1030** may include a valve mechanism **1060** (e.g., a two-way pressure activated valve (PAV) with a slit **1062**) within the internal flow path **1040** (FIGS. **10**A and **10**B). The valve mechanism may deform in the presence of a forward pressure (e.g., toward the outlet **1031**) to allow fluid to flow around the valve mechanism **1060** and through the upper portion **1030**. Additionally, in the presence of a retrograde pressure (e.g., from the outlet **1031**), the slit **1062** may open to allow fluid flow through the upper portion **1030** from the outlet **1031** toward an inlet **1114** in the flow housing **1090** (described in greater detail below). It should be noted that, to avoid low pressure flow (e.g. blood reflux) through the valve mechanism **1060**, the pressure required to open the slit in the retrograde direction should be greater than the venous pressure of the patient.

[0104] To help support the valve mechanism **1060** within the flow path **1040**, the upper portion **1030** of the stabilization body **1010** may include a number of support arms **1036**. In the presence of the forward pressure and as the valve mechanism **1060** deforms, the valve mechanism **1060** may deform away from a seating/sealing surface **1037** within the upper portion **1030** and over the support arms **1036** to allow the fluid flow toward the outlet **1031**, around the valve mechanism **1060** and between the spaces between the support arms **1036**. Additionally, the support arms **1036** may be located radially inward from the seating/sealing surface **1037** to promote deformation (e.g. bending) of the valve mechanism **1060** around the support arms **1036** in the presence of the forward pressure. It should be noted that, although the figures show eight support arms **1036**, other embodiments may have more or less than eight support arms **1036**. For example, some embodiments may have seven or less support arms **1036** and other embodiments may have nine or more support arms **1036**. Furthermore, the number of support arms **1036**, their width(s) and contact area(s), and the amount of open space between each support arm **1036** will at least partially influence the degree that the valve mechanism **1060** bends around the support arms **1060** and the size of the opening between the seating/sealing surface **1037** and valve mechanism **1060** (e.g. size of flow path).

[0105] As shown in FIGS. **9**A-**9**C and **10**A-**10**B, the flow housing **1090** has a sleeve portion **1100** and a pathway portion **1110** extending from the sleeve portion **1100**. The sleeve portion **1100** is located on/around the upper portion **1030** of the stabilization body **1010** such that the flow housing **1090** can rotate with respect to the stabilization body **1010**, for example, between a closed mode (e.g., the position shown in FIGS. **8**A-**8**C) and at least one open mode (e.g., the positions shown in FIGS. **7**A-**7**C and **9**A-**9**C). The pathway portion **1110** has a fluid path **1112** that extends through it and that is fluidly connected to the flow path **1040** within the upper portion **1030** when in the open mode(s). The inlet **1114** of the fluid path **1112** may be connected to the tube leading to the needle

free connector (discussed above). Alternatively, a medical implement (e.g., for fluid transfer in/out of the patient) may be connected directly to the inlet **1114**. It should be noted that the catheter **210** and the stabilization body **1010** are rotationally decoupled from the rotation of the flow housing **1090**. Therefore, any rotation of the flow housing **1090** does not rotate the stabilization body **1010** and/or the catheter.

[0106] To create fluid communication between the flow path **1040** in the upper portion **1030** of the stabilization body **1010** and the fluid path **1112** in pathway portion **1110**, the upper portion **1030** may have one or more holes **1038**A/B extending through the wall of the upper portion **1030**. For example, in the closed mode, the flow housing **1090** may be in the vertical orientation (FIG. **8**A-**8**C) and the fluid path **1112** within the pathway portion **1110** may be fluidly disconnected from the holes **1038**A/B and the flow path **1040** in the upper portion **1030**. To transition the flow housing **1090** to one of the open modes (FIGS. **7**A-**7**C and **9**A-**9**C), the user may rotate the flow housing **1090** to the left or right (depending on the user's preference and the location of the catheter **210** upon the patient). When in one of the open modes, the fluid path **1112** extending through the flow housing **1090** is fluidly connected to one of the holes **1038**A/B and the flow path **1040** in the upper portion **1030**.

[0107] As discussed above, in some applications, it may be necessary to introduce a medical article into the catheter **210**. To that end, the upper portion **1030** may have a port **1050** with split septum **1080** for receiving a medical implement **610**. The split septum **1080** obstructs the port **1050** and normally seals off the interior of the upper portion **1030** (e.g., it seals off the flow path **1040** from the environment/exterior of the upper portion **1030**). As the name suggests, the septum **1080** may include an aperture or a slit **1082** through which the end/distal tip **612** of the medical implement may pass. For example, while engaging the medical implement **610** with the upper portion **1030**, the end/distal tip **612** will deform the septum **1080**, and opens the aperture/slit **1082** to allow the distal tip **612** to enter the interior of the device **1000** (e.g., the flow path **1040**).

[0108] It should be noted that, although the figures show a split septum-style sealing mechanism **1080**, other embodiments may have alternative valving mechanisms for sealing off the flow path **1040** from the environment/exterior of the upper portion **1030** and allow the distal tip **612** to enter the interior of the device **1000**. For example, some embodiments may include a valve structure such as that described in U.S. Pat. No. 9,079,005 (incorporated herein by reference in its entirety). In such embodiments, the sealing mechanism may have a proximal portion located within the port, a wall that extends distally from the proximal portion within the interior of the device **1000** (e.g., within the interior of the upper portion) and an open distal end. The wall may form an interior within the sealing mechanism. To support the sealing mechanism within the device **1000**, the device **1000** may include structures against which the end of the wall may contact.

[0109] As also discussed above, obstructions, bends, turns, etc. within the path between the channel **614** in the medical implement **610** and the catheter **210**/vein may make it difficult to introduce the medical article. To that end, like the flow housing **540** mentioned above, the upper portion **1030** can include one or more engagement features (e.g., protrusions **1070**) that extend out from the device **1000** (e.g., from the flow housing **1090**) and enter an engagement feature (e.g., a recess **617**) within the arms **616** of the medical implement **610** when it is connected to the device **1000**. The location of both the protrusion(s) **1070** and the recess(es) **617** may be such that the distal tip **612** of the medical implement **610** is located at a predetermined longitudinal position within the flow path **1040** and interacts with the valve mechanism **1060**. For example, the distal tip **612** may merely contact the valve mechanism **1060** to make it easier for the medical article to open the slit **1062** or, as shown in FIG. **11**, the distal tip **612** of the medical implement **610** may partially or fully open the slit **1062** within the valve mechanism **1060**.

[0110] As shown in FIG. **11**, in embodiments in which the medical implement **610** partially opens the slit, when the distal tip **612** of the medical implement **610** interacts with the valve mechanism **1060**, the inner portion **1064** of the valve mechanism **1060** around the slit **1062** may deform and/or

move longitudinally towards the first end/outlet **1031** and into the area between the support arms **1036**. Conversely, the longitudinal movement (e.g., towards the outlet **1031**) of the outer portion **1066** of the slit **1062** may be minimized. For example, as the distal tip **612** begins to interact with the valve mechanism **1060**, the outer portion **1066** may contact the support arms **1036** which, in turn, prevent the outer portion **1036** from moving toward the outlet **1031**.

[0111] It should be noted that, although the engagement member on the device **1000** is described as a protrusion/projection and the engagement member on the medical implement **610** is described as a recess, other embodiments may have different configurations and structures. For example, the engagement member on the medical implement **610** may be a protrusion and the engagement member on the device **1000** may be a recess. Additionally or alternatively, the device **1000** and the medical implement **610** may each have both a protrusion and a recess. In addition, the engagement member on the medical implement **610** may not reside on the arm **616** but alternatively or additionally on a feature or surface(s) that make contact with an engagement member on or near an end **1034** (FIG. **10**B) of upper portion **1030**, thereby coupling the medical implement **610** with the device **1000** to achieve placement of the distal tip **612** of the medical implement **610** at a predetermined longitudinal position within the flow path **1040**.

[0112] It should be noted that the engagement between the engagement feature **1070** on the upper portion **1030** and the engagement feature **617** on the medical implement **610** and the contact between the medical implement **610** and the septum **1080** may radially align the distal tip **612** with the flow path (e.g., to keep the distal tip **612** concentric with the flow path **1040**). Additionally or alternatively, to further help appropriately position the distal tip **612** (e.g., longitudinally) and to radially align the distal tip **612** with the flow path **1040**, the flow path **1040** may include a contact surface **1042** that contacts the outer surface of the medical implement **610**. In addition to acting as a stop for the medical implement **610**, the contact surface **1042** may also keep the distal tip **612** (and therefore the channel **614**) concentric with the opening through the valve mechanism **1060** and the male luer connector **1032**. To further help with the radial positioning and keep the distal tip **612** concentric, like the embodiments shown in FIGS. **6**A-**6**E, the device **1000** may have guide ribs (which may be crushable or deformable) extending along a portion of the length of the flow path **1040**.

[0113] It is important to note that by positioning the medical implement **610** in the manner described above, various embodiments of the present invention provide unobstructed medical article delivery, and like the other embodiments described herein, allow the user to configure the J-loop to the left or right and lock the J-loop in place. Additionally the elastomeric pad **520** and/or the stabilization body **1010** allow for patient comfort and maintains a proper catheter angle (e.g., in a manner similar to that described above).

[0114] FIGS. **12-17** schematically show an alternative vascular access site management system **1200** that also rotationally decouples the rotation of a portion of the device (e.g., a flow housing) from the rest of the device and the catheter to which it is connected. In a manner similar to the embodiments described above, the device **1200** may have a stabilization body **1210** with a male luer connector **1211** extending from one side of the stabilization body **1210** and a stabilization body extension **1213** extending from the other side. For example, the stabilization body **1210** may have an inlet body **1214** that forms the stabilization body extension **1213** and an outlet body **1212** that forms the male luer connector **1211**. During use, the male luer connector **1211** may connect to the catheter **210**. The stabilization device **1210** may include a locking mechanism (e.g., a threaded ring **1222**, locking arms, etc.) for securing the male luer connector **1211** to the catheter **210**.

[0115] As best shown in FIGS. **16**A and **16**B, the stabilization body **1210** may have an internal fluid path **1240** extending though the stabilization body **1210**. The inlet **1230** of the fluid path **1240** may be located within the inlet body **1214** and the outlet **1220** of the fluid path **1240** may be located within the outlet body **1212**. Within the fluid path **1240** and to control the flow of fluid through the internal fluid path **1240**, the stabilization body **1210** may have a valve mechanism **1320**

that is positioned within/between the inlet body **1214** and the outlet body **1212**. For example, the valve mechanism **1320** may be a two-way pressure activated valve (PAV) with a slit **1322** extending through it. As described in greater detail below, the valve mechanism may deform in the presence of a forward pressure (e.g., from the inlet **1230** towards the outlet **1220**) to allow fluid to flow around the valve mechanism **1320** and through the stabilization body **1210**. Additionally, in the presence of a retrograde pressure (e.g., from the outlet **1220** toward the inlet **1230**), the slit **1322** may open to allow fluid flow through the stabilization body **1200** from the outlet **1220** toward the inlet **1230**. It should be noted that, to avoid low pressure flow (e.g. blood reflux) through the valve mechanism **1320**, the pressure required to open the slit in the retrograde direction should be greater than the venous pressure of the patient.

[0116] In addition to being positioned between the inlet body **1214** and the outlet body **1212**, the stabilization body **1210** may include a number of support arms **1217** within the fluid path **1240** that mechanically support the valve mechanism **1320** within the fluid path **1240**. To that end, as the valve mechanism **1320** deforms (e.g., in the presence of the forward pressure), the valve mechanism **1320** may deform away from a seating/sealing surface **1215** within the stabilization body **1210** and over the support arms **1217** to allow the fluid flow from the inlet **1230** toward the outlet **1220**, around the valve mechanism **1320** and between the spaces between the support arms **1217**. Additionally, the support arms **1217** may be located radially inward from the seating/sealing surface **1215** to promote deformation (e.g. bending) of the valve mechanism **1320** around the support arms **1217** in the presence of the forward pressure. It should be noted that, although the figures show eight support arms **1217** other embodiments may have more or less than eight support arms **1217**. For example, some embodiments may have seven or less support arms **1217** and other embodiments may have nine or more support arms **1217**. Furthermore, the number of support arms **1217**, their width(s) and contact area(s), and the amount of open space between each support arm **1217** will at least partially influence the degree that the valve mechanism **1320** bends around the support arms **1217** and the size of the opening between the seating/sealing surface **1215** and valve mechanism **1320** (e.g. size of flow path).

[0117] To help stabilize the device **1200** on the patient, the stabilization body **1210** may include a base portion **1250** with a stabilization surface **1252** located on an underside of the base portion **1250** that stabilizes the device/system **1200** on the patient. Additionally or alternatively, the base portion **1250** may include a separate stabilization base **1300** that is located on the underside of the base portion **1250**. In some embodiments, the device **1200** may have a first securement portion **1302** and, perhaps, a second securement portion **1304** located on the underside of the stabilization base **1300** (or the underside of the base portion **1250**). In a manner similar to that described above for prior embodiments, the first and/or second securement portion **1302**/**1304** may include an adhesive layer that secures the device **1200** to the patient. For example, the first securement portion **1302** may have a light tack adhesive layer and the second securement portion **1304** may have a stronger tack adhesive layer (e.g., an adhesive that is stronger than the adhesive on the first securement portion **1302**). As noted above, the first securement portion **1302** with the light tack adhesive allows the user to position and reposition the system/device **1200** as needed. The second securement portion **1304** with the stronger adhesive allows the user to firmly secure the system/device **1200** to the patient once the device/system **1200** is in place.

[0118] In addition to or instead of the adhesive, the first securement portion **1302** may include a gripping or conforming structure that grips and/or conforms to the patient's skin to allow the user to initially position the device **1200** and hold the device **1200** in place while the second securement portion is secured to the patient or instead, no different than the first securement portion. For example, the first securement portion **1302** may include silicone structures (e.g., protrusions, ribs, etc.) that grip and/or conform to the surface of the patient's skin.

[0119] Like the adhesive sections **112**/**114** described above, the first securement portion **1302** may be located at the leading or trailing edge of the stabilization base **1300** (or base portion **1250** of the

stabilization body **1210**) and the second securement portion **1304** may be located on the remainder of the stabilization base **1300** or base portion **1250**. To prevent the securement portions **1302**/**1304** and their respective adhesives from inadvertently sticking to the wrong surface and/or prevent bacteria/contamination from sticking to the adhesive, the device **1200** may have one or more liners **1310** covering the adhesive. The liner **1310** may have a tab **1312** so that the liner **1310** can be easily removed. In some embodiments, the first and second securement portions **1302**/**1304** may have their own liners that can be removed independently as needed.

[0120] As discussed above, it may beneficial to reduce the force/pressure on the catheter **210** and keep the fluid path **1240** in line with the catheter **210**. To that end, the base portion **1250** and/or the stabilization base **1300** may be configured at an angle with respect to the outlet **1220** of the stabilization body **1210** (e.g., with respect to the longitudinal axis of the outlet **1220**). For example, the stabilization base **1300** and/or base portion **1250** may be at an angle that complements the angle of the catheter **210** extending out of the patient (e.g., between 5-10 degrees).

[0121] Once the device/system **1200** is in place and secured to the patient, it may be located over a portion of the vein in which the catheter **210** is inserted. To help relieve the pressure applied to the patient over the vein (and reduce any distortion of the vein by the device **1200**), some embodiments of the device/system **1200** may include a vein relief zone **1254** within the base portion **1250** (as shown in FIGS. **17**A-**17**C). The vein relief zone **1254** has a recessed surface and is axially aligned with the outlet **1220**. Additionally, the relief zone **1254** may include adhesive (e.g., on the base portion **1250** and/or adhesive **1352** on the stabilization base **1300**) that lifts the patient's skin that is over the vein to further reduce the pressure on the vein.

[0122] To facilitate the flow of fluids in and out of the patient, the device **1200** may have a flow housing **1260** that is connected to the stabilization body **1210** and has a sleeve portion **1270** and a pathway portion **1280** extending from the sleeve portion **1270**. As the name suggests, the pathway portion **1280** may include a flow path **1282** that extends through it and that is fluidly connected to the fluid path **1240** within the stabilization body **1210** to allow fluid to pass through the device **1200**. The inlet **1284** of the flow path **1282** may connect directly to a medical implement used to transfer fluid to and/or from the patient through the device **1200**. Alternatively, the device **1200** may include a tube **1330** that is connected to the inlet **1284** of the flow path **1282** at a first end **1332** and a medical connector (e.g., a female luer connector **1340**), a needle free connector (not shown) or other medical device such as a luer activated valve (not shown) at the second end **1334**.

[0123] As best shown in FIGS. **12**A-**12**D, **13**A-**13**D, and **14**A-**14**D, the flow housing **1260** may be rotatably connected to the stabilization body **1210** such that flow housing **1260** can rotate between a first position (FIGS. **12**A-**12**D), a second position (FIGS. **13**A-**13**D) and a third position (FIGS. **14**A-**14**D). To that end, the inlet body **1214** of the stabilization body **1210** may have a protrusion **1232** extending from a surface of the inlet body **1214**. Conversely, the sleeve portion **1270** may include a recess **1272** into which the protrusion **1232** may snap during assembly of the device **1200**. To allow the flow housing **1260** to rotate with respect to the stabilization body **1210**, the recess **1272** may be substantially larger/longer that the protrusion **1232** such that the protrusion **1232** slides within the recess **1272** during rotation. To further help rotation and prevent leakage between the stabilization body **1210** and the flow housing **1260**, the device **1200** may include an o-ring **1290** between an outer diameter/surface of the stabilization body **1210** and an inner diameter/surface of the flow housing **1260**. The o-ring **1290** may also provide some rotational resistance so that the flow housing **1260** does not accidentally rotate.

[0124] It should be noted that, although the stabilization body **1210** is described above as having a protrusion **1232** and the flow housing **1260** is described as having a recess **1272** to facilitate the rotation of the flow housing **1260** with respect to the stabilization body **1210**, other embodiments may have different configurations. For example, in some embodiments, the stabilization body **1210** may have a recess into which a protrusion extending inward from an inner surface of the flow housing **1260** may snap into and slide within during rotation.

[0125] In a manner similar to that described above, the device **1200** may be used to transfer fluids to and/or from a patient and minimize the stress on the catheter **210** and access site. For example, the user (e.g., the medical personnel) may first connect a medical implement to the female luer connector **1340** (or other needle-free connector) or directly to the inlet **1284** of the flow path **1282** and flush (e.g., prime) the device **1200**, for example, with saline. Once the device **1200** is flushed/primed, the user may insert the catheter **210** into the patient (e.g., into the patient's arm).
[0126] The user may then connect the catheter **210** to the management device **1200**. When attaching the catheter **210** and securing the stabilization device **1200**, the user may grab the stabilization body **1210** and press the device **1200** against the catheter **210**. If so equipped, the user may then screw the ring **1222** of the male luer connector **1212** onto the catheter **210** to secure the device **1200** to the catheter **210**. Once the catheter **210** is attached, the user may then remove the liner **1310** stick the stabilization base **1210** to the patient (e.g., via the securement portion(s) **1302**/**1304**).
[0127] It should be noted that, if the device **1200** has more than one securement portion (e.g., the first securement portion **1302** and second securement portion **1304** discussed above) and each securement portion has its own liner, the user may remove the liner for the first securement portion **1302** first. Once the first securement portion **1302** is adhered to the patient and the user has confirmed that there is adequate flow through the system **1200** (e.g., as described above), the user may remove the liner **1310** for the second securement portion **1304** to further secure the system **1200** to the patient.
[0128] After the vascular access site management system **1200** is secured or at a time preferable to the user, the user may rotate the flow housing **1260** (and the tube **1330** and female luer connector **1340** if equipped) to either the right or the left (e.g., from the upright position shown in FIGS. **12**A-**12**D to the position shown in FIG. **13**A-D or **14**A-D). If needed, the user may then place a dressing over at least the catheter insertion site to maintain the cleanliness of the site. It should be noted that, like the embodiments described above, the user may choose either a left or right configuration based on what is the best configuration for the given application.
[0129] Although the embodiment discussed above has a base portion **1250** that is a split base with two legs **1216**A/B that extend out from the base portion **1250** and toward the flow housing **1260** (e.g., and away from the male luer connector **1211**), other embodiments may have different base configurations. For example, as shown in FIG. **18**, the base portion **1250** may have legs **1810**A/B that extend toward the male luer connector **1211** and away from the flow housing **1260**. Alternatively, some embodiments may have legs that extend in both directions or may only have a single leg (e.g., as opposed to being a split base with more than one leg).
[0130] It is important to note that the embodiments described herein, provide numerous benefits. For example, because the devices may be rotated in either direction, the embodiments described above, allow the user to configure the J-loop to either the left or right side and, in some embodiments, lock it in place. Various embodiments also provide two stage stabilization. During the first stage, the clinician has an important “extra hand” during the venous access procedure and the second stage secures catheter to the body to restrict catheter movement and reduce associated clinical complications, such as phlebitis and infiltration/extravasation. The embodiments described herein also reduce the potential for kinking in the tube, reduces clinical variation, and provide a means for the user to know the location of the catheter tip relative to a datum on the device.
[0131] Although the embodiments described above utilize locking arms (e.g., arms **130**A/**130**) and/or a standard rotating collar/ring (e.g., ring **552**) to secure the catheter **210** to the vascular access site management systems, other embodiments may utilize different structures. For example, as shown in FIGS. **19**A to **19**D, the device may have locking arms **710**A and **710**B within hinges **712**A/B (e.g., living hinges) that allow the arms to flex between an open mode (FIGS. **19**B and **19**D) and a closed mode (FIGS. **19**A and **19**C). One of the arms **710**A may have a protrusion **714** that enters a recess **716** (e.g., formed by two protrusion **718**A/B) on the other arm **710**B when in

the closed mode to secure the catheter **210** (FIG. **19**C).
[0132] FIGS. **20**A-**20**D show a further alternatively locking mechanism for the catheter **210**. Like the locking arms **130**A/B described above, the embodiment shown in FIGS. **20**A-**20**D also has arms **810**A/B extending from the device. However, the arms **810**A/B may be attached to the rest of the device via hinges **812**A/B. The hinges **812**A/B allow the arms **810**A/B to transition between an open mode (FIG. **20**A/**20**C) and a closed mode (FIGS. **20**B and **20**D).
[0133] FIGS. **21**A-**21**D show a further embodiment of a locking mechanism that may be used with the vascular access site management systems described herein. This locking mechanism may include a skirt **910** that can transition between an open mode (FIGS. **21**A and **21**C) and a closed mode (FIGS. **21**B and **21**D). For example, once the catheter **210** is secured to the male luer connector **920**, the skirt **910** may be collapsed to transition it to the closed mode. When in the closed mode, the skirt **910** may surround a portion of the catheter hub **214** to secure the catheter **210** to the device.
[0134] The embodiments of the invention described above are intended to be merely exemplary; numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in any appended claims.

Claims

1. A vascular access site management system for transfer of fluid to and/or from a patient, the vascular access site management system comprising: a stabilization body having a first portion and a base portion, the first portion having (1) an inlet at a proximal end, (2) an outlet at a distal end and configured to be connected to a vascular access device, and (3) an internal fluid path extending between the inlet and outlet, the internal fluid path having a fluid path longitudinal axis, the base portion having a stabilization surface located on an underside of the base portion and configured to stabilize the vascular access site management system when on the patient, the base portion extending from the first portion such that the stabilization surface is oriented at an angle with respect to the fluid path longitudinal axis; and a flow housing enclosing the proximal end of the first portion of the stabilization body and having (1) a sleeve portion having a first longitudinal axis and (2) a pathway portion having a second longitudinal axis and extending from the sleeve portion, the first longitudinal axis not parallel to the second longitudinal axis, the pathway portion having a flow path extending through at least a portion of the pathway portion, the sleeve portion defining a chamber located proximal to the inlet of the first portion of the stabilization body, the chamber having a first opening along the fluid path longitudinal axis and a second opening radially outward from the fluid path longitudinal axis and fluidly connected to the flow path, the flow path, the chamber, and the internal fluid path defining a system fluid path through the vascular access site management system, the sleeve portion rotatably coupled to the stabilization body such that the flow housing is rotatable with respect to the stabilization body and between a first position and at least a second position, an inlet of the pathway portion being a first distance from the stabilization surface when in the first position and a second distance from the stabilization surface when in the second position, the second distance being smaller than the first distance.
2. The vascular access site management system according to claim 1, wherein the stabilization body also has a securement mechanism moveably coupled to the stabilization body such that the securement mechanism secures the stabilization body to the vascular access device inserted into a vasculature of the patient.
3. The vascular access site management system according to claim 1, wherein the distal end of the stabilization body contains a male luer structure.
4. The vascular access site management system according to claim 1, further comprising an o-ring located between at least a portion of the stabilization body and at least a portion of the flow

housing.
5. The vascular access site management system according to claim 1, further comprising a first securement portion located on at least a portion of an underside of the stabilization surface, the first securement portion configured to secure the vascular access site management system to the patient.
6. The vascular access site management system according to claim 5, further comprising a second securement portion located on at least a portion of an underside of the stabilization surface, the second securement portion configured to further secure the vascular access site management system to the patient.
7. The vascular access site management system according to claim 6, wherein the first securement portion includes a first tack adhesive and the second securement portion includes a second tack adhesive, the second tack adhesive being stronger than the first tack adhesive.
8. The vascular access site management system according to claim 7, wherein the first securement portion has a first liner covering the first tack adhesive and configured to be removed prior to securing the vascular access site management system to the patient, the second securement portion has a second liner covering the second tack adhesive and configured to be removed prior to securing the vascular access site management system to the patient.
9. The vascular access site management system according to claim 5, wherein the first securement portion includes at least one gripping and/or conforming structure.
10. The vascular access site management system according to claim 1, wherein the stabilization surface resists rotation of the vascular access site management system on the patient during rotation of the sleeve portion, thereby stabilizing the vascular access site management system on the patient.
11. The vascular access site management system according to claim 1, further comprising a valve mechanism located in the fluid path, the valve mechanism configured to selectively prevent and allow fluid flow through the internal fluid path.
12. The vascular access site management system according to claim 11, wherein the stabilization body includes an inlet body and an outlet body, the valve mechanism positioned between the inlet body and outlet body.
13. The vascular access site management system according to claim 11, wherein the valve mechanism is a two way pressure activated valve.
14. The vascular access site management system according to claim 13, wherein the valve mechanism is configured to deform in the presence of a forward pressure within the internal fluid path, thereby allowing fluid flow around the valve mechanism from the inlet to the outlet.
15. The vascular access site management system according to claim 14, wherein the outlet body includes a plurality of support arms supporting the valve mechanism within the stabilization body, the valve mechanism configured to deform over the support arms in the presence of the forward pressure.
16. The vascular access site management system according to claim 13, wherein the valve mechanism includes a slit extending through the valve mechanism, the slit configured to open in the presence of a back pressure within the internal fluid path, thereby allowing fluid flow through the slit and from the outlet to the inlet.
17. The vascular access site management system according to claim 1, further comprising a tube having a first end and a second end, the first end fluidly connected to the flow path of the pathway portion.
18. The vascular access site management system according to claim 1, wherein an inlet of the flow path within the pathway portion is configured to fluidly connect to a medical implement.
19. The vascular access site management system according to claim 1, wherein the stabilization body includes a conforming structure configured to reduce pressure upon the patient when the vascular access site management system is on the patient.
20. The vascular access site management system according to claim 1, wherein the stabilization body includes at least one protrusion extending from a surface of the stabilization body, the flow

housing having at least one recess and configured to snap over the protrusion such that the protrusion enters the recess, thereby axially securing the flow housing to the stabilization body.