

PERIPHERAL SAFETY CATHETERS AND RELATED METHODS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This is a PCT application of U.S. Provisional Application No. 63/592,493, filed October 23, 2023, and U.S. Provisional Application No. 63/616,410, filed December 29, 2023, the contents of each of which are expressly incorporated herein by reference as if set forth in full.

FIELD OF ART

[0002] The disclosed invention generally relates to needle devices and intravenous (IV) infusion devices, including IV catheters, peripheral catheters, safety catheters, and midline catheters. In particular, IV catheter assemblies with separable stabilizers and optional guidewire dispensers are disclosed.

BACKGROUND

[0003] IV catheters are commonly used for a variety of infusion therapies, including infusing fluids into a patient, withdrawing blood from a patient, or monitoring various parameters of the patient's vascular system. Catheters are typically connected to a catheter adapter that accommodates the attachment of IV tubing to the catheter. Blood control catheters include an internal blood control valve that is opened by the insertion of a male Luer or another object into a proximal end of the catheter adapter. Non-limiting examples of blood control valves are disclosed in United States Patent Application Publication No. 2011/0046570, filed Aug. 20, 2009, titled "Systems and Methods for Providing a Flushable Catheter Assembly." Following placement of the catheter into the vasculature of a patient, an IV fluid source can be connected to the catheter adapter or catheter hub, opening the blood control valve. Thus connected, fluid from the IV source can begin flow into a patient through the catheter.

[0004] As is well known in the art, typical blood pressure is 10 to 20 centimeters of water. Infusion bags are usually placed about 100 cm above the patient's heart to direct flow into the patient. At roughly that height, the pressure exerted by the fluid from the infusion bag is much greater than the blood pressure of the patient and therefore can flow into the patient.

[0005] For patients with difficult to access veins, extended dwell catheters can be used to aid in Difficult Intravenous Access (DIVA). An extended dwell catheter is a midline catheter that may be considered a peripherally inserted catheter. The recommended insertion site for the midline catheter is in the upper arm with the tip located just below the axilla. For DIVA patients, a physician can use visualization equipment to aid in identification of deep veins for catheter access. In that case, an extended dwell catheter will provide a longer length and a more flexible catheter for insertion into the patient. With the addition of a guidewire, this can help to reduce the chances of the catheter becoming kinked.

SUMMARY

[0006] Aspects of the invention include a catheter system. The catheter system can comprise: a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip extending distally of an opening of the catheter tube; a stabilizer comprising a frame having a body comprising a seat and a gate having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and a second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame; wherein the needle hub is located in the seat and a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and wherein the first deck gate section and the second deck gate section are held together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are held together by a detent or a control sheet having an adhesive layer attached to both the first gate deck and the second gate deck.

[0007] The first deck gate section and the second deck gate section can have a wedge end at a proximal end with a V-shape contour, said V-shape contour can be sized and shaped to be pushed by a distal end of the catheter hub.

[0008] The control sheet can comprise a perforation line. The perforation line can be straight. The perforation line can embody solid line sections and cut sections of the control sheet along the perforation line. The control sheet can have an adhesive layer for adhesively attaching to the stabilizer.

[0009] The perforation line can align with the seam of the frame.

[0010] The first deck gate section can attach to a first base portion and the first base portion can be pivotably attached to the frame. The pivotable connection can be a living hinge. The pivotable connection can alternatively be around a pin having an axis. The pin can project into a divot or into a bore so that the first deck gate section can rotate about the pin.

[0011] The second deck gate section can attach to a second base portion and the second base portion can pivotably attach to the frame. The pivotable connection can be a living hinge. The pivotable connection can alternatively be around a pin having an axis. The pin can project into a divot or into a bore so that the second deck gate section can rotate about the pin.

[0012] A spring having a first spring leg biased against the first base portion and a second spring leg biased against the second base portion can be incorporated with the pin. The spring can be a torsion spring having two spring legs.

[0013] A needle guard can be located in an interior cavity of the catheter hub. The needle guard can have two arms. The needle guard can be made from a stamped metal material. The needle guard can be made from a single body structure.

[0014] The catheter assembly can further comprise a valve and a valve opener located in the interior cavity of the catheter hub. The valve opener can comprise two plunger elements that have a gap. A needle guard can be located in the gap. In some examples, two stabilizing bridges can be provided with the plunger elements to define a continuous body section of the valve opener in the radial direction. The continuous body can be located proximally of the nose section.

[0015] The body of the stabilizer can have a generally triangular shape along a side view.

[0016] The body of the stabilizer can have a first edge, a second edge angled to the first edge, and a far edge angled to both the first and second edges.

[0017] The body can have an apex located between the first edge and the far edge. The catheter system can rock or pivot about the apex.

[0018] An adapter can project into the opening on the rear wall of the seat and into the proximal opening of the needle hub of the catheter assembly. A guidewire can pass through the adapter and into the needle hub. The guidewire can extend through the needle lumen and out the opening at the needle tip.

[0019] A guidewire dispenser can project into the opening on the rear wall of the seat and the proximal opening of the needle hub, and a guidewire can extend out a tip of the guidewire dispenser

and extend through the needle hub and into the lumen of the needle. Because a catheter tube can be located over the needle, the guidewire also extends through the lumen of the catheter tube.

[0020] The seat of the stabilizer can comprise a first sidewall and a second side wall, and wherein a first arm extends from the first sidewall and a second arm extends from a second side wall.

[0021] The first sidewall of the seat can have a height and the first arm has a length and a height that is orthogonal the length, and wherein the height of the first sidewall can be greater or larger than the height of the first arm.

[0022] The first sidewall of the seat can have an upper edge and a plurality of spaced apart tines extending from the upper edge of the first sidewall.

[0023] The first sidewall of the seat can have a lower edge and a ledge extending from the lower edge.

[0024] The second sidewall of the seat can have an upper edge and a plurality of spaced apart tines extending from the upper edge of the second sidewall.

[0025] A gap can be provided between the plurality of tines extending from the upper edge of the first sidewall and the plurality of tines extending from the upper edge of the second sidewall.

[0026] The first deck gate section of the stabilizer can be located at a distal end of the first arm and the second deck gate section can be located at a distal end of the second arm.

[0027] The control sheet can adhere to a planar surface on the first deck gate section and a planar surface on the second deck gate section.

[0028] The control sheet can be located distally of an undulating surface on the first deck gate section and an undulating surface on the second deck gate section.

[0029] A half cylindrical nose section can extend distally of a distal gate surface of the first deck gate section and a half cylindrical nose section can extend distally of a distal gate surface of the second deck gate section.

[0030] The two half cylindrical nose sections can define a nose section having a bore and the catheter tube and needle can extend through the bore.

[0031] A film hinge can be located between the first sidewall and the first arm, and a second film hinge can be located between the second sidewall and the second arm.

[0032] The two arms of the stabilizer can be pivotable outwardly in a relaxed state and pivotable inwardly in a flexed state.

[0033] The spring can be a torsion spring having a plurality of coils, and wherein the plurality of coils can be mounted around a body of a mounting platform.

[0034] The mounting platform can be located at a distal end of the stabilizer. The mounting platform can have an enlarged head and a base, and wherein the enlarged head can be located proximally of the base. Alternatively, the enlarged head can be located distally of the base.

[0035] The torsion spring can be mounted by sliding the coils over the enlarged head towards the base.

[0036] Aspects of the invention further include a method of making a catheter system. The method can comprise: forming a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip extending distally of an opening of the catheter tube; forming a stabilizer comprising a frame having a body comprising a seat and a gate having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and a second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame; placing the needle hub in the seat such that a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and securing the first deck gate section and the second deck gate section together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are secured together by a detent or a control sheet having an adhesive layer attached to both the first gate deck and the second gate deck.

[0037] The control sheet can have a perforation line and wherein the perforation line can align with the seam of the stabilizer.

[0038] In an alternative example, the two deck gate sections of the deck gate are held together by reversible detents or latches instead of or in addition to using the control sheet.

[0039] A further aspect of the invention includes a method of using a catheter system. The method can comprise: unpacking the catheter system from an outer packaging, wherein the catheter system comprises: a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip extending distally of an opening of the catheter tube; a stabilizer comprising a frame having a body comprising a seat and a gate having a first deck gate section and a second deck gate section joined

together to define a passage along a seam, the first deck gate section and a second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame; wherein the needle hub is located in the seat and a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and wherein the first deck gate section and the second deck gate section are held together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are held together by a detent or a control sheet having an adhesive layer attached to both the first gate deck and the second gate deck; advancing the catheter hub relative to the needle hub so that the catheter hub abuts an actuating gate at a proximal end of the first and second gate decks.

[0040] In an example, a catheter system comprising a catheter assembly mounted to a stabilizer in accordance with aspects of the invention is disclosed. The catheter assembly comprises a catheter unit and a needle unit. In an example, the catheter unit comprises a catheter hub and a catheter tube extending from the catheter hub. The needle unit comprises a needle hub having a needle attached thereto and the needle extending in a distal direction through the catheter hub and through the lumen of the catheter tube with the needle tip projecting distally of the distal opening of the catheter tube in a ready to use position shown. A vent plug is attached to the open proximal end of the needle hub. A removable protective sleeve or cap is positioned over the catheter tube and needle, which is to be removed prior to using the catheter system for vascular access.

[0041] The stabilizer has a body with a seat, a frame extending from the seat, and a gate unit extending from the frame. The seat provides a support surface for supporting or accommodating the needle hub. In an example, the seat comprises a plurality of wall surfaces, including two sidewall surfaces and a bottom wall surface defining a cavity for receiving the needle hub. The two sidewall surfaces can limit the needle hub from lateral movement but not axial movement, relative to the lengthwise axis of the frame. However, the needle hub is preferably fixed relative to the seat during vascular access and only the catheter hub axially advances to place the catheter tube in the vasculature. For example, the needle hub can be frictionally engaged by the seat to prevent axial movement relative to the seat. In other examples, the seat can have internal baffles or ribs that grip or engage surface features of the needle hub to prevent axial movement of the needle hub relative to the seat.

[0042] The frame can extend distally of the distal end of the seat. In an example, the frame is attached to the bottom wall surface and extends in the distal direction. In an example, the frame has a body of varying cross-sections along the lengthwise direction. The body can have a generally triangular shape along a side view. For example, the body can have a first edge, a second edge angled to the first edge, and a far edge or third edge angled to both the first and second edges. The edges define a grip-able or holding surface, or surfaces when considering the two opposing sides of the body, for gripping by a practitioner for performing a venipuncture or procedure.

[0043] In an embodiment, the grip-able or holding surface at or near the low point can be recessed to facilitate gripping. The recessed surfaces, on both sides of the body, allow fingers to be placed thereon or therein. The recessed surfaces can be contoured to receive the contoured tips of the fingers. Additionally, one or more surface features can be incorporated in the recessed surfaces.

[0044] The surface features can be projections, dimples, or combinations thereof. In a particular example, the surface features are projections with each having a diamond shape and a length. The lengths of the diamond shaped surface features can be aligned relative to one another and angled like the third edge.

[0045] In an example, the low point or lower edge of the body resembles an apex along a side view. The low point can be located between the first edge and the third edge. Elevation-wise, the low point can be lower than the first edge and the second edge. The low point allows the frame to rock or pivot about the low point to change the angle of the needle for venipuncture. Thus, in an example, the low point represents the lowest, elevation-wise, point of the frame. The low point connects the first edge and the third or far edge of the frame.

[0046] In an example, when the needle is located horizontally, a line drawn through the low point and normal to the horizontal needle creates two angles relative to the normal line with the first edge and the third edge. The two angles can be equal. In other examples, the angle between the normal line and the first edge is larger than the angle between the normal line and the third or far edge. The angle between the normal line and the third edge allows the frame to rock or tilt forward, in the distal direction, to provide the practitioner with flexibility on finding the most optimum angle for venipuncture.

[0047] If the bottom wall surface of the seat defines a plane, the second edge of the frame can have a bend so that part of the second edge extends radially inwardly across the plane to be closer

to the axis defined by the needle. The bend causes the second edge to move closer to the catheter hub and the catheter tube while the proximal end of the second edge, at the beginning of the incline of the bend, is situated further away in the radial direction than the axis defined by the needle.

[0048] In an example, the catheter hub can slide along the surface of the second edge to advance the catheter tube over the needle for placement in the vasculature. In other examples, the second edge is spaced from the bottom of the catheter hub, but the catheter hub can slide axially against the edge if the needle flexes and the exterior of the catheter hub touches the second edge.

[0049] The gate unit extends at an angle to the second edge. In an example, the second edge has a second bend, and the gate unit extends from a location distal of the second bend. The gate unit can comprise a first gate unit section and a second gate unit section. The gate unit can further comprise a base portion and deck gate. The gate unit is configured, such as being sized and shaped, to split to allow the catheter unit to separate from the needle unit for placement of the catheter tube in the vasculature. That is, the gate unit can split into a first gate unit section and a second gate unit section.

[0050] In an example, the frame has a thickness or depth defined by two opposing surfaces. The base portion of the gate unit has a first base section and a second base section, with each base section attached to the frame via a living hinge. Thus, the two base sections can pivot together or towards one another or away from one another via the two living hinges. In alternative examples, the two base sections can pivot together or towards one another or away from one another via a respective pivot pin, or more than one pivot pins or pin sections aligned along a common rotating axis. In an example, hinge barrels may be incorporated at a shoulder of the body when pivot pins are employed to pivot the respective base sections. Thus, the first gate unit section can have a first base section and the second gate unit section can have a second base section.

[0051] The deck gate can have a first deck gate section and a second deck gate section, each attached to a respective base section. The two deck gate sections can meet along a seam in the ready to use position and separate from one another when pushed from a proximal end by an advancing catheter hub. That is, in the ready to use position, the two deck gate sections can be spaced from one another by a first distance and in the activated position, the two gate sections are spaced from one another a second distance. The second distance being greater than the first distance. The first distance can be zero or a condition in which the two gate sections contact. In other examples, the second distance can be greater than the first distance by at least 3 cm.

[0052] Prior to being separated by the catheter hub, such as when in the ready to use position, the two deck gate sections come closer together or contact to define a passage for the needle and the catheter tube. In an example, the passage defined by the two deck gate sections provide support for the needle and catheter tube as the needle and the catheter tube are advanced during venipuncture. For example, as the needle and catheter tube are advanced, they can be supported by the passage formed by the two deck gate sections. The passage can be provided at a location spaced from the catheter hub and spaced from the needle hub to stabilize the needle and the catheter tube at a location spaced from the catheter hub and the needle hub. In an example, the passage formed by the two deck gate sections has a bore that is larger than the outer diameter of the catheter tube such that the catheter tube and needle can slide through the passage without touching the interior surface of the passage. However, if the catheter tube and the needle flex during the advancement through the passage, some touching with the interior of the passage may be inevitable.

[0053] In an example, the passage defined by the two deck gate sections, which has a length, can stabilize a catheter assembly with extended needle and catheter lengths, in the order of about 7.5 cm to 20 cm. Such a relatively longer catheter and needle are typically found with midline catheters. However, catheter assemblies, usable with the disclosed stabilizers of the present invention are not so limited and may in some instances embody shorter catheters and needles, typically found in peripheral access catheters, or longer catheters. By using the disclosed stabilizers with the catheter system, catheterization with long catheters, up to 100 mm or 10 cm, in length may be used without a guidewire. However, a guidewire may be used to guide the catheter tube as the latter advances into the vein, such as when using a relatively longer catheter in the order of about 100 mm or longer. Optionally, one or more surface features, such as projections, dimples, or combinations thereof, may be provided at the surfaces of the seat and/or the surface of the frame for gripping and aesthetics.

[0054] A catheter system has a flange with a first flange section and a second flange section, which join to form a generally square shape flange having a distal surface for limiting proximal travel of the protective sleeve. The flange can have a split or a seam aligned with the seam of the deck gate. In an example, a control sheet having an adhesive backing is adhered to the deck gate and over the seam. The control sheet is configured to control the separation, such as the resistance of the separation, of the two deck gate sections along the seam when pushed open by the catheter

hub. For example, the control sheet can be selected with a known tear strength so that when the catheter hub is advanced against the two deck gate sections with sufficient pressure, the control sheet will only tear to allow the two deck gate sections to separate along the seam if the distally directed force of the catheter hub exceeds a certain minimal force. The minimal force may be selected to guard against early or inadvertent activation. However, the minimal force should not require more distally directed force than normally required for purposefully advancing the catheter hub during a medical procedure.

[0055] In some examples, the control sheet may be provided with perforation line comprising a plurality of perforated slits or perforations. The perforations reduce the tear strength of the control sheet thereby allowing the control sheet to tear at a lower force compared to a control sheet without any perforations or with fewer perforations.

[0056] The perforations can vary in length and numbers. For example, the longer the perforations and the shorter the solid sections between the perforations, the easier it is for the control sheet to tear along the perforations. Conversely, the shorter the perforations or slits and the longer the solid sections between the perforations, the harder it is for the control sheet to tear along the perforations. Additionally, the paper stock or substrate and the thickness used to form the control sheet also contribute to the tear strength of the control sheet. In an example, the paper stock can be plastic-coated paper, which can be a coated or laminated composite material made of paper or paperboard with a plastic layer or treatment on a surface. In another example, the control sheet is made from a polymer-based film. For example, the control sheet can be made from a polypropylene film. In an embodiment, the perforations and substrate can be selected to readily split upon normal advancement of the catheter hub against the proximal end of the deck gate, which produces a pair of component forces that include a radially directed force to separate the perforations, as further discussed below.

[0057] In an example, the control sheet has edges that form a generally rectangular shape with rounded corners. In an example, two indented perimeter sections or indentations can be provided to decrease the dimension at the mid-section of the control sheet. The two indented perimeter sections together with the perforation line define two wings that are symmetrical about the perforation line. The two indentations can be provided to facilitate placement of the control sheet onto the stabilizer and align the seam with the perforation line. The length of each slit within the perforation line and the length of each solid or non-slit section between two adjacent slits

contribute to the tear strength of the control sheet along the perforation line. Additionally, the thickness of the control sheet and the type of material used can contribute to the tear strength of the control sheet. In some examples, the indentations can be omitted and the overall length of the perforation line at the mid-section can be lengthened to control the tear strength.

[0058] Each of the two deck gate sections has a body with a wedge end or wedge section and an inner surface. Thus, the two wedge ends of the two deck gate sections have sections along respective inner surfaces that do not contact due to the curved or inclined surfaces at the wedge ends. In an example, the two wedge ends of the two deck gate sections form an actuating gate that has a generally V-shape contour. The actuating gate has an end gap at the proximal end-most location and wherein the actuating gate converges as it extends in the distal direction to a narrowest point, wherein the two inner surfaces of the two bodies contact or where only a small gap exists, as is the nature of the generally V-shape contour.

[0059] The end gap of the actuating gate can be larger than a width of the nose end of the catheter hub. Thus, following entry of the needle tip into a vein and then advancing the catheter tube over the needle into the vein for vascular access by pushing on the push tab of the catheter hub, the nose end of the catheter hub can enter the actuating gate where further distal advancement of the catheter hub will cause the nose end of the catheter hub to push against the two wedge ends to cause the two deck gate sections to separate. Once the two deck gate sections separate, by first separating the control sheet at the perforation line or by overcoming a detent that holds the two deck gate sections together, the catheter hub can further distally advance while the stabilizer and needle unit retract in the proximal direction to separate the catheter hub from the needle unit so that the catheter hub and catheter tube remain with the patient while the stabilizer and needle unit are removed, as further discussed below.

[0060] In an example, a stabilizer in accordance with aspects of the invention has a seat that comprises two sidewalls, a rear wall, and a bottom wall. The rear wall connects to the two sidewalls and to the bottom wall. The rear wall has a proximally facing surface and a distally facing surface located radially inwardly of the two sidewalls. That is, the rear wall has a rear wall surface that is more than just end surfaces of the two sidewalls. However, in some examples, the rear wall can be omitted, and internal ribs or tabs can be provided with the two sidewalls and/or the bottom wall to retain the needle hub within the seat. An opening can be provided through the

rear wall. The opening can be provided to accommodate a vent plug in the ready to use position and optionally to accommodate a guidewire dispenser after removal of the vent plug.

[0061] The distance or gap between the two sidewalls of the seat defines a width or depth that is wider or larger than thickness of the frame. In an example, a transition section is provided in which tabs or wall sections are provided to transition between the two sidewalls and the frame due to the difference in dimension. In other examples, the connection is abrupt, similar to a “T” connection in which the narrower frame terminates at the edge of the base, between the two sidewalls.

[0062] The gate can be connected to the distal end of the frame, opposite the seat. In particular, each of the two base sections is attached to the frame via respective living hinge. A living hinge is understood to mean a thin flexible connection made of the same material as the material used to form the frame and the gate, such as being unitarily formed with the frame and the gate. The living hinge allows the two gate sections to pivot about the living hinge, typically over multiple cycles, without breaking. In other examples, the frame can be provided with sockets and the two base sections can be provided with corresponding pins or projections to form two pivotable hinges, which rotate about the pins.

[0063] Each of the two deck gate sections can have a wedge end and an inner surface comprising an elongated groove, which together with the groove of the other deck gate defines a passage for accommodating and supporting the catheter tube and needle of the catheter assembly. Each elongated groove can have sections with varying groove contours. Just distal of the wedge section, each elongated groove has a large groove section that is followed distally by a narrower groove section. The narrower groove section can be constant, such as having a constant partial cylinder, along the length thereof to the distal end. The large groove section immediately distal of the wedge section can have a taper in the radial direction relative to a plane defined by the inner surface, which is less or smaller than the taper of the wedge section. This large groove section allows the distal end of the catheter hub to continue to generate a pair of component forces against the tapered surfaces of the large groove section to separate the two deck gate sections as the catheter hub travels distally during venipuncture.

[0064] In an example, the head section of the stabilizer has a shoulder comprising a hinge barrel or knuckle for receiving a corresponding pin to pivotably secure the first base section to the frame, for a pivotable hinge embodiment instead of a living hinge embodiment. In an example,

the pin can be separate from the first base section and can project through a bore at an end edge of the shoulder, similar to a door hinge, to secure the hinge barrel or knuckle of the shoulder and the first base section. In other examples, the hinge barrel on the shoulder can comprise divots to receive corresponding pin projections integrally formed with the first base section. In still other examples, the positions of the divots on the shoulder and positions of the projections on the first base section can reverse.

[0065] In an example, the head section can include a mounting platform having a body for mounting a biasing member. In an example, the biasing member is a torsion spring comprising a plurality of coils having a coiled internal diameter and two spring legs. The body of the mounting platform can be a cylinder having an outside diameter that is sized and shaped to project into the coiled internal diameter to hold the biasing member in position to bias the two gate sections of the gate outwardly.

[0066] In an example, one of the two spring legs is pressed against the inner surface of the second base section to bias the second base section outwardly away from the lengthwise axis of the frame. The other spring leg of the torsion spring similarly presses against the inner surface of the first base section to bias the first base section outwardly away from the lengthwise axis of the frame. In the configuration described, when the catheter hub advances distally to generate a pair of component forces against the wedge section of the frame to separate the control sheet, the torsion spring can assist with fully separating the two gate sections of the gate to ensure a wide open passage for the catheter hub to separate from the needle unit. The torsion spring also keeps the two gate sections apart.

[0067] In an example, the mounting platform of the frame comprises a socket having a receiving pocket. The mounting platform further comprises a mounting plug having an elongated body and an enlarged head. To mount the torsion spring to the mounting platform, the elongated body can project into the coiled inside diameter and the enlarged head, which has an outside diameter that is larger than the coil inside diameter, retains the torsion spring from displacing off the elongated body in the direction of the enlarged head. The elongated body can then project into the pocket of the socket to position the torsion spring on the frame.

[0068] Detents, interference, and/or adhesive may be used to more permanently secure the mounting plug to the socket. Thus, the mounting platform can have two enlarged ends, represented by the socket and the enlarged head, located at two ends of a smaller diameter elongated body.

The torsion spring can be located on the elongated body with the two spring legs arranged to bias the two gate sections away from one another.

[0069] An alternative stabilizer comprises a frame comprising a mounting platform for accommodating a biasing member and a gate unit, which has a first gate unit section and a second gate unit section. In an embodiment, a mounting plug having a body with an enlarged end can be oriented in the distal direction. Thus, the biasing member can be mounted onto the mounting platform from the distal direction towards the proximal direction. As shown, the coils of the biasing member, which can be a torsion spring, can be positioned on the receiving pocket of the mounting platform and held there by the enlarged head and the base of the mounting platform. The enlarged head is located further distally than the base.

[0070] In an example, the two gate unit sections are pivotable about the frame via respective pivot pins or hinge joints. Further, each hinge joint can be provided with one or more physical stops, such as projections and interference features for limiting the amount that the two gate unit sections can pivot open in the activated position. Locations of the projections can be selected to control how far the two gate unit sections can open and operate and function as hard stops for the two gate unit sections. For example, physical stops can be incorporated at the hinge joints to limit the two gate unit sections from opening beyond a horizontal plane defined by the top surface of the body. In some examples, the physical stops can be selected to permit the two gate unit sections to open beyond the horizontal plane or less than the horizontal plane.

[0071] The two spring legs of the biasing member can be arranged to bias against respective base sections of the two gate unit sections. In an example, the two spring legs can be angled to exert outward spring forces when the stabilizer is in the activated position. That is, in the position, the angled spring legs can bias the two gate unit sections from coming back together as in the ready to use position. The two spring legs can be generally aligned along a straight line (solid lines) or the two spring legs can be angled relative to one another (dashed lines). The angle between the two spring legs can be adjusted to control the amount of torsion spring deflection or biasing forces on the two gate unit sections when in the activated position, to ensure that they remain spaced apart and held apart by a spring bias.

[0072] Numerous catheter assemblies are usable with stabilizers in accordance with aspects of the present invention. Optionally, a guide wire may be incorporated to assist in inserting, positioning, and moving a catheter.

[0073] In an example, a catheter assembly comprises a first hub or catheter hub having an over-the-needle tube or catheter tube attached thereto and a second hub or needle hub having a needle attached thereto. The catheter tube has a lumen or bore for receiving the needle and has a distal opening or distal end opening and the needle tip of the needle extends distally of the distal opening in a ready to use position, in which the assembly is ready for venipuncture. The catheter assembly can also be called a needle assembly.

[0074] The needle can include a change in profile located proximally of the needle tip for use with a needle guard. The needle tip can extend distally of the distal end opening of the catheter tube or tubing in the ready to use position with the change in profile, if incorporated for use with a needle guard, located proximally of the distal end opening. The change in profile can be a crimp, a bump, or a material build-up having different profile than other diameter sections of the needle shaft. As used herein, the term proximal is understood to mean an end or side closer to the practitioner and the term distal is the opposite end or side.

[0075] The change in profile can be used to interact with a needle guard during retraction of the needle following successful venipuncture. A vent plug can be disposed at the proximal open end of the second hub or needle hub. The vent can have a vent filter at a proximal end thereof. The catheter tube can be attached to the first hub or catheter hub by a ferrule or bushing.

[0076] The needle guard can be provided in the interior cavity of the first hub or catheter hub for covering the needle tip in the protective position, where the needle is retracted away from the catheter tube and the needle hub and is covered by the needle guard. When incorporated, the needle guard can be one of the needle guards disclosed in US Patent No. 6,616,630, the contents of which are expressly incorporated herein by reference. In some examples, the needle guard can be omitted. If so, the change in profile on the needle can also be omitted. In still other examples, a needle guard can be included without also including a change in profile on the needle. In yet other examples, the needle guard can be located in a third housing between the first hub and the second hub. An exemplary needle guard located in a third housing is disclosed in US Pat. No. 8,597,249, the contents of which are expressly incorporated herein by reference. In still other examples, the needle guard can include multiple arms or fingers extending in both a first direction and an opposite second direction as disclosed in US Pat. No. 9,387,307, the contents of which are expressly incorporated herein by reference. For example, the needle guard can include a first protector body surrounded by a second protector body.

[0077] In an example, the needle guard can be made from a metal material and can have a resilient portion that can generate a biasing force. For example, the needle guard can be shaped from a stamped metal sheet. The needle guard can comprise a wall surface that is positioned to a side of the needle and is movable distal of the needle tip to guard the needle tip from accidental contact therewith. The wall surface can be a needle trap and can move directly in front or distal of the point of the needle tip. The wall surface can be located at the distal end of a needle guard arm.

[0078] In an example, the needle guard can include a proximal wall and two arms extending distally of the proximal wall. The two arms can intersect one another in the ready to use position when viewed from a side view. In some examples, the two arms of the needle guard can extend in a distal direction without intersecting one another. Two distal walls, one on each arm, can be incorporated to block the needle tip. The two distal walls can be biased outwardly by the needle in the ready to use position and disposed distally of an internal change in profile inside the first hub or catheter hub in the ready to use position.

[0079] The internal change in profile can be a reduced diameter section located next to an inside diameter section of a larger dimension. The elbows on the two arms of the needle guard can have a dimension that is larger than the inside diameter at the internal change in profile of the catheter hub to restrict proximal movement of the needle guard from the catheter hub until the two arms are no longer biased outwardly or until the dimension at the two elbows are reduced.

[0080] Each distal wall of each arm can include a curved lip to facilitate relative movement between the needle guard and the needle. When in the ready to use position, the dimension measured between the two joints or elbows of the two arms, at the intersection between each arm and its respective distal wall, is larger than the inside diameter of the internal change in profile, which prevents the needle guard from moving proximally thereof due to the relative dimensions.

[0081] Once the needle tip moves proximally of the two distal walls, and the two arms no longer biased by the needle, the two arms are allowed to move radially inward and one or both distal walls close over the needle tip to block the needle tip in a protective position. At this point, the dimension between the two joints or elbows decreases and is smaller than the internal dimension of the internal change in profile, which then allows the needle guard to move proximally and be removed from the catheter hub with the needle. In alternative embodiments, the dimension between the two joints can be equal to or slightly larger than the internal dimension of the internal

change in profile and the needle can still move proximally by flexing or squeezing the two joints to get through the internal change in profile.

[0082] The first hub or catheter hub can have a body with a proximal opening having a nose section of the second hub or needle hub disposed therein. The proximal opening of the first hub has a female Luer for receiving a male Luer tip, such as a syringe, an IV tubing connector, a Luer extension set, etc. External threads can be provided on the exterior surface at the proximal end for threaded engagement with a threaded collar of a male threaded Luer tip. A pair of stabilizing wings can extend radially of the first hub to facilitate securement or anchoring of the first hub to a patient following successful venipuncture. Optionally the wings can be omitted. The first hub can embody a standard IV catheter hub without an injection port. In other examples, the first hub can include an injection port, or an integrated extension set. If the wings are not present on the first hub or catheter hub, then the bottom of the first hub can have a flattened surface angled at between 2 to 15 degrees from the through axis of the first hub.

[0083] The first hub or catheter hub can be removably secured to the second hub by receiving the nose section of the second hub into the proximal opening of the first hub. A flange or extension can be provided on the second hub and together with the nose section define a gap having part of the first hub located therein. Optionally the flange or extension can be omitted, and a stub or other surface mating features provided. The stub can be the male part of a key fitting in a gap through or partially into the Luer threads to prohibit rotation of the second hub relative to the first hub. The proximal facing end surface of the first hub abuts the distally facing surface of the step in the outside surface of the second hub which is at the proximal end of the nose section, which is inside the first hub. This abutment can set the amount of projection of the needle tip out of the catheter tubing. The stub can be an optional structural feature.

[0084] The second hub or needle hub has a body having an interior cavity having the proximal end of the needle projecting there-into. The interior cavity can function as a primary blood flashback chamber. The proximal opening of the body can have a female Luer for receiving the vent plug or a syringe tip therein and the exterior can have threads or be without threads. In an example, the exterior of the body of the second hub is generally cylindrical and without threads. The first and second hubs can be made from plastic materials, such as by plastic injection.

[0085] A push tab can be provided with the body of the first hub or catheter hub. The push tab can be located on an exterior surface of the first hub at a location distal of the exterior threads

so as to avoid interfering with the exterior threads. For example, the push tab should be positioned sufficiently distally of the exterior threads so that when a threaded male connector, such as a syringe type with a threaded collar, is connected to the threads of the first hub, the push tab does not interfere with the connection. In some examples, the push tab should be positioned sufficiently distally of the exterior threads so that when the push tab is folded over, the push tab does not interfere with the connection.

[0086] In an example, a catheter assembly incorporates a valve and a valve opener. For example, a valve and a valve opener can both be located within the interior of the catheter hub. After removal of the needle, such as following successful venipuncture, the valve can stop or limit fluid flow across the surface of the valve. In use, such as to form a fluid path through the valve, the valve opener can be pushed distally into the valve to open the one or more slits formed with the valve and therefore open two or more valve flaps to open a fluid passage through the valve for fluid flow. An exemplary valved catheter assembly with a valve opener is disclosed in U.S. Patent No. 8,333,735, the contents of which are expressly incorporated herein by reference.

[0087] The valve opener can have a nose section having a bore and a plunger section located proximally of the nose section. The nose section can be pushed into the valve to open the one or more slits of the valve, such as three slits defining three flaps. The plunger section can comprise two or more plunger components having a gap therebetween. The gap accommodates the needle guard therebetween and can allow fluid to flow through the plunger components and through the bore in the nose section. In an example, two bridges are provided with each bridge connecting to corresponding edges of the two plunger components of the plunger section. The two bridges and the two plunger components or elements therefore form a continuous section in the radial direction. The continuous section is proximal of the nose section of the valve opener and spaced from the nose section.

[0088] In an example, a needle unit comprising a needle hub having a needle with a needle tip is shown with an adaptor and a guidewire dispenser. The needle unit, adaptor, and guidewire dispenser may be used with the catheter unit and stabilizer shown herein, such as when the catheter length of the catheter assembly is in the order of about 100 mm, or even longer. However, if the stabilizer can sufficiently support the catheter, then the guidewire dispenser may be omitted.

[0089] The combination with a needle, needle hub, adaptor, and guidewire dispenser may be referred to as a piercing and guiding unit, or PG unit. A PG unit may be used with a catheter

assembly in which the catheter tube and needle have a relatively longer length, in the order of about 6.0 cm to 20 cm, more typically between about 10 cm to about 20 cm. Such relatively longer catheters and needles are typically found with midline catheters. However, the PG unit in accordance with aspects of the present invention is not so limited to the indicated catheter lengths and may in some instances be used with shorter catheters and needles, typically found in peripheral access catheters. Typically following successful venipuncture, the entire PG unit is removed together as a single unit. Where necessary, components of the PG unit can be removed from the catheter hub via piecemeal, starting first with the dispenser, then the adaptor, then the needle hub with the needle, or combinations thereof. Preferably, the PG unit is removed together as a unit instead of piecemeal.

[0090] In an example, the PG unit does not utilize a vent plug, which has been removed from the needle hub prior to coupling the dispenser to the needle hub via the adaptor. In some examples, the adaptor may be omitted, and the dispenser is coupled directly to the needle hub. A user can first grasp the catheter assembly with the PG unit and guide the tip of the needle through the skin at a suitable insertion site to access a vein. Confirmation of proper vasculature access can be confirmed via primary blood flashback, i.e., the presence of blood in the needle hub and/or in the adaptor. The user can then retract the needle tip proximally of the catheter tube opening to observe secondary blood flash back, i.e., the presence of blood between the outer diameter of the needle and the inner diameter of the catheter tube. In some instances, the needle can have a through notch formed through the wall of the needle shaft, near the needle tip, or a lengthwise groove by forming a depression lengthwise along the needle shaft. These alternatives allow flashback to be observed between the interior of the catheter tube and the exterior of the needle shaft and can be detected relatively quicker than blood flashback at the needle hub.

[0091] After successful venipuncture is confirmed, the dispenser is activated by applying digital pressure on the guidewire at the advancing or advancement platform of the dispenser and then sliding or feeding the guidewire distally. The guidewire, such as the tip of the guidewire, may initially be disposed within the hollow needle, may be only initially disposed in the adaptor, or may be only initially deposited in the catheter hub. In some examples, the guidewire has a length with at least two distinct guidewire sections. For example, the guidewire can have a distal guidewire section of a first diameter and a proximal guidewire section of a second diameter, which can be larger than the first diameter. The first and second diameters can be understood as outside

diameters. A shoulder or a gradual taper can locate between the first and second guidewire sections, which may be used to delimit distal advancement of the guidewire when abutting the shoulder or gradual taper with a structure of the catheter assembly.

[0092] Distal guidewire advancement continues until the guidewire has been extended an appropriate amount within the vessel of the patient. In an example, the amount of extension of the guidewire into the vessel may be controlled by fixing the overall length of the guidewire that can extend at the advancement platform. For example, the guidewire may have two ends, a first end at the distal end extending through the length of the frame of the dispenser and a second end at the proximal end of the guidewire, at least partly coiled within the holding duct or tube, which has a hollow interior and two open ends that connect to the frame or body of the dispenser. The length of the guidewire can be selected so that when the second end of the guidewire is moved to the advancement platform of the body, it marks the full extended position of the guidewire. The user can then stop further advancement of the guidewire at that point. Optionally a physical stop or an indicator may be provided so that when the guidewire is advanced, the stop or the marker indicates how far the first end of the guidewire has extended distally beyond the needle tip. Of course, the user does not have to fully extend the guidewire when using the catheter assembly with the PG unit of the present invention.

[0093] In some examples, the relative lengths of the first and second guidewire sections can be selected to ensure appropriate dispensing of the first guidewire section out of the needle tip, such as to support the catheter tube during catheter insertion. In an example, as the guidewire is dispensed and the first diameter section of the guidewire exits the distal tip opening, the shoulder, the gradual taper, or the second diameter of the guidewire can engage the needle at the crimp to stop distal advancement of the guidewire. A guidewire dispense length is defined from the point where the guidewire engages the crimp to the remote distal end of the guidewire. The guidewire dispense length can be selected to properly support the catheter tube during catheter insertion into the vein. In an example, the length of the guidewire from the far distal end to where the guidewire exits the needle tip, referred to as the support length, is approximately 50% of the length of the catheter tube. In an example, the support length is greater than 50% of the catheter length.

[0094] The catheter tube can now further be inserted into the vessel and be guided by the guidewire. As the catheter tube and the catheter hub move distally forward and the catheter tube guided by the guidewire into the vessel, the catheter hub separates, or further separates, from the

needle hub. As discussed above, the catheter hub pushes the gate to separate the first gate unit section and the second gate unit section to separate from the stabilizer. The catheter tube and catheter hub can be advanced a sufficient amount over the guidewire to ensure successful placement within the vessel. The PG unit can then be removed or separated from the catheter tube and catheter hub. After removal, the PG unit separates from the catheter hub and the catheter tube, with the needle hub situated in the seat of the stabilizer.

[0095] In an example, the dispenser has a connection tip that projects into the receiving end of the adaptor. The connection tip has a first tip section and a smaller diameter second tip section. The size and shape of the connection tip, including the first and second tip sections, are configured to mate with a matching female bore of the adaptor.

[0096] In an example, the engagement between the connection tip and the open proximal end of the adaptor is a taper interference fit, similar to a Luer fit but not necessarily formed to the Luer ISO standard. In yet other examples, the adaptor and the connection tip of the dispenser can be provided with a detent or detent-like engagement. As shown, the connection tip and the receiving bore of the adaptor can include a raised lip or shoulder and a corresponding recess to form a snap fit for the detent-like engagement. In still other examples, rather than a connection tip with different tip sections, such as different tip diameters, the connection tip can embody a single taper for engaging a corresponding taper of the adaptor, similar to a Luer taper but with non-standard ISO sizes. In yet other examples, the connection tip is sized and shaped to engage the needle hub directly without the adaptor. That is, in some embodiments, a guidewire dispenser can have a connection tip that connects directly to the needle hub without the adaptor and wherein the body of the dispenser can have two or three diameter sections or a taper. For the dispenser embodiment without an adaptor, the connection tip can be extended, such as having a sufficient length, to ensure alignment with the needle proximal opening to facilitate guiding the guidewire into the needle lumen. In other examples, the body of the dispenser can be unitarily formed with the adaptor.

[0097] In use, the catheter assembly can be mounted to the frame of the stabilizer and the needle hub located in the seat. If used, the adaptor can project into the opening of the needle hub, after removal of the vent plug, and then the dispenser is projected into the opening of the adaptor, as discussed above, with the guidewire extending through the needle lumen. In other examples, the adaptor can be omitted and the connection tip of the dispenser projects into the open end of the needle hub directly to then dispense the guidewire into the lumen of the needle.

[0098] In an example, the process for using the catheter system in accordance with aspects of the invention can start with gripping the frame of the stabilizer with one hand and removing the protective sleeve with the other hand. Next, place an ultrasound imaging device or ultrasound probe over the targeted vein. The user or practitioner can use the ultrasound probe with the probe hand to monitor the puncture site for proper placement of the needle tip. The user can now poke the targeted vein of the patient using the holding hand that holds the catheter system to access the vein with the needle tip and the catheter tube opening. The user can use the ultrasound probe with the probe hand to monitor the puncture.

[0099] Additionally, proper needle puncture can be confirmed via primary and secondary blood flashback, in addition to verification with the ultrasound probe. Primary flashback occurs when blood flows into the needle lumen and the needle hub hollow interior. Secondary flashback occurs when the needle tip is retracted proximally of the catheter tube opening, or the catheter tube advancing distally relative to the needle tip by a few millimeters, and blood flows in the annular space between the exterior of the needle and the interior of the catheter tube.

[00100] In use, the holding hand, which grips the stabilizer, is held frozen or steady without moving the stabilizer while the catheter hub and the catheter tube are advanced, using different fingers than the holding fingers of one or both hands to push on the catheter hub, such as to push on the push tab. The catheter tube should be advanced slowly into the vein while monitoring resistance feedback from the catheter tube as it travels into the vein. There may be some resistance during the advancement prompting the practitioner to adjust the angle, the speed, and/or direction of advancement to adjust.

[00101] If a guidewire dispenser is used, the dispenser can be attached to the needle hub after removal of the vent plug, either with or without the adaptor. After confirmation of primary and secondary flashbacks, the guidewire is advanced into the vein prior to the catheter advancement relative to the needle.

[00102] The process can also comprise advancing the catheter hub into the wedge ends of the two deck gate sections to then generate a pair of components forces that will cause the control sheet to split at the perforation line. If no resilient or biasing spring is incorporated with the stabilizer, then the catheter hub will move distally until the two deck gate sections fall to the two sides due to gravity to clear a path for the catheter hub. If a biasing spring, such as the torsion spring, is incorporated with the stabilizer, then the two deck gate sections will be pushed radially

by the spring legs to fall to the two sides to clear a path for the catheter hub. The torsion spring can also hold the two deck gate sections in the opening position by providing biasing forces via the two spring legs to keep them open or spaced apart. With the stabilizer still held steady by the holding hand, the catheter hub can further be advanced towards the patient's skin.

[00103] The PG unit and the stabilizer, including the guidewire dispenser if used, can then be retracted away from the catheter tube and the catheter hub. During the retraction, the needle guard, if used, is activated over the needle tip to block the needle tip from inadvertent needle sticks.

[00104] As previously discussed, the valve will close after removal of the needle to block or limit fluid flow across the valve, such as to stop blood flow into the catheter hub and out the proximal opening of the catheter hub. The valve will allow the practitioner to attach an extension line to the catheter hub and apply suitable securement and dressing while preventing blood from spilling back and out of the proximal opening of the catheter hub.

[00105] In an example, the stabilizer of a catheter system has a body comprising a seat and a frame comprising a gate that is configured to separate along a seam when pushed by the catheter hub. The gate comprises a deck gate comprising a first deck gate section and a second deck gate section. In the example shown, the frame comprises two arms extending from the seat and having a deck gate section at the end of each arm. The two deck gate sections join or come together to define a passage to support the catheter tube and needle. Following activation, the two arms spring radially outwardly relative to the central lengthwise axis of the body, or relative to the axis of the needle, to separate the two deck gate sections. However, the two arms can remain connected at the seat following activation.

[00106] In an example, the seat comprises two sidewalls and a rear wall defining a receiving space for accommodating the needle hub. The rear wall can comprise an opening or through hole for accommodating a vent plug. To retain the needle hub within the receiving space, a deck or ledge can extend from each of the two edges of each of the two sidewalls. The two edges on each sidewall can include a first or upper edge and a second or lower edge. The ledges for retaining the needle hub can extend radially inwardly towards the lengthwise axis to form a partial enclosure around the needle hub to prevent the needle hub from falling through or out of the receiving space. In alternative examples, a plurality of tines can extend from the edges to form the holding space for the needle hub, as further discussed below.

[00107] The stabilizer may be made from plastic injection molding. In an example, each of the two arms can extend distally from respective base sidewalls and each can be provided with, such as being molded with, a film hinge. A film hinge is similar to a living hinge but has more girth or thickness that connects two plastic parts, such as the arm and the sidewall. The film hinge has a curvature that allows the two arms to project radially outwardly relative to the plane defined by each of the sidewalls to which the arms attach. The film hinge can be used to provide a resistive or biasing force when moving the arm relative to the sidewall, about the film hinge. While the film hinge is shown in the present embodiment at the intersection between the arm and the sidewall of the seat, the film hinge can be incorporated further distally on the arm.

[00108] When the two arms are brought together, a bias or flexed state is generated at each of the two film hinges that tend to push the two arms radially apart to return to their respective unflexed state. In an example, the two arms are held in their flexed state, or are biased radially inwardly towards one another, by a detent. In a preferred example, the two arms are held together by a control sheet, similar to the control sheets discussed elsewhere herein. The control sheet can be adhered to the surface of the deck gate to hold the two arms and the two deck gate sections together, which tend to separate along the seam at the deck gate.

[00109] Each of the two sidewalls of the seat can be generally rectangular and comprises two edges, including an upper edge and a lower edge. With specific reference to the first sidewall, which resembles that of the second sidewall, the distal end can have a transition section that reduces the height of the sidewall down to match the profile of the first arm. The first arm then extends distally and connects to another transition section, which increases in size to match the profile of the gate. The two transition sections may be referred to as the first or proximal transition section and the second or distal transition section. The two arms between the two sets of transition sections define a low-profile open frame section of the frame to enable easy access and movement of the catheter hub as the same is pushed in the distal direction to advance the catheter hub into the actuation gate, as further discussed below.

[00110] Each of the two deck gate sections can have a body with a wedge end or wedge section and an inner surface. Thus, the two wedge ends of the two deck gate sections can have sections along respective inner surfaces that do not contact. In an example, the two wedge ends of the two deck gate sections form an actuating gate that has a generally V-shape contour. The actuating gate has an end gap at the proximal end-most location and wherein the actuating gate converges as it

extends in the distal direction to a narrowest point, wherein the two inner surfaces of the two bodies of the two deck gate sections contact or where a small gap exists.

[00111] The end gap of the actuating gate is preferably larger than the width of the nose end of the catheter hub. Thus, following entry of the needle tip into a vein and then advancing the catheter tube over the needle into the vein for vascular access by pushing on the push tab of the catheter hub, or by gripping and pushing on the body of the catheter hub, the nose end of the catheter hub will enter the actuating gate where further distal advancement of the catheter hub will cause the nose end to push against the two wedge ends to cause the two deck gate sections to separate. Once the two deck gate sections separate, by first separating the control sheet at the perforation line or by overcoming the detent, the catheter hub can further distally advance while the stabilizer and needle unit retract in the proximal direction to separate the catheter hub from the needle unit so that the catheter hub and catheter tube remain with the patient while the stabilizer and the needle unit are removed, as further discussed below.

[00112] In an example, the two wedge ends of the two deck gate sections form an actuating gate that has a generally V-shape that is not constant or that can have a varying V-shape wedge. This allows the nose end of the catheter hub to push against the actuating gate and exert outward forces and push the two wedge ends to separate at different rates. The V-shaped opening can be adjusted to adjust the manner in which the nose end of the catheter hub pushes and separates the two deck gate sections. For example, the length of the V-shaped opening can shorten to thereby increase the speed of actuation and separation of the two deck gate sections. The V-shaped profile of the actuating gate can also be adjusted to limit or avoid deformation during product placement.

[00113] The gate has a generally planar distal gate surface, which can provide a barrier or a physical stop for the removable sleeve in the proximal direction. The seam extends through the distal gate surface, and through the bottom exterior surface of the deck gate. As further discussed below, a short hollow cylinder extends distally of the distal gate surface for receiving the proximal open end of the sleeve and to serve as part of the passage for supporting the catheter tube. The seam extends through the cylinder to define two half cylinders. The generally rectilinear gate can have surface features for gripping and/or aesthetics. The various corners where the wall surfaces join can each be rounded or can include a radius. Optionally, the corners can have a sharp or straight edge, or can include only a small radius.

[00114] In an example, an upper exterior surface and a lower exterior surface of the two deck gate sections are provided with undulating surfaces and flat or planar surfaces. The undulating surfaces can include recesses located between solid sections. The recesses and the solid sections can align in alternating rows, can have uniform lengths, widths, and depths. In an example, the recesses do not extend completely through the body of the two deck gate sections. In some examples, one or more recesses can extend completely through the upper and lower surfaces of the deck gate sections. In alternative embodiments, the undulating surfaces can embody different solid and recess shapes, such as having rounded projections spaced by rounded recesses, or can have random solid and recess shapes. The undulating surfaces allow the two deck gate sections to be molded with less plastic, breaking up the surface appearance of the gate, and providing a unique aesthetic texture. In alternative embodiments, the undulating surfaces can be omitted, and the upper and lower exterior surfaces of the deck gate sections can have a flat or planar surfaces extending from a proximal end to a distal end.

[00115] The flat planar portion at the distal end of the gate, and specifically at the distal ends of the two deck gate sections, provides a surface for application of the control sheet. In an example, the combined surface area of the two planar surfaces of the two deck gate sections is approximately the same as the surface area of the control sheet. In particular examples, the combined surface area of the two planar surfaces of the two deck gate sections is greater than the surface area of the control sheet. The control sheet is preferably adhered to the gate at a location closer to the distal end than the proximal end of the gate. The location of the control sheet on the gate, such as being located further distally than a proximal position on the gate, can determine the point in time that the control sheet separates along the perforation line relative to when the nose end of the catheter hub contacts the V-shape contour of the actuating gate.

[00116] While embodiments of the invention cover a control sheet having an edge positioned adjacent the distal gate surface, one or more recesses can be provided between the edge and the distal gate surface. If incorporated, the one or more distal recesses can extend partially through or completely through the thickness of the gate. As shown, two distal recesses are provided, one on each of the two deck gate sections. A seam passes through the two distal recesses.

[00117] In an embodiment, a plurality of prongs or tines extending inwardly from the upper edges of the two sidewalls towards the central lengthwise axis of the stabilizer. The plurality of tines can be equally spaced apart along the upper edge of each respective sidewall. Each of the

plurality of tines has a length, which can substantially be the same. The length of each tine is about 20% to 70% of half of the width of the rear wall. That is, each tine extends from the upper edge towards the central lengthwise axis but short of the central lengthwise axis. In an example, at least one tine from each of the two sidewalls can be longer than the other tines and the two longer tines can align and can contact one another when the two arms come together, and the two deck gate sections come together in the ready to use position. The two longer tines can be implemented to fix the width of the seat. The two longer tines can be distally most tines along the two upper edges or can locate anywhere along the upper edges proximal of the distal most tines. The two longer tines can also prevent the needle hub from escaping through the upper opening of the receiving space.

[00118] At the lower or second edge of each of the two sidewalls, a ledge or flange extends radially inwardly towards the central lengthwise axis of the stabilizer. Each ledge on each lower edge can be a single solid piece having a length extending from the rear wall towards the film flange. In an example, the plurality of tines and the two ledges define a receiving space for receiving the needle hub therein. That is, when a needle hub of a needle unit or a catheter assembly is located within the receiving space, the needle hub is retained therein and is too large to fall through the gaps between the two ledges and between the two sets of tines. In an alternative example, the two ledges extending from the lower edges may instead be practiced with tines, similar to the tines extending from the upper edges.

[00119] In an example, an extended ledge is provided with each of the two arms. Each extended ledge is separated from the ledge at the seat by a gap, where the film hinge is located. The extended ledges on the two arms function as a track for the catheter hub as the catheter hub is advanced in the distal direction to move the catheter tube over the needle and into the patient's vein. That is, the catheter hub can ride on the surfaces of the two extended ledges when advanced within the frame of the stabilizer during venipuncture.

[00120] In an example, the two arms of the stabilizer are spaced from one another in their less flexed state or spread apart state, such as in the activated position. In this state, the two arms, just distal of the two film flanges, such as 1 cm distal, 2 cm distal, or 3 cm distal of the film flanges, are spaced from one another a gap Y, which is larger than a gap X at the same distal location when the two arms are in their flexed state, in which the two arms are held together by detents or by the control sheet at the deck gate.

[00121] When the arms are spaced by a gap Y, clearance space is provided between the arms for assembling the catheter assembly into the receiving space at the seat of the stabilizer, by sliding the end with the needle hub from a distal position to a proximal position so that the needle hub is located within the receiving space at the seat, between the two sidewalls and between the set of tines and the set of ledges. When a vent plug is attached to the needle hub, such as shown, the vent plug can slide into the receiving space first and can be located through the opening on the rear wall of the seat so that the vent plug projects proximally of the rear wall. At this point, the two arms can be brought together by pushing the two deck gate sections together and then retaining them via detents or via a control sheet. If a control sheet is used, the control sheet preferably comprises a perforation line, and the perforation line aligns with the seam extending between the two deck gate sections.

[00122] With reference specifically to the second deck gate section, which has similar structures as the first deck gate section, the body of the deck gate has a wedge end and an inner surface comprising an elongated groove that combines with the elongated groove of the first deck gate section to define a passage for accommodating and supporting a catheter tube and a needle of a catheter assembly, as previously discussed. A half cylinder nose section projects distally of the distal gate surface. When the two deck gate sections are joined, the two elongated grooves and the two half cylinder nose sections combine to define a passage for supporting the catheter tube and needle. The two half cylinder nose sections combine to form a cylindrical nose section.

[00123] In an example, the passage defined by the two deck gate sections, which has a length, can stabilize a catheter assembly with extended needle and catheter lengths, in the order of about 7.5 cm to 20 cm. Such relatively longer catheters and needles are typically found with midline catheters. However, the catheter assembly 102 usable with the stabilizer of the present invention is not so limited and may in some instances be used as shorter catheters and needles, typically found in peripheral access catheters, or longer catheters. By using the disclosed stabilizer with the catheter system, catheterization with long catheters, up to 100 mm or 10 cm, in length may be used without a guidewire. However, if a guidewire becomes necessary, a guidewire dispenser may be used as described elsewhere herein.

[00124] In an example, the process for using the catheter system can start with gripping the frame with one hand and removing the protective sleeve with the other hand. Next, place an ultrasound imaging device or ultrasound probe over the targeted vein. The user or practitioner can

use the ultrasound probe with the probe hand to monitor the puncture site for proper placement of the needle tip. The user can now poke the targeted vein of the patient using the holding hand that holds the catheter system to access the vein with the needle tip and the catheter tube opening. The user can use the ultrasound probe with the probe hand to monitor the puncture.

[00125] Additionally, proper needle puncture can be confirmed via primary and secondary blood flashbacks, in addition to verification with the ultrasound probe. Primary flashback occurs when blood flows into the needle lumen and the needle hub hollow interior. Secondary flashback occurs when the needle tip is retracted proximally of the catheter tube opening, or the catheter tube advancing distally relative to the needle tip by a few millimeters, and blood flows in the annular space between the exterior of the needle and the interior of the catheter tube.

[00126] In use, the holding hand, which grips the stabilizer, is re-gripped to hold the stabilizer at the rear of the frame, such as to grip the seat. The catheter hub is then advanced using the other hand, or the non-holding hand, such as by pushing on the catheter hub at the push tab. In another example, the catheter hub can be gripped from above and below the frame to advance the catheter tube using two gripping fingers, such as with the thumb and the index finger. The catheter tube should be advanced slowly into the vein while monitoring resistance feedback from the catheter tube as it passes into the vein. There may be some resistance during the advancement prompting the practitioner to adjust the angle, the speed, and/or direction of advance to adjust.

[00127] If a guidewire dispenser is used, the dispenser can be attached to the needle hub after removal of the vent plug, either with or without the adaptor. After confirmation of primary and secondary flashbacks, the guidewire may be advanced into the vein prior to the catheter advancement relative to the needle.

[00128] In use, the holding hand can grip the frame of the stabilizer with the thumb and middle finger, possibly also with the ring finger, while advancing the catheter hub in the distal direction with the index finger on the push tab or with two fingers gripping the catheter hub from above and below the frame. The catheter hub is advanced into the wedge ends of the two deck gate sections to then generate a pair of components forces that will cause the control sheet to split at the perforation line. Once the perforation line splits, the self-biasing of the two arms at the two film hinges will unflex and move the two arms radially away from one another to provide clearance for the catheter hub. With the stabilizer still held steady by the holding hand, the catheter hub is further advanced towards the patient's skin.

[00129] While the foregoing summary of technical features or aspects of an exemplary configuration of the disclosure are provided for reference, the invention should typically be considered as available and applicable to other similar features or aspects in another exemplary configuration of the disclosure. Accordingly, technical features described herein according to one exemplary configuration of the disclosure may be applicable to other exemplary configurations of the disclosure, and thus duplicative descriptions may be omitted herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[00130] These and other features and advantages of the present devices, systems, and methods will become appreciated as the same becomes better understood with reference to the specification, claims and appended drawings wherein:

[00131] FIG. 1 is a perspective view of a catheter system comprising a catheter assembly and a stabilizer.

[00132] FIG. 2 is a partial enlarged view of the catheter system of FIG. 1.

[00133] FIG. 3 is a top or plan view of a control sheet in accordance with aspects of the invention.

[00134] FIG. 4 is a perspective view of the stabilizer of FIG. 1 in an activated configuration, shown without the catheter assembly.

[00135] FIGs. 4A and 4B are schematic end views of a stabilizer having an alignment mechanism for axially and radially aligning features or components of the stabilizer.

[00136] FIG. 5 is an enlarged partial perspective view of the stabilizer shown with a bias member.

[00137] FIG. 5A is a top view of a stabilizer with two gate unit sections biased outwardly by a biasing member.

[00138] FIG. 6 is a perspective view of a biasing member in accordance with aspects of the invention.

[00139] FIG. 6A is a perspective view of a biasing member in accordance with aspects of the invention with two spring legs (dashed lines) shaped to have a relatively larger working angle than linear configured spring legs (solid lines) to generate biasing on the two gate unit sections when in the activated configuration.

[00140] FIG. 7A is a cross-sectional side view of a catheter assembly provided in accordance with aspects of the invention.

[00141] FIG. 7B is a partial cross-sectional side view of an alternative catheter assembly with a valve and a valve opener.

[00142] FIG. 8 is a perspective view of a piercing and guiding unit, which includes a needle unit and a guidewire dispenser.

[00143] FIG. 9 is a partial cross-sectional side view of a guiding unit and catheter unit.

[00144] FIGs. 10A-10F show a sequence of views representative of a method for using a catheter system in accordance with aspects of the invention.

[00145] FIG. 11 is a perspective view of an alternative catheter system comprising a catheter assembly and a stabilizer.

[00146] FIG. 12 is a partial enlarged perspective view of the catheter system of FIG. 11.

[00147] FIG. 13 is a partial plan view of the stabilizer of FIG. 11, specifically showing the seat of the stabilizer.

[00148] FIG. 14 is a partial plan view of the stabilizer of FIG. 11, specifically showing the seat of the stabilizer and a needle unit, with the two arms in a relaxed state.

[00149] FIG. 15 is a front perspective view of the stabilizer of FIG. 11 with the two arms in a relaxed state.

[00150] FIGs. 15A and 15B are partial top view and bottom view, respectively, of the stabilizer of FIG. 15.

[00151] FIG. 15C is a schematic top view of a stabilizer provided in accordance with further aspects of the invention.

[00152] FIG. 15D is a front view of a stabilizer in accordance with aspects of the invention.

[00153] FIGs. 16A-16F show a sequence of views representative of a method for using a catheter system in accordance with aspects of the invention.

DETAILED DESCRIPTION

[00154] The detailed description set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of catheter systems and components thereof, including catheter assemblies and stabilizers, provided in accordance with aspects of the present devices, systems, and methods and is not intended to represent the only

forms in which the present devices, systems, and methods may be constructed or utilized. The description sets forth the features and the steps for constructing and using the embodiments of the present devices, systems, and methods in connection with the illustrated embodiments. It is to be understood, however, that the same or equivalent functions and structures may be accomplished by different embodiments that are also intended to be encompassed within the spirit and scope of the present disclosure. As denoted elsewhere herein, like element numbers are intended to indicate like or similar elements or features.

[00155] Descriptions of technical features or aspects of an exemplary configuration of the disclosure should typically be considered as available and applicable to other similar features or aspects in another exemplary configuration of the disclosure. Accordingly, technical features described herein according to one exemplary configuration of the disclosure may be applicable to other exemplary configurations of the disclosure, and thus duplicative descriptions may be omitted herein.

[00156] With reference now to FIG. 1, a catheter system 100 comprising a catheter assembly 102 mounted to a stabilizer 104 is shown in accordance with aspects of the invention. The catheter assembly 102 comprises a catheter unit 106 and a needle unit 108. In an example, the catheter unit 106 comprises a catheter hub 110 and a catheter tube 112 extending from the catheter hub 110. The needle unit 108 comprises a needle hub 116 having a needle 117 (FIG. 7A) attached thereto and the needle extending in a distal direction through the catheter hub 110 and through the lumen of the catheter tube 112 with the needle tip 118 projecting distally of the distal opening of the catheter tube in a ready to use position shown. A vent plug 114 is attached to the open proximal end of the needle hub 116. A removable protective sleeve or cap 120 is positioned over the catheter tube and needle, which is to be removed prior to using the catheter system 100 for vascular access.

[00157] As shown, the stabilizer 104 has a body 124 with a seat 126, a frame 128 extending from the seat 126, and a gate unit 130 extending from the frame. As further discussed below, the seat 126 provides a support surface for supporting or accommodating the needle hub 108. In an example, the seat 126 comprises a plurality of wall surfaces 134, including two sidewall surfaces 134a, 134a and a bottom wall surface 134b, defining a cavity 138 for receiving the needle hub 116. The two sidewall surfaces 134a, 134a limit the needle hub 116 from lateral movement but not axial movement, relative to the lengthwise axis of the frame 128. However, the needle hub 116 is preferably fixed relative to the seat 126 during vascular access and only the catheter hub 110

axially advances to place the catheter tube in the vasculature. For example, the needle hub 116 can frictionally engage the seat to prevent axial movement relative to the seat. In other examples, the seat can have internal baffles or ribs that grip or engage surface features of the needle hub to prevent axial movement of the needle hub relative to the seat. In still other examples, detents, interference, and/or snap fit may be used to secure the needle hub 116 within the seat 126 to resist rotation and/or axial movement relative to the seat. In an example, the needle hub 116 can be provided with laterally spaced notches and the seat 126 of the stabilizer 104 can be provided with projections that mate with the notches. For example, a notch or divot on each of two sides of the needle hub can be incorporated on the body of the needle hub and a projection on each of the inner surfaces of the two sidewalls 134a, 134b of the seat 126 can be incorporated to engage the two notches or divots on the needle hub.

[00158] The frame 128 can extend distally of the distal end of the seat 126. As shown, the frame 128 is attached to the bottom wall surface 134b and extends in the distal direction. In an example, the frame 128 has a body 141 of varying cross-sections along the lengthwise direction. As shown, the body 141 has a generally triangular shape along a side view. For example, the body 141 can have a first edge 144a, a second edge 144b angled to the first edge 144a, and a far edge or third edge 144c angled to both the first and second edges. In some examples, the third edge is straight or has a single straight edge and the frame is generally V-shaped. The edges define boundaries of a grip-able or holding surface 146, or surfaces when considering the two opposing sides of the body 141, for gripping by a practitioner for performing a venipuncture or procedure, as further discussed below.

[00159] In an embodiment, the grip-able or holding surface 146 at or near the low point 145 can be recessed to facilitate gripping. The recessed surfaces, on both sides of the body, allow fingers to be placed thereon or therein. The recessed surfaces can be contoured to receive the contoured tips of the fingers. Additionally, one or more surface features 125 (FIG. 1) can be incorporated in the recessed surfaces. The surface features can be projections, dimples, or combinations thereof. In a particular example, the surface features are projections with each having a diamond shape and a length. The lengths of the diamond shaped surface features can be aligned relative to one another and angled like the third edge 144c (FIG. 1).

[00160] In an example, the low point or lower edge 145 of the frame 128 resembles an apex along a side view. The low point 145 is located between the first edge 144a and the far edge 144c.

Elevation-wise, the low point 145 is lower than the first edge and the far edge. The low point 145 allows the frame 128 to rock or pivot about the low point to change the advancing angle of the needle for venipuncture. Thus, in an example, the low point 145 represents the lowest, elevation-wise, point of the frame. The low point connects the first edge 144a and the third or far edge 144c of the frame.

[00161] In an example, when the needle is located horizontally relative to the ground, a line drawn through the low point 145 and normal to the horizontal needle creates two angles relative to the normal line with the first edge 144a and the third edge or far edge 144c, which can have a non-linear edge as shown or can have a single straight edge. The two angles can be equal. In other examples, the angle between the normal line and the first edge 144a is larger than the angle between the normal line and the third or far edge 144c. The angle between the normal line and the third edge 144c allows the frame 128 to rock or tilt forward, in the distal direction, to provide the practitioner with flexibility on finding the most optimum angle for venipuncture.

[00162] If the bottom wall surface 134b of the seat 126 defines a plane, the second edge 144b of the frame 128 can have a bend so that part of the second edge 144b extends radially inwardly across the plane to be closer to the axis defined by the needle. The bend causes the second edge 144b to move closer to the catheter hub and the catheter tube while the proximal end of the second edge 144b, at the beginning of the incline of the bend, is situated further away, in the radial direction, than the axis defined by the needle. In an example, the catheter hub 110 can slide along the surface of the second edge 144b to advance the catheter tube over the needle for placement in the vasculature. In other examples, the second edge 144b is spaced from the bottom of the catheter hub but the catheter hub can slide axially against the edge if the needle flexes and the exterior of the catheter hub touches the second edge.

[00163] The gate unit 130 extends at an angle to the second edge 144b. As shown, the second edge 144b has a second bend and the gate unit 130 extends from a location distal of the second bend. The gate unit 130 comprises a first gate unit section 130a and a second gate unit section 130b. The gate unit 130 further comprises a base portion 148 and deck gate 150. The gate unit 130 is configured, such as being sized and shaped, to split to allow the catheter unit 106 to separate from the needle unit 108 for placement of the catheter tube in the vasculature. That is, the gate unit 130 can split into a first gate unit section 130a and a second gate unit section 130b (FIG. 4) to then allow the catheter hub to separate from the needle hub.

[00164] In an example, the frame 128 has a thickness or depth defined by two opposing surfaces 152, 152 (FIG. 1). The base portion 148 of the gate unit 130 has a first base section 148a and a second base section 148b (FIG. 4), with each base section attached to the frame via a living hinge 154. Thus, the two base sections 148a, 148b can pivot together or towards one another or away from one another via the two living hinges 154, 154 (FIG. 4). In alternative examples, the two base sections 148a, 148b can pivot together or towards one another or away from one another via a respective pivot pin, or more than one pivot pin aligned along a common rotating axis. As shown in FIG. 5, hinge barrels 204 having sockets may be incorporated when pivot pins are employed to pivot the respective base sections 148a, 148b. Hinge barrels 204 can cooperate with pivot pins to allow base sections 148a, 148b to pivot, as further discussed below. Thus, the first gate unit section 130a has a first base section 148a and the second gate unit section 130b has a second base section 148b.

[00165] The deck gate 150 has a first deck gate section 150a and a second deck gate section 150b, each attached or connected to a respective base section 148a or 148b. The two deck gate sections 150a, 150b meet along a seam 158 (FIG. 2) in the ready to use position and separate from one another when pushed from a proximal end by an advancing catheter hub 110. That is, in the ready to use position, the two deck gate sections 150a, 150b are spaced from one another by a first distance and in the activated position, the two gate sections 150a, 150b are spaced from one another a second distance. The second distance being greater than the first distance. The first distance can be zero or a condition in which the two gate sections 150a, 150b contact. In other examples, the second distance is greater than the first distance by at least 3 cm.

[00166] Prior to being separated by the catheter hub 110, such as when in the ready to use position, the two deck gate sections 150a, 150b come closer together or contact to define a passage for the needle and the catheter tube. In an example, the passage defined by the two deck gate sections 150a, 150b provide support for the needle and catheter tube as the needle and the catheter tube are advanced during venipuncture. For example, as the needle and catheter tube are advanced, they can be supported by the passage formed by the two deck gate sections 150a, 150b. The passage is provided at a location spaced from the catheter hub 110 and spaced from the needle hub to stabilize the needle and the catheter tube at a location spaced from the catheter hub and the needle hub. In an example, the passage formed by the two deck gate sections 150a, 150b has a bore that is larger than the outer diameter of the catheter tube such that the catheter tube and needle

can slide through the passage without touching the interior surface of the passage. However, if the catheter tube and the needle flex during the advancement through the passage, some touching with the interior of the passage may be inevitable. For example, some touching can be expected along a lower section of the passage.

[00167] In an example, the passage defined by the two deck gate sections 150a, 150b, which has a length, can stabilize a catheter assembly having extended needle and catheter lengths, in the order of about 7.5 cm to 20 cm. Such a relatively longer catheter and needle are typically found with midline catheters. However, the catheter assembly 102 of the present invention, usable with the disclosed stabilizer 104, is not so limited and may in some instances embody shorter catheters and needles, typically found in peripheral access catheters, or longer catheters. By using the disclosed stabilizer 104 with the catheter system 100, catheterization with long catheters, up to 100 mm or 10 cm, in length may be used without a guidewire. However, a guidewire may be used to guide the catheter tube as the latter advances into the vein, such as when using a relatively longer catheter in the order of about 100 mm or longer, as further discussed below. Optionally, one or more surface features 125, such as projections, dimples, or combinations thereof, may be provided at the surfaces of the seat 126 and/or the surface of the frame 128 for gripping and aesthetics.

[00168] With reference now to FIG. 2, a blown-up partial perspective view of the catheter system 100 of FIG. 1 is shown. The present view shows a flange 160 with a first flange section 160a and a second flange section 160b, which join to form a generally square shape flange having a distal surface for limiting proximal travel of the protective sleeve or cap 120. The flange 160 has a split or a seam aligned with the seam 158 of the deck gate 150. In an example, a control sheet 166 having an adhesive backing is adhered to the deck gate 150 and over the seam 158. The control sheet 166 is configured to control the separation, such as the resistance to the separation, of the two deck gate sections 150a, 150b along the seam 158 when pushed open by the catheter hub 110.

[00169] For example, the control sheet 166 can be selected with a known tear strength so that when the catheter hub 110 is advanced against the two deck gate sections 150a, 150b with sufficient pressure, the two deck gate sections 150a, 150b are forced open by the advancing catheter hub, which then applies a tear force or a separation force on the control sheet to tear or separate the control sheet to then allow the two deck gate sections to separate along the seam 158. Inherent in the design is therefore a separation force that is higher than the tear force of the control

sheet, which distally directed force needs to exceed a certain minimal force. The minimal force may be selected to guard against early or inadvertent activation or separation of the two deck gate sections 150a, 150b. However, the minimal force to separate the control sheet should not be materially or significantly higher than a typical distally directed force to advance the catheter hub during a medical procedure.

[00170] In some examples, the control sheet 166 may be provided with perforation line 168 comprising a plurality of perforated slits or perforations 168a to minimize the separation force of the control sheet from its rupture limit when no perforations are incorporated. The perforations reduce the tear strength of the control sheet thereby allowing the control sheet to tear at a lower force compared to a control sheet without any perforations or with fewer perforations. The perforations can vary in length and numbers. For example, the longer the perforations and the shorter the solid sections 168b (FIG. 3) between the perforations, the easier it is for the control sheet 166 to tear along the perforations. Conversely, the shorter the perforations or slits 168a and the longer the solid sections 168b between the perforations, the harder it is for the control sheet 166 to tear along the perforations.

[00171] Additionally, the paper stock or substrate and the thickness used to form the control sheet also contribute to the tear strength of the control sheet. In an example, the control sheet 166 is made from a polymer-based film. For example, the control sheet 166 can be made from a polypropylene film. In an embodiment, the perforations and substrate are selected to readily split upon normal advancement of the catheter hub 110 against the proximal end of the deck gate 150, which produces a pair of component forces that include a radially directed force to separate the perforations, as further discussed below.

[00172] FIG. 3 is a plan view of a control sheet 166 in accordance with aspects of the invention. As shown, the control sheet 166 has edges 167 that form a generally rectangular shape with rounded corners 170. In the example shown, two indented perimeter sections or indentations 172, 172 are provided to decrease the dimension at the mid-section of the control sheet. The two indented perimeter sections together with the perforation line 168 define two wings 174, 176 that are symmetrical about the perforation line 168. The two indentations 172, 172 can be provided to facilitate placement of the control sheet 166 onto the stabilizer and align the seam 158 with the perforation line 168. The length of each slit 168a within the perforation line 168 and the length of each solid or non-slit sections 168b between two adjacent slits contribute to the tear strength of the

control sheet along the perforation line. Additionally, the thickness of the control sheet 166 and the type of material used can contribute to the tear strength of the control sheet. In some examples, the indentations 172, 172 can be omitted and the overall length of the perforation line at the mid-section can be lengthened to control the tear strength.

[00173] With reference again to FIG. 2, each of the two deck gate sections 150a, 150b has a body 177 with a wedge end or wedge section 178 and an inner surface 180. Thus, the two wedge ends of the two deck gate sections 150a, 150b have sections along respective inner surfaces that do not contact due to the curved or inclined surfaces at the wedge ends that diverge. In an example, the two wedge ends 178 of the two deck gate sections 150a, 150b form an actuating gate 182 that has a generally V-shape contour. The actuating gate 182 has an end gap 203 (FIG. 1) at the proximal end-most location and wherein the actuating gate 182 converges as it extends in the distal direction to a narrowest point, wherein the two inner surfaces 180 of the two bodies 177 contact or where only a small gap exists, as is the nature of the generally V-shape contour. The end gap 203 of the actuating gate 182 between the two inner surfaces 180 is preferably larger than the width of the nose end 186 of the catheter hub 110. Thus, following entry of the needle tip into a vein and then advancing the catheter tube over the needle into the vein for vascular access by pushing on the push tab 278 of the catheter hub 110, the nose end 186 of the catheter hub 110 will enter the actuating gate 182 at the end gap 203 where further distal advancement of the catheter hub will cause the nose end 186 of the catheter hub to push against the two wedge ends 178 to cause the two deck gate sections 150a, 150b to separate. Once the two deck gate sections 150a, 150b separate, by first separating the control sheet 166 at the perforation line or by overcoming a detent that holds the two deck gate sections 150a, 150b together, or both, the catheter hub 110 can further distally advance to move relative to the stabilizer 104 and to separate from the needle unit 108. After complete separation, the catheter hub and the catheter tube remain with the patient while the stabilizer and needle unit are removed, as further discussed below.

[00174] With reference now to FIG. 4, a perspective view of the stabilizer 104 in the activated position is shown, shown without the needle unit 108 following venipuncture, as discussed above. The stabilizer 104 is shown without the needle unit to show features of the stabilizer that otherwise would be obstructed from view. As shown, the seat 126 comprises two sidewalls 134a, 134a and a bottom wall 134b. A rear wall 134c connects to the two sidewalls and to the bottom wall 134b. The rear wall 134c has a proximally facing surface and a distally facing surface located radially

inwardly of the two sidewalls. That is, the rear wall 134c has a rear wall surface that is more than just open-end surfaces of the two sidewalls 134a, 134a. However, in some examples, the rear wall 134c can be omitted and internal ribs or tabs can be provided with the two sidewalls 134a, 134b and/or the bottom wall 134b to retain the needle hub within the seat 126 during use. The rear wall is preferably solid and does not split, like that of the two deck gate sections 150a, 150b. An opening 188 can be provided through the rear wall 134c. The opening 188 can accommodate a vent plug 114 (FIG. 1) in the ready to use position and to accommodate a guidewire dispenser, if one is used, after removal of the vent plug, as further discussed below.

[00175] The distance or gap between the two sidewalls 134a, 134a of the seat 126 defines a width or depth that is wider or larger than the thickness or width of the frame 128. In an example, a transition section 190 is provided in which tabs or wall sections are provided to transition between the two sidewalls and the frame due to the difference in dimensions. In other examples, the connection is abrupt, similar to a “T” connection in which the narrower frame terminates at the edge of the base, between the two sidewalls.

[00176] The gate 130 is connected to the distal end of the frame 128, opposite the seat 126. In particular, each of the two base sections 148a, 148b of the gate is attached to the frame via a respective living hinge 154. A living hinge is understood to mean a thin flexible connection made of the same material as the material used to form the frame 128 and the gate 130, such as being unitarily formed with the frame and the gate. The living hinge 154 allows the two gate sections to pivot about the living hinge, typically over multiple cycles, without breaking. In other examples, the frame can be provided with a hinge barrel or knuckle having one or more sockets and the two base sections 148a, 148b can be provided with corresponding pins or projections to form two pivotable hinges with the sockets, thereby allowing the two base sections to rotate about the pins. Hinge barrels with sockets are shown in FIG. 5.

[00177] Each of the two deck gate sections 150a, 150a of the deck gate 150 has a wedge end 178 and an inner surface 180 comprising an elongated groove 194, which together with the groove 194 of the other deck gate defines a passage 196 for accommodating and supporting the catheter tube and needle of the catheter assembly, as previously discussed. As shown, each elongated groove 194 has sections with varying groove contours. Just distal of the wedge section 178, each elongated groove 194 has a large groove section 194a that is followed distally by a narrower groove section 194b. A groove transition is located between the large and narrower groove sections. The

narrower groove section 194b can be constant, such as having a constant partial cylinder, along the length thereof to the distal end. The large groove section 194a immediately distal of the wedge section 178 can have a taper in the radial direction relative to a plane defined by the inner surface 180, that is less or smaller than the taper of the wedge section. This large groove section 194a allows the distal end 186 of the catheter hub 110 to continue to generate a pair of component forces against the tapered surfaces of the large groove section 194a to separate the two deck gate sections 150a, 150b as the catheter hub travels distally during venipuncture.

[00178] In an example, the interior surface 180 of the first deck gate section 150a and the interior surface of the second deck gate section 150b may be provided with an alignment mechanism 393 for axially and radially alignment features or components of the stabilizer. As shown, the alignment mechanism 393 comprises a receptacle 390 provided on the inner surface of the second deck gate section 150b. The receptacle 390 can embody a recess having a length, a width, and a depth. The recess can bisect the elongated groove 194. The receptacle 390 is configured to cooperate with prongs or projections 392 located on the surface of the first deck gate section 150a. Two spaced apart and axially offset projections 392 are provided, on either side of the lengthwise elongated groove. However, three or more projections may be practiced. The projections should be located within the area boundary of the receptacle for mating engagement, as discussed below.

[00179] When the first and second deck gate sections 150a, 150b move together, as shown in FIGs. 1 and 2, the projections 392 enter the receptacle 390 and the lip or ledge 394 provided by the depth of the recess. The engagement limits play between the two deck gate sections 150a, 150b along the plane defined by the seam whether the two meet. The engagement can be finetuned by adjusting the play, such as dimensions of the length and/or width of the receptacle relative to the area boundary defined by the projections. In some examples, the engagement can be a detent engagement that keeps the two deck gate sections 150a, 150b against the open bias of the biasing member 212.

[00180] With reference now to FIG. 4A, a schematic end view of an alternative alignment mechanism 393 for the gate unit 130 of the stabilizer of FIG. 4 is shown. The schematic view shows the stabilizer looking from the distal end towards the proximal end, where the seat for supporting the needle hub is located. As shown, the lower regions of the two deck gate sections 150a, 150b have been enlarged to provide spaces for incorporating the projections 392 and the

receptacle 390, which form the alignment mechanism of the present embodiment. Both the projection 392 and the receptacle 390 have been modified to locate below the elongated grooves 194 on the two inner surfaces 180. Further, the projection 392 has been modified to embody a single outwardly extending sloping structure that resembles a right triangle.

[00181] FIG. 4B shows the two deck gate sections 150a, 150b coming together and the two elongated grooves 194 defining the passage 196 for supporting the needle and catheter tube, as previously discussed. The two deck gate sections 150a, 150b can be held in the joined configuration shown by a control sheet 166 (FIG. 3), detents, or both. In the assemble position, the lip or ledge 394 of the receptacle and the perimeter surfaces 398 of the projection 392 contact to limit relative movement of the two deck gate sections 150a, 150b along the plane 400 defined by the seam between the two.

[00182] With reference now to FIG. 5, an enlarged partial perspective view of the stabilizer 104 of FIG. 4 is shown, without the first base section 148a and the first deck gate section 150a to more clearly show the head section 200 of the frame 128. As shown, the head section 200 has a shoulder 202 comprising a hinge barrel or knuckle 204 having a number of sockets for receiving a corresponding number of pins to pivotably secure the first base section 148a to the frame 128. In an example, for each hinged joint, the pin can be separate from the first base section 148a and can project through a bore at an end edge of the shoulder, similar to a door hinge, to secure the hinge barrel or knuckle of the shoulder 202 and the first base section 148a. In other examples, the hinge barrel 204 on the shoulder can comprise divots or sockets to receive corresponding pin projections integrally formed with the first base section 148a. In still other examples, the positions of the divots or sockets on the shoulder 202 and positions of the projections on the first base section 148a, and the second base section 148b, can reverse.

[00183] In an example, the head section 200 can include a mounting platform 208 having a body 210 for mounting a biasing member 212. In an example, the biasing member 212 is a torsion spring comprising a plurality of coils 214 having a coiled internal diameter 216 and two spring legs 218 (FIG. 6). The body 210 of the mounting platform 208 can be a cylinder having an outside diameter that is sized and shaped to project into the coiled internal diameter 216 to hold the biasing member in position to bias the two gate sections 130a, 130b of the gate 130 outwardly. As shown, one of the two spring legs 218 is pressed against the inner surface 180 of the second base section 148b to bias the second base section outwardly away from the lengthwise axis of the frame 128.

The other spring leg 218 of the torsion spring 212 similarly presses against the inner surface 180 of the first base section 148a to bias the first base section outwardly away from the lengthwise axis of the frame 128 when the first base section 148a is attached to the frame 128. In the configuration described, when the catheter hub advances distally to generate a pair of component forces against the wedge section 178 (FIG. 2) of the frame to separate the control sheet 166 or detents, the torsion spring 212 can assist with fully separating the two gate sections 130a, 130b of the gate 130 to ensure a wide open passage for the catheter hub to separate from the needle unit 108 (FIG. 1).

[00184] In an example, the mounting platform 208 of the frame 128 comprises a receiver 222 having a structure with a receiving pocket 224. The mounting platform 208 further comprises a mounting plug 228 having an elongated body 230 and an enlarged head 232. The mounting plug 228 can attach to the receiving pocket 224 of the receiver. To mount the torsion spring 212 to the mounting platform 208, the elongated body 230 can project into the coiled inside diameter 216 from the end without the enlarged head and the enlarged head 232, which has an outside diameter that is larger than the coil inside diameter 216, retains the torsion spring 212 from displacing off the elongated body 230 in the direction of the enlarged head. The elongated body 230 can then project into the pocket 224 of the receiver 222 to position the torsion spring on the frame. Detents, interference, and/or adhesive may be used to more permanently secure the mounting plug 228 to the receiver 222. Thus, the mounting platform can have two enlarged ends, represented by the receiver 222 and the enlarged head 232, located at two ends of a smaller diameter elongated body. The torsion spring 212 can be located on the elongated body with the two spring legs 218 arranged to bias the two gate sections 130a, 130b away from one another. In an alternative example, the mounting plug 228 is unitarily formed with the mounting platform and is provided without the enlarged head. Thus, the spring can be mounted onto the elongated body of the mounting plug with the plug already attached. The two spring arms can then be located in respective slots formed in the base sections 148a, 148b to prevent the spring from sliding axially off of the mounting plug.

[00185] With reference now to FIG. 5A, a top view of a stabilizer 104 provided in accordance with further aspects of the invention is shown in an activated position, in which the two base sections 148a, 148b have been activated to open by the catheter hub, similar to the stabilizer described above. The present stabilizer 104 is similar to the stabilizer of FIGs. 1, 4, and 5 with a few exceptions. The present stabilizer 104 comprises a frame 128 comprising a mounting platform 208 for accommodating a biasing member 212 and a gate unit 130, which has a first gate unit

section 130a and a second gate unit section, like that of FIGs. 1, 4 and 5. In the present embodiment, a mounting plug 228 having a body 210 with an enlarged end or head 232 is oriented in the distal direction. Thus, the biasing member 212 can be mounted onto the mounting platform 208 from the distal direction towards the proximal direction. The spring arms of the biasing member can be located in corresponding slots on the two base sections 148a, 148b to deter separation of the biasing member from the mounting platform. In another example, the biasing member 212 is first mounted onto the mounting plug 228 and then the mounting plug is inserted into a pocket on the frame and then secured thereto via interference fit, detents, adhesive, or combinations thereof.

[00186] As shown, the coils 214 of the biasing member 212, which can be a torsion spring, can be positioned on the receiving pocket 224 of the mounting platform 208 and held there by the enlarged head 232 and the base 233 of the mounting platform. The enlarged head is located further distally than the base 233.

[00187] In an example, the two gate unit sections 130a, 130b are pivotable about the frame 128 via respective pivot pins or hinge joints. Further, each hinge joint can be provided with one or more physical stops, such as projections and interference features for limiting the range that the two gate unit sections 130a, 130b can pivot open in the activated position. Locations of the projections can be selected to control how far the two gate unit sections can open and operate as hard stops for the two gate unit sections 130a, 130b. For example, physical stops can be incorporated at the hinge joints to limit the two gate unit sections 130a, 130b from opening beyond a horizontal plane defined by the top surface 211 of the body 210. In some examples, the physical stops can be selected to permit the two gate unit sections 130a, 130b to open beyond the horizontal plane or less than the horizontal plane.

[00188] The two spring legs 218 of the biasing member 212 are arranged to bias against respective base sections 148a, 148b of the two gate unit sections 130a, 130b. With reference to FIG. 6A in addition to FIG. 5A, the two spring legs 218 can be angled to exert outward spring forces when the stabilizer is in the activated position. That is, in the position of FIG. 5A, the angled spring legs 218a, 218a bias the two gate unit sections 130a, 130b from coming back together as in the ready to use position. The two spring legs 218, 218 can be generally aligned along a straight line (solid lines) or the two spring legs 218a, 218a can be angled relative to one another (dashed lines). The angle between the two spring legs 218a, 218a can be adjusted to control the

amount of torsion spring deflection or biasing forces on the two gate unit sections 130a, 130b when in the activated position, to ensure that they remain spaced apart and held apart by a spring bias.

[00189] With reference now to FIG. 7A, a catheter assembly 102 usable with a stabilizer 104 to form the catheter system 100 of FIG. 1 is shown. The stabilizer can alternatively be the device of FIG. 5A. The presently shown catheter assembly 102 and similar catheter assemblies may be used with the stabilizer 104 to form the catheter system 100 in accordance with aspects of the present invention. Optionally, a guide wire may be incorporated to assist in inserting, positioning, and moving a catheter, as further discussed below.

[00190] In an example, the catheter assembly 102 comprises a first hub or catheter hub 110 having an over-the-needle tube or catheter tube 112 attached thereto and a second hub or needle hub 116 having a needle 117 attached thereto. The catheter tube 112 has a lumen or bore for receiving the needle 117 and has a distal opening or distal end opening 112a and the needle tip 118 of the needle 117 extends distally of the distal opening 112a in a ready to use position, in which the assembly 102 is ready for venipuncture. The catheter assembly 102 can also be called a needle assembly.

[00191] The needle 117 can include a change in profile 234 located proximally of the needle tip 118 for use with a needle guard. The needle tip 118 extends distally of the distal end opening 112a of the catheter tube or tubing 112 in the ready to use position with the change in profile 234, if incorporated for use with a needle guard, located proximally of the distal end opening 112a. The change in profile 234 can be a crimp, a bump, or a material build-up having different profile than other diameter sections of the needle shaft. As used herein, the term proximal is understood to mean an end or side closer to the practitioner and the term distal is the opposite end or side.

[00192] The change in profile 234 can be used to interact with a needle guard 238 during retraction of the needle 117 following successful venipuncture, as further discussed below. A vent plug 114 is disposed at the proximal open end 240 of the second hub or needle hub 116. The vent can have a vent filter 242 at a proximal end thereof, which is conventional. As shown, the catheter tube 112 is attached to the first hub or catheter hub 110 by a ferrule or bushing 244.

[00193] The needle guard 238 can be provided in the interior cavity 244 of the first hub or catheter hub 110 for covering the needle tip 118 in the protective position, where the needle is retracted away from the catheter tube and the needle hub and is covered by the needle guard 238. When incorporated, the needle guard 238 can be one of the needle guards disclosed in US Patent

No. 6,616,630, the contents of which are expressly incorporated herein by reference. In some examples, the needle guard 238 can be omitted. If so, the change in profile 234 on the needle can also be omitted. In still other examples, a needle guard 238 can be included without also including a change in profile on the needle. In yet other examples, the needle guard 238 can be located in a third housing between the first hub 110 and the second hub 116. An exemplary needle guard located in a third housing is disclosed in US Pat. No. 8,597,249, the contents of which are expressly incorporated herein by reference. In still other examples, the needle guard can include multiple arms or fingers extending in both a first direction and an opposite second direction as disclosed in US Pat. No. 9,387,307, the contents of which are expressly incorporated herein by reference. For example, the needle guard can include a first protector body surrounded by a second protector body.

[00194] In an example, the needle guard can be made from a metal material and can have a resilient portion that can generate a biasing force. For example, the needle guard can be shaped from a stamped metal sheet. The needle guard can comprise a wall surface that is positioned to a side of the needle and is movable distal of the needle tip to guard the needle tip from accidental contact therewith. The wall surface can be a needle trap and can move directly in front or distal of the point of the needle tip. The wall surface can be located at the distal end of a needle guard arm.

[00195] As shown, the needle guard 238 can include a proximal wall and two arms extending distally of the proximal wall. The two arms can intersect one another in the ready to use position of FIG. 7A, and when viewed from the side view of FIG. 7A. In some examples, the two arms of the needle guard 140 can extend in a distal direction without intersecting one another. Two distal walls, one on each arm, can be incorporated to block the needle tip. The two distal walls can be biased outwardly by the needle 117 in the ready to use position of FIG. 7A and disposed distally of an internal change in profile 250 inside the first hub or catheter hub 110 in the ready to use position. The internal change in profile 250 can be a reduced diameter section located next to an inside diameter section of a larger dimension. The elbows on the two arms of the needle guard can have a dimension that is larger than the inside diameter at the internal change in profile 250 of the catheter hub to restrict proximal movement of the needle guard from the catheter hub until the two arms are no longer biased outwardly or until the dimension at the two elbows are reduced.

[00196] Each distal wall of each arm can include a curved lip to facilitate relative movement between the needle guard 238 and the needle 117. When in the ready to use position, the dimension measured between the two joints or elbows of the two arms, at the intersection between each arm and its respective distal wall, is larger than the inside diameter of the internal change in profile 250, which prevents the needle guard 238 from moving proximally thereof due to the relative dimensions. Once the needle tip 118 moves proximally of the two distal walls, and the two arms no longer biased by the needle, the two arms are allowed to move radially inward and one or both distal walls close over the needle tip to block the needle tip in a protective position. At this point, the dimension between the two joints or elbows decreases and is smaller than the internal dimension of the internal change in profile 250, which then allows the needle guard to move proximally and be removed from the catheter hub with the needle. In alternative embodiments, the dimension between the two joints can be equal to or slightly larger than the internal dimension of the internal change in profile 250 and the needle can still move proximally by flexing or squeezing the two joints to get through the internal change in profile 250.

[00197] The first hub or catheter hub 110 can have a body with a proximal opening 252 having a nose section 254 of the second hub or needle hub 116 disposed therein. The proximal opening 252 of the first hub has a female Luer for receiving a male Luer tip, such as a syringe, an IV tubing connector, a Luer extension set, etc. External threads 256 can be provided on the exterior surface at the proximal end for threaded engagement with a threaded collar of a male threaded Luer tip. A pair of stabilizing wings can extend radially of the first hub 110 to facilitate securement or anchoring of the first hub 110 to a patient following successful venipuncture. Optionally the wings can be omitted. The first hub 110 can embody a standard IV catheter hub without an injection port. In other examples, the first hub can include an injection port, or an integrated extension set. If the wings are not present on the first hub or catheter hub 110, then the bottom of the first hub can have a flattened surface angled at between 2 to 15 degrees from the through axis of the first hub.

[00198] The first hub or catheter hub 110 is removably secured to the second hub 116 by receiving the nose section 254 of the second hub into the proximal opening 252 of the first hub. A flange or extension 260 can be provided on the second hub 116 and together with the nose section 254 define a gap 262 having part of the first hub 110 located therein. Optionally the flange or extension 260 can be omitted and a stub 264 or other surface mating features provided. The stub

264 can be the male part of a key fitting in a gap through or partially into the Luer threads to prohibit rotation of the second hub 116 relative to the first hub 110. The proximal facing end surface of the first hub abuts the distally facing surface of the step in the outside surface of the second hub which is at the proximal end of the nose section 254, which is inside the first hub. This abutment can set the amount of projection of the needle tip 118 out of the catheter tubing 112. The stub 264 can be an optional structural feature.

[00199] The second hub or needle hub 116 has a body 270 having an interior cavity 272 having the proximal end 119 of the needle 117 projecting there-into. The interior cavity 272 can function as a primary blood flashback chamber. The proximal opening 240 of the body 270 can have a female Luer for receiving the vent plug 114 or a syringe tip therein and the exterior can have threads or be without threads. In an example, the exterior of the body 270 of the second hub 116 is generally cylindrical and without threads. The first and second hubs can be made from plastic materials, such as by plastic injection.

[00200] A push tab 278 can be provided with the body 280 of the first hub or catheter hub 110. The push tab 278 can be located on an exterior surface 282 of the first hub 110 at a location distal of the exterior threads 256 so as to avoid interfering with the exterior threads. For example, the push tab 278 should be positioned sufficiently distally of the exterior threads 256 so that when a threaded male connector, such as a syringe type with a threaded collar, is connected to the threads of the first hub, the push tab 278 does not interfere with the connection. In some examples, the push tab 278 should be positioned sufficiently distally of the exterior threads 256 so that when the push tab 278 is folded over, the push tab does not interfere with the connection.

[00201] FIG. 7B is a partial cross-sectional side view of a catheter assembly 102 provided in accordance with further aspects of the invention. The present catheter assembly 102 is similar to the catheter assembly of FIG. 7A with a few exceptions. In the present embodiment, the catheter assembly 102 incorporates a valve 40 and a valve opener 42. For example, a valve and a valve opener can both be located within the interior 244 of the catheter hub 110. After removal of the needle, such as following successful venipuncture, the valve 40 can stop or limit fluid flow across the surface of the valve. In use, such as to form a fluid path through the valve, the valve opener 42 can be pushed distally into the valve 40 to open the one or more slits formed with the valve to open a fluid passage through the valve for fluid flow. An exemplary valved catheter assembly with a valve opener is disclosed in U.S. Patent No. 8,333,735, the contents of which are expressly

incorporated herein by reference. The valve opener 42 can have a nose section 44 having a bore and a plunger section 46 located proximally of the nose section. The nose section 44 can be pushed into the valve to open the one or more slits of the valve, such as three slits defining three flaps. The plunger section 46 can comprise two or more plunger components having a gap therebetween. The gap accommodates the needle guard 235 therebetween and can allow fluid to flow through the plunger components and through the bore in the nose section. In an example, two bridges 48, 50 are provided with each bridge connecting to corresponding edges of the two plunger components of the plunger section. The two bridges and the two plunger components or elements therefore form a continuous section in the radial direction. The continuous section is proximal of the nose section of the valve opener and spaced from the nose section.

[00202] With reference now to FIG. 8, a needle unit 108 comprising a needle hub 116 having a needle 117 with a needle tip 118 is shown with an adaptor 288 and a guidewire dispenser 290. The needle unit 108, adaptor 288, and guidewire dispenser 290 may be used with the catheter unit 106 and stabilizer 104 shown in FIG. 1, such as when the catheter length of the catheter assembly is in the order of about 100 mm, or even longer. However, if the stabilizer 104 can sufficiently support the catheter tube, then the guidewire dispenser may be omitted. The combination shown in FIG. 8 is understood to show a separated view of the components separated from the catheter unit and the stabilizer to more clearly show features of the disclosed components.

[00203] The combination shown in FIG. 8, the needle 112, needle hub 116, adaptor 288, and guidewire dispenser 290, may be referred to as a piercing and guiding unit 294, or PG unit 294. A PG unit 294 may be used with a catheter assembly in which the catheter tube and needle have a relatively longer length, in the order of about 6.0 cm to 20 cm, more typically between about 10 cm to about 20 cm. Such a relatively longer catheter and needle are typically found with midline catheters. However, the PG unit 294 of the present invention is not so limited to the indicated catheter lengths and may in some instances be used with shorter catheters and needles, typically found in peripheral access catheters. Typically following successful venipuncture, the entire PG unit 294 is removed together as a single unit. The PG unit 294 may separate from the catheter hub following successful venipuncture while still coupled to the stabilizer. Where necessary, components of the PG unit 294 can be removed from the catheter hub via piecemeal, starting first with the dispenser 290, then the adaptor 288, then the needle hub 116 with the needle 117, or

combinations thereof. Preferably, the PG unit 294 is removed together as a unit instead of piecemeal.

[00204] The PG unit 294 of FIG. 8, when used with a catheter system 100, such as that of FIG. 1, would replace or substitute for the needle 117, the needle hub 116 and the vent plug 114 shown in FIG. 1. As shown, the PG unit 294 does not utilize a vent plug, which has been removed from the needle hub 116 prior to coupling the dispenser 290 to the needle hub 116 via the adaptor 288. In some examples, the adaptor 288 may be omitted and the dispenser 290 is coupled directly to the needle hub 116. The PG unit 294 shown in FIG. 8 represents a removal state of the PG unit, following successful venipuncture. For example, a user can first grasp the catheter assembly 102 of FIG. 1 with the PG unit 294 of FIG. 8 and guide the tip 118 of the needle 117 through the skin at a suitable insertion site to access a vein. Confirmation of proper vasculature access can be confirmed via primary blood flashback, i.e., the presence of blood in the needle hub 116 and/or in the adaptor 288. The user can then retract the needle tip proximally of the catheter tube opening to observe secondary blood flash back, i.e., the presence of blood between the outer diameter of the needle 117 and the inner diameter of the catheter tube 112 (FIG. 7A). In some instances, the needle can have a through notch formed through the wall of the needle shaft, near the needle tip, or a lengthwise groove by forming a depression lengthwise along the needle shaft. These alternatives allow flashback to be observed between the interior of the catheter tube and the exterior of the needle shaft and can be detected relatively quicker than blood flashback at the needle hub.

[00205] After successful venipuncture is confirmed, the dispenser 290 is activated by applying digital pressure on the guidewire 296 at the advancing or advancement platform 298 of the dispenser 290 and then sliding or feeding the guidewire 296 distally. The guidewire 296, such as the tip of the guidewire, may initially be disposed within the hollow needle 117, may be only initially disposed in the adaptor 288, or may be only initially deposited in the catheter hub 110 (FIG. 7A). In some examples, the guidewire 296 has a length with at least two distinct guidewire sections. For example, the guidewire 296 can have a distal guidewire section of a first diameter and a proximal guidewire section of a second diameter, which can be larger than the first diameter. The first and second diameters can be understood as outside diameters. A shoulder or a gradual taper can locate between the first and second guidewire sections, which may be used to delimit

distal advancement of the guidewire when abutting the shoulder or gradual taper with a structure of the catheter assembly, such as with a crimp in the needle or a reduced gap in the adaptor.

[00206] Distal guidewire advancement continues until the guidewire 296 has been extended to an appropriate amount within the vessel of the patient. In an example, the amount of extension of the guidewire into the vessel may be controlled by fixing the overall length of the guidewire 296 that can extend at the advancement platform 298. For example, the guidewire 296 may have two ends, a first end at the distal end extending through the length of the frame of the dispenser and a second end at the proximal end of the guidewire, at least partly coiled within the holding duct or tube 300, which has a hollow interior and two open ends that connect to the frame or body 301 of the dispenser. The length of the guidewire 296 can be selected so that when the second end of the guidewire is moved to the advancement platform 298 of the body 301, it marks the full extended position of the guidewire 296. The user can then stop further advancement of the guidewire at that point. Optionally a physical stop or an indicator may be provided so that when the guidewire is advanced, the stop or the marker indicates how far the first end of the guidewire has extended distally beyond the needle tip 118. A physical stop is preferred to limit the maximum length the guidewire can extend out of the needle tip. Of course, the user does not have to fully extend the guidewire when using the catheter assembly with the PG unit 294 of the present invention.

[00207] In some examples, the relative lengths of the first and second guidewire sections can be selected to ensure appropriate dispensing of the first guidewire section out of the needle tip, such as to support the catheter tube during catheter insertion. In an example, as the guidewire is dispensed and the first diameter section of the guidewire exits the distal tip opening, the shoulder, the gradual taper, or the second diameter of the guidewire 296 can engage the needle at the crimp to stop distal advancement of the guidewire. A guidewire dispense length is defined from the point where the guidewire engages the crimp to the remote distal end of the guidewire. The guidewire dispense length can be selected to properly support the catheter tube during catheter insertion into the vein. In an example, the length of the guidewire from the far distal end to where the guidewire exits the needle tip, referred to as the support length, is approximately 50% of the length of the catheter tube. In an example, the support length is greater than 50% of the catheter length.

[00208] The catheter tube 112 (FIG. 7A) can now further be inserted into the vessel and be guided by the guidewire 296. As the catheter tube 112 and the catheter hub 110 move distally forward and the catheter tube guided by the guidewire into the vessel, the catheter hub 110

separates, or further separates, from the needle hub 116. As discussed above, the catheter hub pushes the gate 130 to separate the first gate unit section 130a and the second gate unit section 130b (FIGs. 2 and 4) to allow the catheter hub to separate from the stabilizer 104. The catheter tube 112 and catheter hub 110 can be advanced a sufficient amount over the guidewire to ensure successful placement within the vessel. The PG unit 294 can then be removed or separated from the catheter tube and catheter hub with the stabilizer. After removal, the PG unit 294 resembles the PG unit of FIG. 8, separated from the catheter hub and catheter tube, with the needle hub 116 situated in the seat 126 of the stabilizer.

[00209] Where the PG unit 294 of FIG. 8 is used with or as part of the catheter system 100, such as the catheter system 100 of FIG. 1, the method of using the assembly is similar to the process described immediately above except that when the catheter hub 110 is advanced to move the catheter tube 112 over the guidewire 296 (FIG. 8), the catheter hub can open the gate 130 at the distal end of the stabilizer 104 to allow separation of the catheter hub from the frame 128. The PG unit 294 (FIG. 8) can separate from the catheter hub at about the same time.

[00210] FIG. 9 is a partial enlarged cross-sectional view of the catheter assembly 102 of FIG. 7A in use with an adaptor 288 and a dispenser 290. FIG. 9 may also be viewed as the PG unit 294 of FIG. 8 with a catheter unit 106 having a catheter hub 110 located over the needle 117 and the nose section 254 of the needle hub 116 projecting into the open proximal end of the catheter hub 110. As shown, the dispenser 290 has a connection tip 304 that projects into the receiving end of the adaptor 288. The connection tip 304 has a first tip section 306 and a smaller diameter second tip section 308. The size and shape of the connection tip 304, including the first and second tip sections 306, 308, are configured to mate with a matching female bore of the adaptor 288.

[00211] In an example, the engagement between the connection tip 304 and the open proximal end of the adapter 288 is a taper interference fit, similar to a Luer fit but not necessarily formed to the Luer ISO standard. In yet other examples, the adaptor 288 and the connection tip 304 of the dispenser 290 can be provided with a detent or detent-like engagement 310. As shown, the connection tip 304 and the receiving bore of the adaptor 288 can include a raised lip or shoulder and a corresponding recess to form a snap fit for the detent-like engagement. In still other examples, rather than a connection tip 304 with different tip sections, such as different tip diameters, the connection tip can embody a single taper for engaging a corresponding taper of the adaptor, similar to a Luer taper but with non-standard ISO sizes. In yet other examples, the

connection tip 304 is sized and shaped to engage the needle hub directly without the adaptor. That is, in some embodiments, a guidewire dispenser can have a connection tip that connects directly to the needle hub 116 without the adaptor 288 and wherein the body 301 of the dispenser 290 can have two or three diameter sections or a taper. For the dispenser embodiment 290 without an adaptor 288, the connection tip 304 can be extended, such as having a sufficient length, to ensure alignment with the needle proximal opening to facilitate guiding the guidewire 296 into the needle lumen. In other examples, the body of the dispenser 290 can be unitarily formed with the adaptor 288.

[00212] In use, the catheter assembly 102 can be mounted to the frame 128 of the stabilizer 104 and the needle hub 116 located in the seat 126 (FIG. 1). If used, the adaptor 288 can project into the opening of the needle hub 116, after removal of the vent plug, and then the dispenser 290 is projected into the opening of the adaptor 288, as discussed above, with the guidewire extending through the needle lumen. In other examples, the adaptor 288 can be omitted and the connection tip 304 of the dispenser 290 projects into the open end of the needle hub directly to then dispense the guidewire into the lumen of the needle.

[00213] FIGs. 10A-10F show a sequence of views representative of a method for using the catheter system 100 of FIG. 1, or alternatively with the stabilizer of FIG. 5A, and its various components shown in FIGs. 1-7. Although a guidewire dispenser is not shown with respect to these figures, one can be used with the catheter system 100 as described with respect to FIGs. 8 and 9. Refer now to FIG. 10A, the process 312 for using the catheter system 100 can start with gripping the frame 128 of the stabilizer with one hand and removing the protective sleeve or cap 120 with the other hand. Next, place an ultrasound imaging device or ultrasound probe 314 over the targeted vein, as shown in FIG. 10B. The user or practitioner can use the ultrasound probe 314 with the probe hand to monitor the puncture site for proper placement of the needle tip 118. The user can now poke the targeted vein of the patient using the holding hand that holds the catheter system to access the vein with the needle tip 118 and the catheter tube opening 112a. The user can use the ultrasound probe with the probe hand to monitor the puncture. Additionally, proper needle puncture can be confirmed via primary blood flashback and optionally with secondary blood flashback, in addition to verification with the ultrasound probe. Primary flashback occurs when blood flows into the needle lumen and the needle hub hollow interior. Secondary flashback occurs when the needle tip is retracted proximally of the catheter tube opening, or the catheter tube

advancing distally relative to the needle tip by a few millimeters, and blood flows in the annular space between the exterior of the needle and the interior of the catheter tube.

[00214] FIG. 10C shows the catheter hub 110 advanced in the distal direction, and therefore the catheter tube 112 also advanced in the distal direction and into the vein. The holding hand, which grips the stabilizer 104, is held frozen or steady without moving the stabilizer while the catheter hub 110 and the catheter tube are advanced, using different fingers than the holding fingers of one or both hands to push on the catheter hub in the distal direction, such as to push on the push tab 278 (FIG. 7A). The catheter tube should be advanced slowly into the vein while monitoring resistance feedback from the catheter tube as it travels into the vein. There may be some resistance during the advancement prompting the practitioner to adjust the angle, the speed, and/or direction of advancement to adjust.

[00215] If a guidewire dispenser is used, such as the guidewire dispenser 290 of FIGs. 8 and 9, the dispenser can be attached to the needle hub after removal of the vent plug, either with or without the adaptor 288. After confirmation of primary blood flashback, the guidewire may be advanced into the vein prior to the catheter advancement relative to the needle. The practitioner may advance the catheter tube opening just distal off of the needle tip and observe secondary blood flashback before committing to fully advancing the catheter.

[00216] FIG. 10D shows the holding hand gripping the frame 128 of the stabilizer 104 with the thumb and middle finger, possibly also with the ring finger, while advancing the catheter hub 110 in the distal direction with the index finger. The catheter hub 110 is advanced into the wedge ends 178 (FIG. 2) of the two deck gate sections 150a, 150b to then generate a pair of components forces that will cause the control sheet 166, and/or detent engagement, to split at the perforation line 168 (FIG. 3). If no resilient or biasing spring is incorporated with the stabilizer 104, then the catheter hub will move distally until the two deck gate sections 150a, 150b fall to the two sides due to gravity to clear a path for the catheter hub. If a biasing spring, such as the torsion spring 212 of FIG. 6, is incorporated with the stabilizer as shown in FIG. 5, then the two deck gate sections 150a, 150b will be pushed radially by the spring legs to fall to the two sides to clear a path for the catheter hub, which is shown in FIG. 10E. With the stabilizer still held steady by the holding hand, the catheter hub is further advanced towards the patient's skin.

[00217] FIG. 10F shows complete catheter advancement, in which the catheter hub 110 is near the puncture site 318. The PG unit 294 and the stabilizer 104, including the guidewire dispenser

if used, are then retracted away from the catheter tube and the catheter hub. During the retraction, the needle guard 238 is activated over the needle tip to block the needle tip from inadvertent needle sticks. In some instances, the guidewire is removed prior to the needle guard activating to block the needle tip.

[00218] As discussed with reference to FIG. 7B, when a valve and a valve opener are used, the valve 40 will close after removal of the needle to block or limit fluid flow across the valve, such as to stop blood flow into the catheter hub and out the proximal opening of the catheter hub. The valve 40 will allow the practitioner to attach an extension line to the catheter hub and apply suitable securement and dressing while preventing blood from spilling back and out of the proximal opening of the catheter hub.

[00219] With reference now to FIG. 11, a catheter system 100 provided in accordance with further aspects of the invention is shown. The present catheter system 100 comprises a catheter assembly 102 positioned with a stabilizer 104. The catheter assembly 102 can be similar to the catheter assembly discussed above with reference to FIGs. 1, 7A, and 7B and comprises a catheter unit 106 and a needle unit 108. The present catheter system 100 can optionally be used with a guidewire dispenser, similar to the guidewire dispenser shown with reference to FIGs. 8 and 9.

[00220] In the present catheter system 100, the stabilizer 104 has a body 141 comprising a seat 126 and a frame 128 comprising a gate 130 that is configured to separate along a seam 158 when pushed by the catheter hub 110 (FIG. 12), similar to catheter systems described elsewhere herein. The gate 130 comprises a deck gate 150 comprising a first deck gate section 150a and a second deck gate section 150b, similar to the stabilizer 104 of FIGs. 1 and 5A. In the example shown, the frame 128 comprises two arms 324, 326 extending from the seat 126 and having a deck gate section at an end of each arm. The two deck gate sections 150a, 150b join or come together to define a passage to support the catheter tube and the needle, similar to the deck gate 150 of FIGs. 1, 4, and 5A. Following activation, as further discussed below, the two arms 324, 326 spring radially outwardly relative to the central lengthwise axis of the body 320, or relative to the axis of the needle, to separate the two deck gate sections 150a, 150b. However, the two arms 324, 326 remain connected at the seat following activation, as further discussed below.

[00221] In an example, the seat 126 comprises two sidewalls 330a, 330b and a rear wall 330c defining a receiving space 332 for accommodating the needle hub 116. The rear wall 330c can comprise an opening or through hole 188 (FIG. 15) for accommodating a vent plug, an adaptor,

and/or a guidewire dispenser, similar to the rear wall of FIG. 1. The vent plug has been removed in FIG. 11, depicting a situation in which a guidewire dispenser, with an adaptor or without an adaptor, may then be inserted through the opening 188 at the rear wall to couple to the needle hub 116. To retain the needle hub 116 within the receiving space 332, a deck or ledge can extend from each of the two edges 336 of each of the two sidewalls 330a, 330b. The two edges 336 on each sidewall can include a first or upper edge 336a and a second or lower edge 336b. The ledges, which can embody ribs or projections, for retaining the needle hub 116 can extend radially inwardly towards the lengthwise axis to form a partial enclosure around the needle hub 118 to prevent the needle hub from moving distally forward relative to the frame or falling through or out of the receiving space 332, as further discussed below with reference to FIG. 13. In alternative examples, a plurality of tines can extend from the edges 336 to form the holding space for the needle hub, as further discussed below. Said differently, the seat can include structures to physical restrain the needle hub from moving.

[00222] In an example, the seat 126 comprises a plurality of wall surfaces, including two sidewall surfaces 330a, 330b and bottom ribs 370 (FIG. 13), defining a receiving space 332 for receiving the needle hub 116. The two sidewall 330a, 330b limit the needle hub 116 from lateral movement but not axial movement, relative to the lengthwise axis of the frame 128. However, the needle hub 116 is preferably fixed relative to the seat 126 during vascular access and only the catheter hub 110 axially advances to place the catheter tube in the vasculature. For example, the needle hub 116 can frictionally engage the seat 126 to prevent axial movement relative to the seat. In other examples, the seat can have internal baffles or ribs that grip or engage surface features of the needle hub 116 to prevent axial movement of the needle hub relative to the seat. In still other examples, detents, interference, and/or snap fit may be used to secure the needle hub 116 within the seat 126 to resist rotation and/or axial movement relative to the seat. In an example, the needle hub 116 can be provided with laterally spaced notches and the seat 126 of the stabilizer 104 can be provided with projections that mate with the notches. For example, a notch on each of two sides of the needle hub 116 can be incorporated on the body of the needle hub and a notch on each of the inner surface of the two sidewalls 330a, 330b of the seat 126 can be incorporated to engage the two notches on the needle hub.

[00223] The stabilizer 104 may be made from plastic injection molding. In an example, each of the two arms 324, 326 can extend distally from respective base sidewalls and each can be

provided with a film hinge 340. A film hinge 340 is also known as a ribbon spring, which is primarily formed from a flat metal sheet that is malleable and bendable. The bending capability of the film hinge 340 to elastically deform and return to its relaxed state may be used with the present stabilizer. In an example, the flat metal sheet is a stamped stainless-steel sheet that is elongated, generally rectangular in shape, with a length and a width. However, other commercially available metal materials are contemplated, such as an alloy.

[00224] A living hinge 343 and a film hinge or ribbon spring 340 may be used in combination with the present embodiment. In the present embodiment, a living hinge 343 may be provided between each of the two arms 324, 326 and the two respective sidewalls 330a, 330b. The two living hinges allow the arms to be molded with the sidewalls but still allow the two arms to pivot about the two living hinges. A slot 347 is provided through the thickness of each pair of arm and sidewall for receiving the film hinge 340. Thus, the present stabilizer 104 has two slots and two ribbon springs. As shown, each slot is provided through the upper edge of each pairing of arm and sidewall. For example, each slot 347 can have a sidewall slot section 347a and an arm slot section 347b and the slot is sized and shaped to receive a ribbon spring 340. Once installed into the slot 347, the ribbon spring or film hinge 340 is located in both the sidewall slot section 347a and the arm slot section 347b of the slot and straddles the living hinge 343. In an alternative example, a hinge joint with a pivot pin may be used instead of the living hinge shown.

[00225] To restrict the two ribbon springs from falling out of their respective slots, bumps or projections can be molded into the two slots to form narrow sections of the slots. For example, one or more bumps or projections can be molded into the sidewall slot section 347a and the arm slot section 347b of the slot. The narrow sections of the slots squeeze the ribbon springs against interior surfaces of the slots to retain the ribbon springs within the slots. In other words, the ribbon springs are in an interference fit when located inside the respective slot. Optionally, surfaces of the ribbon springs may be scuffed or scraped to increase friction with the bumps or projections inside the slots to further facilitate retention of the ribbon springs within the two slots.

[00226] In an example, each film hinge or ribbon spring 340 is rolled to have a natural bend so that when located in the respective slot 347, the arm 324 or 326 is rotated outwardly away from the lengthwise axis of the stabilizer or relative to the plane defined by each of the sidewalls to which the arms attach, as shown in FIG. 14 and further discussed below. Each film hinge 340 can

be used to provide a resistive or biasing force when moving the arm relative to the sidewall, about the film hinge.

[00227] When the two arms 324, 326 are brought together as shown in FIGs. 11 and 13, a bias or flexed state is generated at each of the two film hinges 340 that tend to push the two arms radially apart to return to their respective unflexed state. In an example, the two arms 324 326 are held in their flexed state, or are biased radially inwardly towards one another, by a detent. In a preferred example, the two arms are held together against the bias of the two ribbon springs 340 by a control sheet 166, similar to the control sheets discussed elsewhere herein. The control sheet 166 of FIG. 11, which has adhesive backing, is adhered to the surface of the deck gate 150 to hold the two arms 324, 326 and the two deck gate sections 150a, 150b together, which tend to separate along the seam 158 at the deck gate 150.

[00228] Each of the two sidewalls 330a, 330b of the seat 126 is generally rectangular and comprises two edges 336, including an upper edge 336a and a lower edge 336b, as previously discussed. With specific reference to the first sidewall 330a, which resembles that of the second sidewall 330b, the distal end has a transition section 342 that reduces the height of the sidewall down to match the profile of the first arm 324. The first arm 324 then extends distally and connects to another transition section 344, which increases in size to match the profile of the gate 130. The two transition sections 342, 344 may be referred to as the first or proximal transition section 342 and the second or distal transition section 344. The two arms 324, 326 between the two sets of transition sections 342, 344 define a low profile open frame section 348 of the frame 128 to enable easy access and movement of the catheter hub 110 as the same is pushed in the distal direction to advance the catheter hub 110 into the actuation gate 182, as further discussed below.

[00229] Like the stabilizer 104 of FIGs. 1, 2, and 4, each of the two deck gate sections 150a, 150b has a body with a wedge end or wedge section 178 and an inner surface 180. Thus, the two wedge ends of the two deck gate sections 150a, 150b have sections along respective inner surfaces 180 that do not contact. In an example, the two wedge ends 178 of the two deck gate sections 150a, 150b form an actuating gate 182 that has a generally V-shape contour. The actuating gate 182 has an end gap 203 (FIG. 12) similar to the end gap of FIG. 1 at the proximal end-most location and wherein the actuating gate 182 converges as it extends in the distal direction to a narrowest point, wherein the two inner surfaces 180 of the two bodies of the two deck gate sections contact

or where a small gap exists. The end gap 203 of the actuating gate 182 is preferably larger than the width of the nose end 186 of the catheter hub 110.

[00230] Thus, following entry of the needle tip into a vein and then advancing the catheter tube over the needle into the vein for vascular access by pushing on the push tab 278 of the catheter hub 110, or by gripping and pushing on the body of the catheter hub, the nose end 186 of the catheter hub 110 will enter the actuating gate 182 where further distal advancement of the catheter hub will cause the nose end to push against the two wedge ends 178 of the actuating gate 182 to cause the two deck gate sections 150a, 150b to separate, such as by first tearing the control sheet 166 along the perforation line, by separating a detent engagement that holds the two deck gate sections together, or both. Once the two deck gate sections separate, by first separating the control sheet at the perforation line or by overcoming the detent, the catheter hub 110 can further distally advance while the stabilizer 104 and needle unit 108 retract in the proximal direction to separate the catheter hub from the needle unit so that the catheter hub and catheter tube remain with the patient while the stabilizer and the needle unit are removed, as further discussed below.

[00231] In an example, the two wedge ends 178 of the two deck gate sections 150a, 150b form an actuating gate 182 that has a generally V-shape that is not constant or that can have a varying V-shape wedge. This allows the nose end 186 of the catheter hub 110 to push against the actuating gate 182 and exert outward forces and push the two wedge ends 178 to separate at different rates. The V-shaped opening can be adjusted to adjust the manner in which the nose end of the catheter hub pushes and separates the two deck gate sections 150a, 150b. For example, the length of the V-shaped opening can shorten to thereby increase the speed of actuation and separation of the two deck gate sections 150a, 150b. The V-shaped profile of the actuating gate 182 can also be adjusted to limit or avoid deformation during product placement.

[00232] The gate 130 has a generally planar distal gate surface 350, which can provide a barrier or a physical stop for the removable sleeve or cap 120 in the proximal direction. Two optional end tabs 129 may be located on the distal gate surface 350 and laterally of the nose section. The seam 158 extends through the distal gate surface 350, and through the bottom exterior surface of the deck gate 150. As further discussed below, a short hollow cylinder extends distally of the distal gate surface for receiving the proximal open end of the sleeve or cap 120 and to serve as part of the passage for supporting the catheter tube. The seam 158 extends through the cylinder to define two half cylinders. The generally rectilinear gate 130 can have surface features for gripping and/or

aesthetics. The various corners 170 where the wall surfaces join can each be rounded or can include a radius and surface features 125 can be incorporated. Optionally, the corners can have a sharp or straight edge, or can include only a small radius.

[00233] FIG. 12 is a partial enlarged view of the catheter system 100 of FIG. 11. The enlarged view shows exemplary surface features of the stabilizer 104. In an example, an upper exterior surface 352 and a lower exterior surface of the two deck gate sections 150a, 150b are provided with undulating surfaces 354 and flat or planar surfaces 356. The undulating surfaces 354 can include recesses 358 located between solid sections 360. The recesses and the solid sections can align in alternating rows, can have uniform lengths, widths, and depths. In an example, the recesses 358 do not extend completely through the body of the two deck gate sections. In some examples, one or more recesses can extend completely through the upper and lower surfaces of the deck gate sections 150a, 150b.

[00234] In alternative embodiments, the undulating surfaces 354 can embody different solid and recess shapes, such as having rounded projections spaced by rounded recesses, or can have random solid and recess shapes. The undulating surfaces 354 allow the two deck gate sections 150a, 150b to be molded with fewer plastic, break up the surface appearance of the gate 130, and provide a unique aesthetic texture. In alternative embodiments, the undulating surfaces can be omitted, and the upper and lower exterior surfaces of the deck gate sections 150a, 150b can have a flat or planar surfaces extending from a proximal end to a distal end.

[00235] The flat planar surface 356 at the distal end of the gate 130, and specifically at the distal ends of the two deck gate sections 150a, 150b, provides a surface for application of the control sheet 166. In an example, the combined surface area of the two planar surfaces 356 of the two deck gate sections is approximately the same as the surface area of the control sheet 166. In particular examples, the combined surface area of the two planar surfaces 356 of the two deck gate sections is greater than the surface area of the control sheet 166. The control sheet 166 is preferably adhered to the gate 130 at a location closer to the distal end than the proximal end of the gate 130. The location of the control sheet 166 on the gate 130, such as being located further distally than a proximal position on the gate, can determine the point in time that the control sheet separates along the perforation line 168 relative to when the nose end 186 of the catheter hub contacts the V-shape contour of the actuating gate 182.

[00236] While embodiments of the invention cover a control sheet 166 having an edge 167 positioned adjacent the distal gate surface 350, one or more recesses 358 can be provided between the edge 167 and the distal gate surface. If incorporated, the one or more distal recesses 358 can extend partially through or completely through the thickness of the gate 130. As shown, two distal recesses 358 are provided, one on each of the deck gate section. A seam 158 passes through the two distal recesses.

[00237] With reference now to FIG. 13, a partial top view of the stabilizer 104 of FIG. 11 is shown, in particular of the seat 126. In the embodiment shown, a plurality of prongs or tines 364 extending inwardly from the upper edges 336a of the two sidewalls 330a, 330b towards the central lengthwise axis of the stabilizer 104. The plurality of tines 364 can be equally spaced apart along the upper edge 336a of each respective sidewall. Each of the plurality of tines 364 has a length, which can substantially be the same. The length of each tine is about 20% to 70% of half of the width of the rear wall 330c. That is, each tine 364 extends from the upper edge 336a towards the central lengthwise axis but short of the central lengthwise axis. In an example, at least one tine 364a from each of the two sidewalls can be longer than the other tines 364 and the two longer tines 364a, 364a can align and can contact one another when the two arms 324, 326 come together and the two deck gate sections 150a, 150b come together in the ready to use position. The two longer tines 364a, 364a can be implemented to fix the width of the seat. The two longer tines 364a, 364 can be distally most tines along the two upper edges or can locate anywhere along the upper edges proximal of the distal most tines. The two longer tines 364a, 364b can also prevent the needle hub from escaping through the upper opening of the receiving space 332.

[00238] At the lower or second edge 336b of each of the two sidewalls, 330a, 330b a ledge or flange 370 extends radially inwardly towards the central lengthwise axis of the stabilizer 104. Each ledge 370 on each lower edge can be a single solid piece having a length extending from the rear wall 330c towards the living hinge 343. The two lower ledges 370 provide a bottom support for the lower surface of the catheter hub. In an example, the plurality of tines 364 and the two ledges 370 define a receiving space 332 for receiving the needle hub therein. That is, when a needle hub of a needle unit or a catheter assembly is located within the receiving space 332, the needle hub is retained therein and is too large to fall through the gaps between the two ledges 370 and between the two sets of tines 364. In an alternative example, the two ledges 370 extending

from the lower edges 336b may instead be practiced with tines, similar to the tines 364 extending from the upper edges 336a.

[00239] In an example, an extended ledge 372 is provided with each of the two arms 324, 326. Each extended ledge 372 is separated from the ledge 370 at the seat 126 by a gap 376, approximately where the living hinge 343 is located. The extended ledges 372 on the two arms 324, 326 function as a track for the catheter hub 110 as the catheter hub is advanced in the distal direction to move the catheter tube over the needle and into the patient's vein. That is, the catheter hub 110 can ride on the surfaces of the two extended ledges 372, 372 when advanced within the frame 128 of the stabilizer 104 during venipuncture. Each extended ledge 372 can have a constant width extending towards the central lengthwise axis as shown or can include tapered or slanted ends as necessary for manufacturing or for clearance purposes, such as to avoid interference between the various components of the catheter system.

[00240] FIG. 14 shows a catheter system 100, in partial view, prior to closing the stabilizer 104 to secure the two arms 324, 326 in their flexed state, such as with detents or a control sheet 166, as discussed above. As shown, the two arms 324, 326 of the stabilizer 104 are spaced from one another in their less flexed state or spread apart state, such as in the activated position. In this state, the two arms, just distal of the two living hinges 343, such as 1 cm distal, 2 cm distal, or 3 cm distal of the film flanges, are spaced from one another a gap Y, which is larger than a gap X at the same distal location when the two arms are in their flexed state, as shown in FIGs. 11 and 13, in which the two arms are held together by detents or by the control sheet at the deck gate 150.

[00241] When the arms 324, 326 are spaced by a gap Y, clearance space is provided between the arms for assembling the catheter assembly 102 into the receiving space 332 at the seat 126 of the stabilizer 104, by sliding the end with the needle hub 116 from a distal position to a proximal position so that the needle hub is located within the receiving space 332 at the seat, between the two sidewalls 330a, 330b and between the set of tines 364 and the set of ledges 370. When a vent plug 114 is attached to the needle hub 116, such as shown, the vent plug 114 can slide into the receiving space 332 first and can be located through the opening 188 (FIG. 15) on the rear wall 330c of the seat so that the vent plug 114 projects proximally of the rear wall 330c. At this point, the two arms 324, 326 can be brought together by pushing the two deck gate sections 150a, 150b together and then retaining them via detents or via a control sheet 166. If a control sheet is used,

the control sheet preferably comprises a perforation line, as shown in FIG. 3, and the perforation line aligns with the seam 158 (FIG. 11) extending between the two deck gate sections 150a, 150b.

[00242] FIG. 15 shows the stabilizer 104 with the two arms 324, 326 in their relaxed or spread apart state, similar to the state shown in FIG. 14. With reference specifically to the second deck gate section 150b, which has similar structures as the first deck gate section 150a, the body of the deck gate has a wedge end 178 and an inner surface 180 comprising an elongated groove 194 that combines with the elongated groove of the first deck gate section 150a to define a passage 196 for accommodating and supporting a catheter tube and a needle of a catheter assembly, as previously discussed. A half cylinder nose section 378 projects distally of the distal gate surface 350. When the two deck gate sections 150a, 150b are joined, the two elongated grooves 194 and the two half cylinder nose sections 378 combine to define the passage 196 for supporting the catheter tube and needle. The two half cylinder nose sections 378 combine to form a cylindrical nose section.

[00243] In an example, the passage 196 defined by the two deck gate sections 150a, 150b, which has a length, can stabilize a catheter assembly with extended needle and catheter lengths, in the order of about 7.5 cm to 20 cm. Such a relatively longer catheter and needle are typically found with midline catheters. However, the catheter assembly 102 usable with the stabilizer of the present invention is not so limited and may in some instances be used as shorter catheters and needles, typically found in peripheral access catheters, or longer catheters. By using the disclosed stabilizer 104 with the catheter system 100, catheterization with long catheters, up to 100 mm or 10 cm, in length may be used without a guidewire. However, if a guidewire becomes necessary, a guidewire dispenser, such as that shown in FIGs. 8 and 9, may be used as described elsewhere herein.

[00244] With reference now to FIG. 15A and 15B, a partial top view and a partial bottom view, respectively, of the stabilizer 104 of FIG. 15 are shown. From the top view, the two wedge ends 178 of the two deck gate sections 150a, 150b are shown, which defines an actuation gate 182, as previously discussed. With further reference to FIG. 15, each of the two deck gate sections 150a, 150b is further provided with a rib 430 extending from a lower edge 432. Each rib 430 can have a thickness and a length, in the lengthwise direction of the stabilizer, and a width that is measured orthogonally to the lengthwise direction. Each rib 430 has a shape that is approximately a reverse taper of the wedge end 178 so that the two end surfaces 434 of the two ribs 430 contact one another along a contact line 438. The contact line 438 can be inline with the seam 158. When incorporated,

the contact between the two end surfaces 434 of the two ribs prevent the two inner surfaces 180 of the two deck gate sections 150a, 150b from coming together and possibly into contact when a sufficiently high squeezing pressure is applied to the two arms 324, 326.

[00245] FIG. 15C depicts a schematic top view of a stabilizer 104 provided in accordance with further aspects of the invention is shown. Schematically, the stabilizer comprises two deck gate sections 150a, 150b, two arms 324, 326, and a seat 126, similar to the stabilizer of FIGs. 11-15B. In the present embodiment, an alignment mechanism 450 is provided for aligning relative axial positions of components of the stabilizer. For example, when the two deck gate sections 150a, 150b are forced together and held together by detents and/or a control sheet 166 (FIG. 3) as previously discussed, end surfaces of the two half-cylinder nose sections 378 that form part of the passage 196 are aligned, such as not materially shifted relative to one another. In an example, the alignment mechanism 450 is practiced by incorporating a recessed receptacle 452 on the upper surface 454 of the first deck gate section 150a. The recessed receptacle 452 has lips 458 that are generally U-shaped for receiving a tab 460 extending from the second deck gate section 150b. The tab 460 has a plurality of edges 462 that are sized and shaped to fit within the recessed receptacle 452 and bounded by the plurality of lips 458. Thus, when the two deck gate sections 150a, 150b are joined and the tab 460 engages the recessed receptacle 452, the alignment mechanism 450 ensures axial alignment of the various components of the stabilizer, such as axial alignment of end surfaces of the two half cylinders 378 at the distal ends of the two deck gate sections.

[00246] In yet another alternative embodiment, the stabilizer 104 of FIGs. 11, 12, and 15 may incorporate the alignment mechanism 393 of FIGs. 4A and 4B, instead of or in addition to the alignment mechanism of FIG. 15C.

[00247] FIG. 15D is a front view of an exemplary stabilizer 104 in accordance with aspects of the invention. The stabilizer 104 is shown with two half cylinders 378 joined together along a seam 158 and defining a passage 196, as previously discussed. In the present embodiment, a baffle system 470 is incorporated at the inner surfaces of the two deck gate sections 150a, 150b so that when they meet at the seam 158, a baffle 472 from one deck gate section, which can be a rib or a tab, fits within a groove 474 of the other deck gate section. As shown, each deck gate section has a baffle and a groove and two engagements between opposing baffle and groove are formed when the two gate sections are joined. Optionally, only a lower set of baffle and groove is implemented. When incorporated, the baffle system 470 helps to prevent the two arms 324, 326 and the two deck

gate sections 150a, 150b of the stabilizer from separating upon downward force exerted by the needle, such as when pressing the needle tip down and lifting the proximal end up. The baffle system provides physical support against downward push on the needle.

[00248] In alternative examples, the baffle system 470 is located on the inner surfaces of the first deck gate section 150a and the second deck gate section 150b. For example, baffles and grooves can be located in the elongated grooves 194 of the first and second deck gate sections or can be located below the elongated grooves.

[00249] FIGs. 16A-16F show a sequence of views representative of a method for using the catheter system 100 of FIG. 11 and its various components shown in FIGs. 3, 7A, 7B, and 12-15. Although a guidewire dispenser is not shown with respect to these figures, one can be used with the catheter system as described with respect to FIGs. 8 and 9 and elsewhere herein. Refer now to FIG. 16A, the process 380 for using the catheter system 100 can start with gripping the frame 128 with one hand and removing the protective sleeve or cap 120 with the other hand. Next, place an ultrasound imaging device or ultrasound probe 314 over the targeted vein, as shown in FIG. 16B. The user or practitioner can use the ultrasound probe 314 with the probe hand to monitor the puncture site for proper placement of the needle tip 118. The user can now poke the targeted vein of the patient using the holding hand that holds the catheter system to access the vein with the needle tip 118 and the catheter tube opening 112a (FIG. 7). The user can use the ultrasound probe with the probe hand to monitor the puncture. Additionally, proper needle puncture can be confirmed via primary blood flashback, in addition to verification with the ultrasound probe. Primary flashback occurs when blood flows into the needle lumen and the catheter hub hollow interior. Optionally, secondary flashback, which occurs when the needle tip is retracted proximally of the catheter tube opening or the catheter tube advancing distally relative to the needle tip by a few millimeters and blood flows in the annular space between the exterior of the needle and the interior of the catheter tube, may be observed before fully advancing the catheter tube.

[00250] FIG. 16C shows the catheter hub 110 advanced in the distal direction, and therefore the catheter tube 112 also advanced in the distal direction and into the vein. The holding hand, which grips the stabilizer 104, is re-gripped to hold the stabilizer at the rear of the frame 128, such as to grip the seat 126. The catheter hub 106 is then advanced using the other hand, or the non-holding hand, such as by pushing on the catheter hub at the push tab 278 (FIG. 7A). In another example, the catheter hub can be gripped from above and below the frame to advance the catheter tube using

two gripping fingers, such as with the thumb and the index finger. The catheter tube should be advanced slowly into the vein while monitoring resistance feedback from the catheter tube as it passes into the vein. There may be some resistance during the advancement prompting the practitioner to adjust the angle, the speed, and/or direction of advance to adjust.

[00251] If a guidewire dispenser is used, such as the guidewire dispenser 290 of FIGs. 8 and 9, the dispenser can be attached to the needle hub after removal of the vent plug, either with or without the adaptor 288. After confirmation of primary flashback, the guidewire may be advanced into the vein prior to the catheter advancement relative to the needle. Optionally, after the guide wire is advanced and there is partial catheter advancement over the advanced guidewire, secondary flashback may be observed to ensure the catheter is in the vein prior to more fully advancing the catheter.

[00252] FIG. 16D shows the holding hand gripping the frame 128 of the stabilizer 104 with the thumb and middle finger, possibly also with the ring finger, while advancing the catheter hub in the distal direction with the index finger on the push tab or with two fingers gripping the catheter hub from above and below the frame. The catheter hub 110 is advanced into the wedge ends 178 (FIGs. 11 and 15) of the two deck gate sections 150a, 150b to then generate a pair of components forces that will cause the control sheet 166, or detents, to split at the perforation line 168 or at the seam (FIG. 3). Once the perforation line splits, the self-biasing of the two arms by the two film hinges or ribbon springs 340 (FIGs. 11 13, and 14) will unflex and move the two arms 324, 326 radially away from one another to provide clearance for the catheter hub, as shown in FIG. 16E. With the stabilizer 104 still held steady by the holding hand, the catheter hub 110 is further advanced towards the patient's skin.

[00253] FIG. 16F shows complete catheter advancement, in which the catheter hub 110 is near the puncture site 318. The PG unit 294 and the stabilizer 104, including the guidewire dispenser if used, are then retracted away from the catheter tube and the catheter hub. During the retraction, the needle guard 238 (FIG. 7A) is activated over the needle tip to block the needle tip from inadvertent needle sticks.

[00254] Methods of making and of using catheter systems and components thereof, such as catheter assemblies, stabilizers, and guidewire dispensers, are within the scope of the present invention.

[00255] As used herein, the spelling of the word adapter and adaptor are understood to have the same general meaning, but which can be modified with further disclosed structures about specific type of adapters.

[00256] Although limited embodiments of catheter systems and their components, such as catheter assemblies, stabilizers and guidewire dispensers, have been specifically described and illustrated herein, many modifications and variations will be apparent to those skilled in the art. Accordingly, it is to be understood that the catheter systems and their components constructed according to principles of the disclosed device, system, and method may be embodied other than as specifically described herein. The disclosure is also defined in the following claims.

[00257] Example Embodiments:

[00258] The following are numbered example embodiments of methods, systems, and devices involving a medical device comprising a stabilizer and a catheter assembly for use with the stabilizer. Examples 1-106 or any other examples disclosed herein may be combined in whole or in part unless indicated otherwise. Elements of the examples disclosed herein, if applicable, are not limiting.

[00259] Example 1. A catheter system comprising: a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip of the needle extending distally of an opening of the catheter tube; a stabilizer comprising a frame having a body comprising a seat and a gate unit having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and the second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame; wherein the needle hub is located in the seat and a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and wherein the first deck gate section and the second deck gate section are held together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are held together by a detent or a control sheet having an adhesive layer attached to both the first deck gate section and the second deck gate section.

[00260] Example 2. Wherein each of the first deck gate section and the second deck gate section can have a wedge end at a proximal end and wherein the two wedge ends, when the first deck gate section and the second deck gate section are held together, can have a generally V-shape contour,

said generally V-shape contour being sized and shaped to be pushed by a distal end of the catheter hub.

[00261] Example 3. Wherein the first deck gate section and the second deck gate section can be held together by the control sheet comprising a perforation line.

[00262] Example 4. Wherein the perforation line is aligned with the seam.

[00263] Example 5. Wherein the first deck gate section is attached to a first base portion and the first base portion is pivotably attached to the frame.

[00264] Example 6. Wherein the second deck gate section is attached to a second base portion and the second base portion is pivotably attached to the frame.

[00265] Example 7. A spring can be provided, the spring having a first spring leg biased against the first base portion and a second spring leg biased against the second base portion.

[00266] Example 8. Wherein the seat is unitarily formed with the body of the frame and the gate unit is pivotably attached to the frame.

[00267] Example 9. Wherein the seat comprises a plurality of wall surfaces defining a cavity having the needle hub located therein, the plurality of wall surfaces including two spaced apart sidewalls, a bottom wall, and the rear wall.

[00268] Example 10. The rear wall of the seat can have an upper edge that is the same as the upper edges of the two sidewalls, can be higher than the upper edges of the two sidewalls, or lower than the upper edges of the two sidewalls.

[00269] Example 11. A plurality of raised surface features can be located on respective exterior surfaces of the two sidewalls.

[00270] Example 12. A needle guard can be located in an interior cavity of the catheter hub.

[00271] Example 13. The needle guard can have a proximal wall and two extends extending distally of the proximal wall.

[00272] Example 14. Each of the two arms of the needle guard can have a distal blocking wall.

[00273] Example 15. The two arms on the needle guard can intersect one another along a side view.

[00274] Example 16. A valve and a valve opener located in the interior cavity of the catheter hub.

[00275] Example 17. The valve opener can have two plunger elements and two bridges connected to the plunger elements.

- [00276] Example 18. At least part of the needle guard can be located inside the valve opener.
- [00277] Example 19. The body of the stabilizer can have a generally triangular shape along a side view.
- [00278] Example 20. The triangular shaped body of the frame can have a first edge, a second edge angled to the first edge, and a far edge angled to both the first and second edges.
- [00279] Example 21. An apex or low point of the body can be located between the first edge and the far edge.
- [00280] Example 22. The second edge of the body can have a bend and the gate unit extends from a location distal of the bend.
- [00281] Example 23. A transition section that enlarges a width of the second edge to a second width at an end of the transition section can be provided on the second edge of the body.
- [00282] Example 24. The seat can have a width that is approximately equal to the second width.
- [00283] Example 25. The seat and the gate unit can have wall surfaces that extend upwardly higher, elevation-wise, than the second edge of the body of the frame.
- [00284] Example 26. An adapter can project into the opening on the rear wall of the seat and the proximal opening of the needle hub and a guidewire can pass through the adapter.
- [00285] Example 27. The adapter can have a nose section with an opening projecting into the needle hub.
- [00286] Example 28. A proximal end of the needle can project into the opening on the nose section of the adapter.
- [00287] Example 29. A guidewire dispenser and the guidewire can pass through a passage on the dispenser before passing through the adapter.
- [00288] Example 30. A guidewire dispenser can project into the opening on the rear wall of the seat and the proximal opening of the needle hub and a guidewire can extend out a tip of the guidewire dispenser and extend through the catheter hub and the catheter tube.
- [00289] Example 31. The seat can comprise a first sidewall and a second side wall, and wherein the frame can have a first arm that extends from the first sidewall and a second arm that extends from a second side wall.
- [00290] Example 32. The seat can comprise a first sidewall and a second side wall, and wherein the frame can have a first arm that extends distally of the first sidewall and a second arm that extends distally of a second side wall.

[00291] Example 33. The first sidewall can have a height, and the first arm can have a length and a height that is orthogonal the length, and wherein the height of the first sidewall is larger than the height of the first arm.

[00292] Example 34. The first sidewall can have an upper edge and a plurality of spaced apart tines extending from the upper edge.

[00293] Example 35. The first sidewall has a lower edge and a ledge extending from the lower edge.

[00294] Example 36. The second sidewall can have an upper edge and a plurality of spaced apart tines extending from the upper edge of the second sidewall.

[00295] Example 37. A gap is provided between the plurality of spaced apart tines extending from the upper edge of the first sidewall and the plurality of spaced apart tines extending from the upper edge of the second sidewall.

[00296] Example 38. The first deck gate section is located at a distal end of the first arm and the second deck gate section is located at a distal end of the second arm.

[00297] Example 39. The first deck gate section can be unitarily formed with the first arm and the second deck gate section can be unitarily formed with the second arm.

[00298] Example 40. The control sheet can adhere to a planar surface on the first deck gate section and a planar surface on the second deck gate section.

[00299] Example 41. The control sheet can have two opposed indentations aligned with a perforation line passing through the control sheet.

[00300] Example 42. The perforation line can comprise a plurality of slits and solid sections.

[00301] Example 43. The control sheet can be located distally of an undulating surface on the first deck gate section and an undulating surface on the second deck gate section.

[00302] Example 44. The passage through the gate unit along the seam can comprise a first groove section that is larger than a distally located second groove section.

[00303] Example 45. The first deck gate section and the second deck gate section can be hinged to the frame.

[00304] Example 46. The first deck gate section can be hinged to the frame by a first living hinge and the second deck gate section can be hinged to the frame by a second living hinge.

[00305] Example 47. The first deck gate section can be hinged to the frame by one or more pins aligned with one or more hinge barrels to pivot along a first common axis, and the second

deck gate section can be hinged to the frame by one or more pins aligned with one or more hinge barrels to pivot along a second common axis.

[00306] Example 48. A half cylindrical nose section can extend distally of a distal gate surface of the first deck gate section and a half cylindrical nose section can extend distally of a distal gate surface of the second deck gate section.

[00307] Example 49. The two half cylindrical nose sections can define a nose section have a bore and the catheter tube and the needle extending through the bore.

[00308] Example 50. A film hinge can be provided between the first sidewall and the first arm and a second film hinge can be provided between the second sidewall and the second arm.

[00309] Example 51. An adapter can project into the opening on the rear wall of the seat and the proximal opening of the needle hub and a guidewire can pass through the adapter.

[00310] Example 52. A guidewire dispenser can project into the opening on the rear wall of the seat and the proximal opening of the needle hub and a guidewire can extend out a tip of the guidewire dispenser and extend through the catheter hub and the catheter tube.

[00311] Example 53. The two arms, including the first arm and the second arm, can be pivotable outwardly in a relaxed state and pivotable inwardly in a flexed state.

[00312] Example 54. The spring can be a torsion spring having a plurality of coils, and wherein the plurality of coils can be mounted around a body of a mounting platform.

[00313] Example 55. The body of the mounting platform can have an enlarged head and a base, and wherein the enlarged head can be located proximally of the base.

[00314] Example 56. The body of the mounting platform can have an enlarged head and a base, and wherein the enlarged head can be located distally of the base.

[00315] Example 57. The body of the mounting platform can have a receiving pocket located between the enlarged head and the base and the plurality of coils can be located around the receiving pocket.

[00316] Example 58. The body of the mounting platform can have a receiving pocket located between the enlarged head and the base and the plurality of coils can be located around the receiving pocket.

[00317] Example 59. The body of the frame can comprise a recessed surface at or adjacent a low point of the frame, the recessed surface being sized and shaped for gripping.

[00318] Example 60. A plurality of spaced apart diamond-shaped projections can be located at the recessed surface.

[00319] Example 61. The first arm can comprise an arm slot section having a ribbon spring located therein.

[00320] Example 62. The arm slot section can comprise a projection pressing against a surface of the ribbon spring.

[00321] Example 63. The first sidewall can have a sidewall slot section and wherein the ribbon spring is located in the sidewall slot section.

[00322] Example 64. The sidewall slot section can comprise a projection pressing against a surface of the ribbon spring, spaced from the projection in the arm slot section.

[00323] Example 65. A hinge can be located between the first sidewall and the first arm.

[00324] Example 66. The second arm can comprise an arm slot section having a ribbon spring located therein, wherein the ribbon spring located in the arm slot of the first arm can be a first ribbon spring and the ribbon spring located in the arm slot of the second arm can be a second ribbon spring.

[00325] Example 67. The arm slot section of the second arm can comprise a projection pressing against a surface of the second ribbon spring.

[00326] Example 68. The second sidewall can have a sidewall slot section and wherein the second ribbon spring can be located in the sidewall slot section of the second sidewall.

[00327] Example 69. The sidewall slot section of the second sidewall can comprise a projection pressing against a surface of the second ribbon spring, spaced from the projection in the arm slot section of the second arm.

[00328] Example 70. A hinge can be located between the second sidewall and the second arm.

[00329] Example 71. The seat can be mechanically coupled to the needle hub by a combination of projections and notches or divots to prevent rotation of the needle hub relative to the seat.

[00330] Example 72. The notches or divots can be located on the needle hub and the projections can be located on the seat.

[00331] Example 73. The first deck gate section can be attached to the first arm and the second deck gate section can be attached to the second arm.

[00332] Example 74. Wherein each of the first deck gate section and the second deck gate section can have a wedge end at a proximal end and wherein the two wedge ends, when the first

deck gate section and the second deck gate section come into contact, have a generally V-shape contour, said generally V-shape contour being sized and shaped to be pushed by a distal end of the catheter hub.

[00333] Example 75. The first deck gate section can have a lower edge, and wherein a first rib can extend from the lower edge towards a lengthwise axis of the stabilizer and has an end surface.

[00334] Example 76. The second deck gate section can have a lower edge, and wherein a second rib can extend from the lower edge of the second deck gate section towards the lengthwise axis of the stabilizer and has an end surface.

[00335] Example 77. The end surface of the first rib can contact the end surface of the second rib along a contact line.

[00336] Example 78. The contact line and the seam can be parallel.

[00337] Example 79. The first deck gate section can have a planar distal gate surface, and the second deck gate section can have a planar distal gate surface and the planar distal gate surface.

[00338] Example 80. A baffle system can comprise a baffle and a groove on the needle hub can engage one another to limit axial movement of the needle hub.

[00339] Example 81. The first deck gate section can have one of a tab or a recessed receptacle and the second deck gate section can have the other one of the tab or the recessed receptacle.

[00340] Example 82. Wherein the tab can be received in the recessed receptacle for axial alignment.

[00341] Example 83. The control sheet can be made from a plastic-based material.

[00342] Example 84. The opening on the rear wall of the seat can have a non-continuous perimeter.

[00343] Example 85. The opening on the rear wall of the seat can have a continuous perimeter.

[00344] Example 86. The rear wall on the seat can provide physical obstruction to prevent proximal movement of the needle hub.

[00345] Example 87. A method of making a catheter system comprising: forming a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip extending distally of an opening of the catheter tube; forming a stabilizer comprising a frame having a body comprising a seat and a gate having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and a second deck gate section are located at a first end

of the frame and spaced from the seat, which is located at a second end of the frame; placing the needle hub in the seat such that a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and securing the first deck gate section and the second deck gate section together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are secured together by a detent or a control sheet having an adhesive layer attached to both the first gate deck and the second gate deck.

[00346] Example 88. A method of using a catheter system comprising: unpacking the catheter system from an outer packaging, wherein the catheter system comprises: a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip extending distally of an opening of the catheter tube; a stabilizer comprising a frame having a body comprising a seat and a gate having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and the second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame; wherein the needle hub is located in the seat and a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and wherein the first deck gate section and the second deck gate section are held together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are held together by a detent or a control sheet having an adhesive layer attached to both the first gate deck and the second gate deck; advancing the catheter hub relative to the needle hub so that the catheter hub abuts an actuating gate at a proximal end of the first and second gate decks.

[00347] Example 89. Wherein the control sheet has a perforation line aligned with the seam and wherein a distal force is generated when advancing the catheter hub that tears the perforation line.

[00348] Example 90. A catheter system comprising: a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip of the needle extending distally of an opening of the catheter tube; a stabilizer comprising a frame having a body comprising a seat and a gate unit having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate

section and the second deck gate section are located at a first end of the frame and spaced from the seat; wherein the needle hub is located in the seat and a vent plug or a guidewire from a guidewire dispenser projects through the needle hub; wherein the first deck gate section and the second deck gate section are held together by a detent or a control sheet having an adhesive layer attached to both the first deck gate section and the second deck gate section; and wherein the first deck gate section and the second deck gate section are pivotable relative to the seat.

[00349] Example 91. A stabilizer for use with a catheter assembly, the stabilizer comprising: a frame having a body comprising a seat and a gate unit having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and the second deck gate section are located at a first end of the frame and spaced from the seat; wherein the first deck gate section and the second deck gate section are held together by a detent or a control sheet having an adhesive layer attached to both the first deck gate section and the second deck gate section; wherein the first deck gate section and the second deck gate section are pivotable relative to the seat; and wherein a wedge end on each of the first deck gate section and the second deck gate section define an actuating gate that is configured to separate along the seam.

[00350] Example 92. The stabilizer wherein the first deck gate section is located at an end of a first arm and the second deck gate section is located at an end of a second arm.

[00351] Example 93. The stabilizer wherein the first arm is hinged to the seat and the second arm is hinged to the seat.

[00352] Example 94. The stabilizer wherein the first arm is hinged to the seat by a first film hinge and the second arm is hinged to the seat by a second film hinge.

[00353] Example 95. The stabilizer wherein the first deck gate section is hinged to the body of the frame and the second deck gate section is hinged to the body of the frame.

[00354] Example 96. Wherein the hinge is a living hinge or a pin and barrel type hinge.

[00355] Example 97. A method of making a stabilizer for use with a catheter assembly, the stabilizer comprising: forming a frame having a body comprising a seat and a gate unit having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and the second deck gate section are located at a first end of the frame and spaced from the seat; wherein the first deck gate section and the second deck gate section are held together by a detent or a control sheet having an adhesive layer attached to both the first deck gate section and the second deck gate section; wherein the first deck gate section and the

second deck gate section are pivotable relative to the seat; and wherein a wedge end on each of the first deck gate section and the second deck gate section define an actuating gate that is configured to separate along the seam.

[00356] Example 98. A catheter hub assembly can be used with the stabilizer.

[00357] Example 99. An adapter can be used with the catheter hub.

[00358] Example 100. A guidewire dispenser can be used with the adapter or directly with the catheter hub.

[00359] Example 101. Wherein an alignment mechanism comprises a first alignment part located on an interior of the first deck gate section and a second alignment part for engagement with the first alignment part located on an interior of the second date gate section.

[00360] Example 102. Wherein the first alignment part is a groove or a projection and the second alignment part is the other of the groove or the projection.

[00361] Example 103. Wherein the body of the frame has a first sidewall slot having a first film hinge located therein and a second sidewall slot having a second film hinge located therein.

[00362] Example 104. Wherein the first sidewall slot has an arm slot section located on a first arm and a sidewall slot section located on a first sidewall of the seat on the frame of the stabilizer.

[00363] Example 105. Wherein the second sidewall slot has an arm slot section located on a second arm and a sidewall slot section located on a second sidewall of the seat on the frame of the stabilizer.

[00364] Example 106. Wherein a first living hinge connects the first arm and the first sidewall and a second living hinge connects the second arm and the second sidewall.

CLAIMS

What is claimed is:

1. A catheter system comprising:

a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip of the needle extending distally of an opening of the catheter tube;

a stabilizer comprising a frame having a body comprising a seat and a gate unit having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and the second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame;

wherein the needle hub is located in the seat and a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and

wherein the first deck gate section and the second deck gate section are held together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are held together by a detent or a control sheet having an adhesive layer attached to both the first deck gate section and the second deck gate section.

2. The catheter system of claim 1, wherein each of the first deck gate section and the second deck gate section has a wedge end at a proximal end and wherein the two wedge ends, when the first deck gate section and the second deck gate section are held together, have a V-shape contour, said V-shape contour being sized and shaped to be pushed by a distal end of the catheter hub.

3. The catheter system of any one of claims 1 or 2, wherein the first deck gate section and the second deck gate section are held together by the control sheet comprising a perforation line.

4. The catheter system of claim 3, wherein the perforation line is aligned with the seam.

5. The catheter system of any one of claims 1 to 4, wherein the first deck gate section is attached to a first base portion and the first base portion is pivotably attached to the frame.

6. The catheter system of claim 5, wherein the second deck gate section is attached to a second base portion and the second base portion is pivotably attached to the frame.

7. The catheter system of any one of claims 1 to 6, wherein the seat is unitarily formed with the body of the frame and the gate unit is pivotably attached to the frame.

8. The catheter system of any one of claims 1 to 7, further comprising a needle guard located in an interior cavity of the catheter hub.

9. The catheter system of any one of claims 1 to 8, wherein the body of the stabilizer has a generally triangular shape along a side view.

10. The catheter system of any one of claims 1 to 9, further comprising an adapter projecting into the opening on the rear wall of the seat and the proximal opening of the needle hub and a guidewire

11. The catheter system of claim 10, further comprising a guidewire dispenser and the guidewire passes through a passage on the guidewire dispenser before passing through the adapter.

12. The catheter system of any one of claims 1 to 11, further comprising a guidewire dispenser projecting into the opening on the rear wall of the seat and the proximal opening of the needle hub and a guidewire extends out a tip of the guidewire dispenser and extending through the catheter hub and the catheter tube.

13. The catheter system of any one of claims 1 to 12, wherein the seat comprises a first sidewall and a second side wall, and wherein the frame has a first arm that extends from the first sidewall and a second arm that extends from a second side wall.

14. The catheter system of any one of claims 1 to 13, wherein the control sheet is adhered to a planar surface on the first deck gate section and a planar surface on the second deck gate section.

15. The catheter system of any one of claims 1 to 14, wherein the control sheet is located distally of an undulating surface on the first deck gate section and an undulating surface on the second deck gate section.

16. The catheter system of any one of claims 1 to 15, wherein the passage along the seam comprises a first groove section that is larger than a distally located second groove section.

17. The catheter system of any one of claims 1 to 16, further comprising a half cylindrical nose section extending distally of a distal gate surface of the first deck gate section and

a half cylindrical nose section extending distally of a distal gate surface of the second deck gate section.

18. The catheter system of any one of claims 1 to 17, wherein the body of the frame comprises a recessed surface at or adjacent a low point of the frame, the recessed surface being sized and shaped for gripping.

19. The catheter system of any one of claims 1 to 18, wherein the opening on the rear wall of the seat has a non-continuous perimeter.

20. The catheter system of any one of claims 1 to 19, wherein the opening on the rear wall of the seat has a continuous perimeter.

21. The catheter system of any one of claims 1 to 20, wherein the rear wall on the seat provides physical obstruction to prevent proximal movement of the needle hub.

22. A method of making a catheter system comprising:

forming a catheter assembly comprising a catheter hub having a catheter tube and a needle hub having a needle projecting through the catheter tube with a needle tip extending distally of an opening of the catheter tube;

forming a stabilizer comprising a frame having a body comprising a seat and a gate having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and a second deck gate section are located at a first end of the frame and spaced from the seat, which is located at a second end of the frame;

placing the needle hub in the seat such that a proximal opening of the needle hub is aligned with an opening on a rear wall of the seat for receiving a vent plug or a guidewire from a guidewire dispenser; and

securing the first deck gate section and the second deck gate section together against a bias force tending to push the first deck gate section and the second deck gate section away from one another, the first and second deck gate sections are secured together by a detent or a control sheet having an adhesive layer attached to both the first gate deck and the second gate deck.

23. A stabilizer for use with a catheter assembly, the stabilizer comprising:

a frame having a body comprising a seat and a gate unit having a first deck gate section and a second deck gate section joined together to define a passage along a seam, the first deck gate section and the second deck gate section are located at a first end of the frame and spaced from the seat;

wherein the first deck gate section and the second deck gate section are held together by a detent or a control sheet having an adhesive layer attached to both the first deck gate section and the second deck gate section;

wherein the first deck gate section and the second deck gate section are pivotable relative to the seat; and

wherein a wedge end on each of the first deck gate section and the second deck gate section define an actuating gate that is configured to separate along the seam.