

LOW PROFILE ACCESS SHEATHS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Patent App. Nos. 63/272,750, filed 28 October 2021, and 63/413,098, filed 4 October 2022, the entire contents of each of which are incorporated by reference herein.

TECHNICAL FIELD

[0002] The present disclosure is directed to non-peel away introducer sheath assemblies and dilator assemblies that may permit the introduction of one or more medical devices into a patient at a single insertion site, such introducer sheath assemblies having a hemostatic valve to reduce or eliminate the discharge of body fluids from the patient through the insertion site of an introducer sheath assembly.

BACKGROUND

[0003] A mechanical circulatory support device (*e.g.*, an intracardiac heart pump assembly) or other medical devices, can be introduced into a patient in various ways. A common approach is to introduce the device through the vascular system either surgically or percutaneously during a cardiac procedure. If the medical device is expected to remain in the patient for an extended period of time, typically utilized peel-away introducer sheaths may be peeled away and replaced with a smaller diameter sheath preinstalled on the medical device (*e.g.*, a repositioning sheath), to reduce the risk of blockages in the bloodstream.

BRIEF SUMMARY

[0004] A first aspect is drawn to a device for insertion into a vasculature of a patient, where the device comprises a primary tubular sheath body, an intermediate tubular sheath body connected to a proximal end of the primary tubular sheath body, and a hub connected to a proximal portion of the intermediate tubular sheath body. The primary tubular sheath body is comprised of a first material, the intermediate tubular sheath body is comprised of a second material, and the hub is comprised of a third material, where a theoretical interfacial bonding strength between the first and second material, and a theoretical interfacial bonding strength between the third material and the second material, are both greater than a theoretical interfacial bonding strength between the first material and the third material.

[0005] In some embodiments, the intermediate tubular sheath body may have a first inner diameter at its distal end, and a second inner diameter at an axial distance proximal to the distal end, the second inner diameter being greater than the first inner diameter. In some embodiments, the second inner diameter may be between 5 mm and 6 mm.

[0006] In some embodiments, the first material may comprise a polyether block amide (PEBA). In some embodiments, the second material may comprise a thermoplastic styrene-butadiene copolymer. In some embodiments, the third material may comprise acrylonitrile butadiene styrene.

[0007] In some embodiments, the primary tubular sheath body may comprise a plurality of layers. These layers may include, *e.g.*, a frame layer and an outer jacket. In some embodiments, the frame layer may comprise nitinol, and the outer jacket may comprise a polyether block amide (PEBA).

[0008] In some embodiments, the device may include a sideport extending from the hub.

[0009] In some embodiments, the hub may comprise a rotatable portion that is rotatable relative to the hub, the primary tubular sheath body, and the intermediate tubular sheath body, the rotatable portion being connected to a distal portion of the hub. In some embodiments, the rotatable portion may be rotatable (*i.e.*, capable of being rotated) by at least 180 degrees. In some embodiments, the rotatable portion may be rotatable by at least 360 degrees. In some embodiments, the rotatable portion may be configured to allow a sideport extending from the hub to lie flat against a patient. In some embodiments, the rotatable portion may comprise a butterfly, a suture pad, or a combination thereof.

[0010] A second aspect is drawn to an apparatus comprising a hub, a sheath with a tubular sheath body operably coupled to the hub, a dilator having a dilator body receivable through the tubular sheath body, a dilator hub coupled to a proximal end of the dilator body, and a dilator handle coupled to the dilator cap. The hub includes one or more threads extending partially around circumference of hub, each thread having a locking portion that has a different axial thickness than a different portion of the thread. The tubular sheath body extending from a proximal end to a distal end, the proximal end operably coupled to the hub, and the dilator cap includes a groove or channel configured to receive the thread when the dilator is received through the sheath body, the groove or channel configured to have a ridge or depression adapted to engage with the locking portion of the thread.

[0011] In some embodiments, the groove or channel may be configured to have a ridge and the locking portion has a smaller axial thickness than that a different portion of the thread. In some

embodiments, a height of the ridge or depression may be the same as a difference in the axial thickness between the locking portion and the different portion.

[0012] In some embodiments, the hub and the dilator cap may each contain an indicator on an external surface configured to convey when the groove or channel is aligned with the thread prior to being locked into position.

[0013] In some embodiments, the dilator cap may define an opening extending from a proximal surface to a distal surface along a central axis, the opening having a central circular portion and one or more spokes extending outward from the central circular portion, each spoke configured to align with a ridge on a distal surface of the dilator handle.

[0014] In some embodiments, the apparatus is configured to provide an indicium to a user that the dilator is locked into place, such as an auditory sound, a vibration through the dilator handle, or a combination thereof.

[0015] A third aspect is drawn to a hemostatic valve assembly, comprising a foam member configured to secure an elastomeric member at least partially within a housing and provide structural support against a proximal end of the elastomeric member, the foam member having a proximal surface defining a first opening extending along a longitudinal axis from the proximal surface to a distal surface a longitudinal axis of the hemostatic valve assembly, and the foam member having at least one visibly identifiable portion a predetermined distance from at least one edge of the first opening.

[0016] In some embodiments, the foam may contain a silicone oil. In some embodiments, the first opening may be laser cut.

[0017] In some embodiments, the at least one visibly identifiable portion may comprise one or more additional openings extending at least partially from the proximal surface towards the distal surface. In some embodiments, each of the one or more additional openings may be equidistant from the at least one edge. In some embodiments, each of the one or more additional openings may have a diameter less than 0.5 mm. In some embodiments, the one or more additional openings may comprise between 2 and 4 additional openings.

[0018] In some embodiments, the at least one visible identifiable portion may comprise a portion that is visibly darker or lighter than a different portion of the foam.

BRIEF DESCRIPTION OF DRAWINGS

[0019] Figure 1A is a 2D schematic of an embodiment of an introducer sheath with a hemostatic valve.

[0020] Figure 1B is a 2D schematic of an embodiment of an introducer sheath with a hemostatic valve and a dilator assembly inserted.

[0021] Figure 2 is a 2D schematic of an embodiment of a hub.

[0022] Figures 3A and 3B are orthogonal representations of embodiments of dilator caps.

[0023] Figure 4 is an orthogonal representation of an embodiment of a dilator handle.

[0024] Figure 5 is an orthogonal representation of an embodiment of a foam member of a hemostatic valve.

[0025] Figures 6A-6D are 2D representations of different embodiments of the foam member.

[0026] Figure 7 is a representation of a still another embodiment of a foam member.

[0027] Figures 8A and 8B are representations of a foam member in a hub.

DETAILED DESCRIPTION

[0028] For mechanical circulatory support devices, peel-away introducer sheaths may be used when the device is expected to remain in a patient for an extended period of time (e.g., by peeling away the introducer sheath and replacing it with a smaller diameter sheath preinstalled on the medical device). However, as it becomes more desirable to utilize a single point of insertion into the body to introduce multiple medical devices, peel-away introducers may become less desirable due to the intentionally reduced sidewall strength of such introducers. Additionally, typical peel-away introducers have a large outer diameter, which can undesirably obstruct blood flow past the introducer and lead to lower limb ischemia.

[0029] Thus, the inventors have appreciated that a low-profile non-peel away introducer sheath may be desirable. However, to maintain the desirable features of such sheaths, further changes to the design may be required, as the dimensions cannot simply be reduced proportionally and remain useable and manufacturable.

[0030] To that end, a low-profile non-peel away introducer sheath assembly, and dilator assemblies that enable such sheaths to be useful, that incorporate design features that allow the benefits of current non-peel away introducer sheaths while remaining manufacturable are desirable.

[0031] As seen in FIGS. 1A and 1B, a system for insertion into the vasculature of a patient can be seen. The system generally comprises a hub **40** operably connected to a sheath **105**, the hub comprising a hemostatic valve **200** through which, *e.g.*, a dilator assembly **110**, a heart pump, or other medical devices may be inserted.

[0032] A first aspect of the present disclosure is drawn to a device **10** for insertion into a vasculature of a patient can be seen. The device **10** may include a primary tubular sheath body

20 coupled to a distal end of an intermediate tubular sheath body 30, and a hub 40 coupled to a proximal portion of the intermediate tubular sheath body 30. The hub 40 may be connected to a sideport 50. A rotatable portion 60 or member may be operably coupled to a distal end of the hub.

[0033] Primary Tubular Sheath Body

[0034] The primary tubular sheath body 20 may include a first material, and the primary tubular sheath body may extend from a proximal end 21 to a distal end 22.

[0035] In some embodiments, the first material may comprise a polyether block amide (PEBA), such as the PEBAX® elastomers sold by Arkema.

[0036] In some embodiments, the primary tubular sheath body 20 may comprise a plurality of layers. In some embodiments, the primary tubular sheath body 20 may comprise an outer jacket 23 (which may comprise or consist of a PEBA), and an inner frame layer 24 (which may comprise or consist of nitinol).

[0037] Intermediate Tubular Sheath Body

[0038] The device also may include an intermediate tubular sheath body 30 (see FIGS. 1A and 1B) comprising or consisting of a second material, the intermediate sheath body extending from a proximal end 31 to a distal end 32. The distal end 32 of the intermediate tubular sheath body 30 may be connected to the proximal end 21 of the primary tubular sheath body 20. In some embodiments, the distal end of the intermediate tubular sheath body may be butt welded to the proximal end of the primary tubular sheath body, though it should be understood that other types of joints between the primary and intermediate tubular sheath bodies may be suitable.

[0039] In some embodiments, the intermediate tubular sheath body 30 may comprise or consist of a thermoplastic styrene-butadiene copolymer, such as the STYROLUX® resins sold by Entec Polymers.

[0040] In some embodiments, the intermediate tubular sheath body 30 may have a proximal portion 35 with a constant inner diameter 39 and a distal portion 33 that necks down linearly from the inner diameter 39 of the proximal portion to a smaller inner diameter 38 at the distal end 32. In some embodiments, the intermediate tubular sheath body may have a first inner diameter 38 at the distal end 32, and a second inner diameter 39 at an axial distance proximal to the distal end 34. In some embodiments, the second inner diameter 39 may be greater than the first inner diameter. In some embodiments, the second inner diameter 39 is between 5 mm and 6 mm. In some embodiments, this inner diameter may be the same as the inner diameter of the primary tubular sheath.

[0041] Hub

[0042] The device also may comprise a hub **40** (see, e.g., FIG. 1A). The hub may comprise or consist of a third material, and the hub **40** may be connected to a proximal portion **35** of the intermediate sheath body **30** and be separated from the primary tubular sheath body **20** by the intermediate tubular sheath body **30**.

[0043] In some embodiments, the third material may be acrylonitrile butadiene styrene.

[0044] In some embodiments (see, e.g., FIGS. 1A and 1B), an inner surface **41** of the hub **40** may be connected to a portion of the outer surface **36** of the intermediate tubular sheath body **30** and not connected with the primary tubular sheath body **20**. In some embodiments, the hub is only connected to the proximal portion **35** of the intermediate tubular sheath body **30** with a constant diameter **39** and is not connected to the distal portion **33** that necks down to a smaller inner diameter.

[0045] Because different properties are needed for the hub than for the primary tubular sheath body, the materials that comprise each of these parts are necessarily different, and these differences often result in the two components not being able to bond the components together effectively. Thus, in some embodiments, the intermediate layer aids in bonding by having an intermediate layer that the two components bond to more effectively than each other. Therefore, in the present disclosure, the first material, second material, and third material may be configured such that a theoretical interfacial bonding strength between the first and second material, and a theoretical interfacial bonding strength between the third material and the second material, are both greater than a theoretical interfacial bonding strength between the first material and the third material. As is known in the art, Interfacial bonding strength (IBS) is the strength that bonds two layers at the interface, and can be tested via, e.g., tensile tests or shear tests, although tensile is more typically utilized.

[0046] Sideport

[0047] As also shown in FIGS. 1A and 1B, the device may also comprise a sideport **50** extending from the hub **40**. A first end **51** of the sideport **50** may be connected an entrance **44** defined by an exterior surface **42** of the hub **40** that extends to the interior surface **41** of the hub **40**.

[0048] Rotatable Portion

[0049] The device may also comprise a rotatable portion **60** (see e.g., FIG. 1A) that is rotatable around a central axis relative to the primary tubular sheath body **20**. In some embodiments, the intermediate tubular sheath body **30**, the hub **40**, and the rotatable portion may be connected to a distal portion of the hub **40**.

[0050] In some embodiments, the rotatable portion **60** may be attached in a non-removable (or not easily removable) fashion, such as via a plurality of snap-fit joints **61**. In some embodiments, the rotatable portion may comprise a butterfly, a suture pad, or a combination thereof.

[0051] In some embodiments, the rotatable portion **60** may be rotatable around a central axis (in FIGS. 1A and 1B, the central axis being the centerline of the primary tubular sheath body **20** and the intermediate tubular sheath body **30**) by at least 180 degrees. For example, in some embodiments, the rotatable portion (when attached to a patient) can still allow the hub to be rotated such that (at a minimum) the sideport can face towards the right side of the patient or towards the left side of the patient. In some embodiments, the rotatable portion **60** may be rotatable around a central axis by at least 360 degrees, up to and including being freely rotatable without restriction.

[0052] In some embodiments, the rotatable portion **60** may be configured to allow the sideport **50** extending from the hub **40** to lie substantially flat against a patient, regardless of the orientation of the rotatable portion **60** on the body of the patient. For example, in some embodiments, by allowing the hub to be rotated such that the entrance **44** of the hub where the sideport **50** is connected to is directed towards a patient's body (or at least, not be directed away from the patient's body), the sideport can readily lie substantially flat against a patient.

[0053] In some embodiments, the rotatable portion **60** may be configured to encircle the portion of the device **10** where some or all of the intermediate tubular sheath body **30** is positioned, as well as encircling the point of connection between the primary tubular sheath body **20** and the intermediate tubular sheath body **30** (e.g., encircling at least a portion of the proximal end of the tubular sheath body **20**).

[0054] Also disclosed is an apparatus (or system) **100**. In some embodiments, the apparatus **100** comprises a hub **40**, a sheath **105**, and a dilator **110**.

[0055] Hub

[0056] Referring to FIG. 2, a hub **40** can be seen, the hub having a distal end **46** and a proximal end **47**. The hub **40** may include one or more threads **43** (two threads are shown in FIG. 2 by way of an example), each thread extending at least partially around the circumference of hub **40**. As will be appreciated, the threads may have other suitable arrangements in other embodiments. As shown in FIG. 2, the threads **43** may be disposed in a proximal portion **101** of the hub **40**, at or near the proximal end **47**.

[0057] As shown in FIG. 2, in some embodiments, each thread may have portions with different axial thicknesses (e.g., a thickness of the thread in an axial direction). For example,

in one embodiment, each thread **43** may have a first, locking portion **104** with a first axial thickness **49** that may be different than a second axial thickness **48** in a second portion **103** of each thread **43**.

[0058] In some embodiments, the locking portion **104** may have first axial thickness **49** that is less than the second axial thickness **48** of the second portion **103**. In some embodiments, the locking portion **104** may have first axial thickness **49** that is greater than the second axial thickness **48** of the second portion **103**.

[0059] In some embodiments, each thread may have one locking portion **104** and one second portion **103**. In some embodiments, each thread may have one locking portion **104** and two second portions **103** (one on each side of the locking portion).

[0060] In some embodiments, the interface **109** of the locking portion **104** and the second portion **103** may extend in a non-radial direction. In some embodiments, the interface **109** of the locking portion **104** and the second portion **103** may extend in a radial direction.

[0061] The hub **40** may also comprise an indicator **107**, such as a shape or design molded or etched into or onto an outer surface of the hub, to aid in aligning the hub **40** and the dilator **110**.

[0062] Sheath

[0063] Referring again to FIG. 1B, the apparatus **100** also may comprise a sheath **105**. The sheath **105** may include a primary tubular sheath body **20** extending from a proximal end **21** to a distal end **22**. In some embodiments, the proximal end **21** may be operably coupled to the hub **40**, such as via an intermediate tubular sheath body **30** as described previously.

[0064] Dilator

[0065] The apparatus **100** also may include a dilator **110** (see, e.g., FIG. 1B). The dilator **110** may comprise a dilator body **120** receivable through the tubular sheath body **20**, and a dilator hub **125** coupled to a proximal portion of the dilator body **120**. The dilator hub **125** may comprise or consist of a dilator cap **130** and a dilator handle **140**. In some embodiments, the dilator handle **140** may be coupled to a proximal surface of the dilator cap **130**.

[0066] Referring to FIG. 3A, the dilator cap **130** may include at least one groove or channel **131** configured to receive the one or more threads **43** on the hub **40** when the dilator body **120** is received through the primary tubular sheath body **20**. In this regard, the size and shape of the at least one groove or channel **131** may correspond to the size and shape of the one or more threads **43** on the hub **40**.

[0067] In some embodiments, one or more of the grooves or channels **131** may be configured to have a ridge or depression **132** adapted to engage with the locking portion **104** of the thread **43**. In some embodiments, every groove or channel **131** may be configured with a ridge or

depression **132** adapted to engage with the respective locking portion of the respective thread. In some embodiments, the groove or channel **131** may be configured to have the ridge **132**, and the locking portion may a smaller first axial thickness than the second portion of the thread (e.g., to allow for engagement between the ridge or depression and the locking portion).

[0068] In some embodiments, the dilator cap **130** may also contain an indicator **136**, such as a shape or design molded or etched into or onto an outer surface of the dilator cap **130**, to aid in aligning the hub **40** and the dilator **110** (and more specifically, aligning the dilator cap and the hub). In some embodiments, the hub **40** and the dilator cap **130** may each contain an indicator (**107**, **136**) configured to convey when the groove or channel is aligned with the thread prior to being locked into position. In some embodiments, the hub **40** and the dilator cap **130** may each contain an indicator (**107**, **136**) configured to convey when the groove or channel is locked into the locked position. In some embodiments, the dilator cap **130** may contain one indicator (**136**) and the hub may contain two indicators (**107**) configured to convey both when the groove or channel is aligned with the thread prior to being locked in the locked position, and also when the groove or channel is locked in the locked position.

[0069] The dilator cap **130** may be configured such that any ridge or depression **132** has a height in the axial direction that is equal or substantially equal to the difference in height between the locking portion **104** and the (one or more) second portion **103**.

[0070] The dilator **110** may be configured to provide an indicium, such as a non-visual indicium, to a user that the dilator is locked into place (e.g., locked onto the hub). By configuring the dimensions and composition of the components, such as the dilator cap **130**, the dilator can be configured to, e.g., produce an auditory sound. For example, the dilator cap may produce a noticeable “click” sound, a vibration through the dilator handle, or a combination thereof when the dilator is locked into place. Other indicia may be utilized as appropriate to indicate a locking status of the dilator.

[0071] In some embodiments, the dilator cap **130** has a proximal surface **137** that defines an opening **133** extending from the proximal surface **137** to a distal surface **138** of the dilator cap (see, e.g., FIG. 3A). The opening **133** may be circular or substantially circular in shape, and the center of the opening may be aligned with a centerline **135** of the dilator cap **130**. In some embodiments, the opening **133** may have a diameter between, e.g., 7 and 8 mm. The proximal surface **137** may also define one or more “spoke” or “wing” channels **134** that extend outwardly from the central opening **133**. In this regard, the spoke or wing channels **134** are additional openings defined by the proximal surface and extend from the proximal surface **137** to the distal surface **138**.

[0072] In some embodiments, the central opening 133 may have an inner surface 150 that includes straight-cut sides extending in the axial direction (*e.g.*, parallel to the central axis 135) from the proximal surface 137 to the distal surface 138. In some embodiments, a proximal edge 151 of the inner surface 150 of the central opening may be shaped to ease assembly. Referring to FIG. 3B, the inner surface 150 of the central opening 133 also may include a chamfer 152 at the proximal surface 137 (*e.g.*, at least a portion of the proximal edge may be chamfered). In such embodiments, the inner surface central opening 133 may be rounded at the proximal surface 137 (*e.g.*, at least a portion of the proximal edge may be rounded).

[0073] In some embodiments, there may be additional text or images provided on the proximal surface 137. For example, in some embodiments, one or more words or icons are embossed on the proximal surface. In some embodiments, such words or icons provides directions or use instructions to a user (*e.g.*, “twist” or “push”), or information related to the size of the opening of the dilator (*e.g.*, “14F” to indicating the dilator is a 14 French dilator, etc.).

[0074] In some embodiments, the spokes or wing channels 134 may help align the dilator handle 140 with the dilator cap 130. In some embodiments, the spokes or wings 134 may aid in transferring force from the handle to the cap, such as when the handle and cap are coupled to one another.

[0075] In some embodiments, a single spoke or wing channel 134 may be present. In some embodiments, the distal cap 130 comprises between 2 and 4 spoke or wing channels 134. In some embodiments, the spoke or wing channel 134 are symmetrically arranged around the central opening 133. In some embodiments, each spoke or wing channel 134 may extend radially a same distance 139 from an edge of the central opening 133 towards an outer edge of the proximal surface. In some embodiments, each spoke or wing channel may have the same size and shape. As will be appreciated, the spoke or wing channels may have a size and shape that corresponds to corresponding coupling regions on the dilator handle.

[0076] Referring to FIG. 4, an embodiment of a dilator handle 140 is seen. The dilator handle 140 may include a dilator handle body 141 that has a proximal end 142 and a distal end 143. The dilator handle body 141 may define a central lumen 144 extending from the proximal end 142 to the distal end 143.

[0077] In some embodiments, the distal portion of the dilator handle may comprise a coupling portion 145 that is configured to allow the dilator handle 140 to be coupled to the dilator cap 130. In some embodiments, the coupling portion may include one or more locking extensions configured to pass through the central opening and the one or more spoke or wing channels on the dilator cap. For example, in some embodiments, the coupling portion 145 comprises a

central extension **146** configured to pass through the central opening **133** on the dilator cap **130**. The central extension **146** may comprise one or more locking ridge **147** configured to pass through the central opening **133** and interact with a distal surface **138** of the dilator cap, holding the dilator handle **140** to the dilator cap **130**. In some embodiments, the distal surface of the dilator handle may comprise one or more additional spoke or wing extensions **148** configured to extend at least partially into the spoke or wings channels **134** when the dilator handle is connected to the dilator cap. In some embodiments, there are 2-4 additional spoke or wing extensions **148**. In some embodiments, each additional spoke or wing extension may connect to a surface of the central extension **146**. In some embodiments, each additional spoke or wing extension is configured such that a distal surface of each additional spoke or wing extension **148** is parallel with the distal surface **138** of the distal cap when the dilator handle is connected to the dilator cap. The central axis **149** of the dilator handle **140** may be configured to align with the central axis **135** of the dilator cap **130**.

[0078] The dilator handle may comprise one or more threads at the proximal end **142** for receiving one or more additional dilator components through the central lumen **144** along the central axis **135**.

[0079] A third aspect of the present disclosure is a drawn to a hemostatic valve assembly. Referring to FIGS. 1A and 1B, a hemostatic valve assembly **200** is seen. The hemostatic valve assembly generally comprises a foam member **210** configured to secure an elastomeric member **220** at least partially within a housing **230** and provide structural support against a proximal end **221** of the elastomeric member **220**.

[0080] In some embodiments, the foam member **210** may contain a lubricant, such as a silicone oil, *e.g.*, in the pores of the foam.

[0081] Referring to FIG. 5, it can be seen that the foam member **210** has a proximal surface **211** defining a first opening **215** extending along a longitudinal axis **213** from the proximal surface **211** to a distal surface **212** of the foam member **210**. In some embodiments, the first opening may be laser cut.

[0082] The foam member **210** may have at least one visibly identifiable portion **216** that is distinct from at least one other portion **217** on the proximal surface **211**. The at least one visible identifiable portion **216** may be a predetermined distance **218** from at least one edge of the first opening **215**.

[0083] In some embodiments, the predetermined distance is a distance between 1 mm and 8 mm, such as between 2 mm and 5 mm.

[0084] In some embodiments, the at least one visibly identifiable portion may comprise a portion that is visibly darker or lighter than a different portion of the foam. In some embodiments, the at least one visible identifiable portion may comprise one or more additional openings extending at least partially from the proximal surface towards the distal surface. In some embodiments, each of the one or more additional openings may have a diameter less than 0.5 mm. In some embodiments, the one or more additional openings may comprise between 2 and 4 additional openings. In some embodiments, the at least one visible identifiable portion may comprise one or more additional openings extending at least partially from the proximal surface towards the distal surface and a portion that is visibly darker or lighter than a different portion of the foam.

[0085] Referring to FIG. 6A, a simplified schematic of an alternative embodiment is seen, where the foam member **300** has an oval-shaped opening **301** and two additional openings **302**, each additional opening extending at least partially from the proximal surface towards the distal surface. In FIG. 6A, the two additional openings are shown as being equidistant from an edge of the opening **301**.

[0086] Referring to FIG. 6B, a simplified schematic of an alternative embodiment is seen, where the foam member **305** has an oval-shaped opening **306** which is surrounded at a distance by the at least one visibly identifiable portion **307** that is darker than a different portion **308** that is closer to the oval-shaped opening **306**.

[0087] Referring to FIG. 6C, a simplified schematic of an alternative embodiment is seen, where the foam member **315** has an circular opening **316** which is surrounded at different distances by the at least one visibly identifiable portions **312**, **313**, **314**, where each visibly identifiable portion comprises both additional openings **312** each extending at least partially from the proximal surface towards the distal surface, and each additional opening surrounded by a portion **313**, **314** that is visibly lighter or darker (here, darker) than a different portion **315** closer to the opening **311**. Further, one of the visibly identifiable portions **314** is closer to an edge of the opening **311** than another visible identifiable portion **313**.

[0088] Referring to FIG. 6D, a simplified schematic of an alternative embodiment is seen, almost an inverse of FIG. 6B. Here, the foam member **329** has a circular opening **321** which is surrounded at a distance by the at least one visibly identifiable portion **322** that is lighter than a different portion **323** that is closer to the oval-shaped opening **321**.

[0089] In some embodiments, the foam may include more than one piece. In some embodiments, the pieces are adjacent to each other.

[0090] Referring to FIG. 7, in some embodiments, there may be cuts **410** (which may be, *e.g.*, slits) in the foam member, extending at least partially, or in some cases entirely, through at least a portion of the foam member. In some embodiments, the cuts may be only in a single direction (*e.g.*, only parallel to the x-axis). In some embodiments, the cuts may extend radially from a central axis. In some embodiments, there be at least one cut that is perpendicular to another cut.

[0091] In some embodiments, there may be one or more openings **420** extending through the foam and having a substantially circular cross-section. Such openings are helpful to guide physicians on where to puncture for single access.

[0092] In some embodiments, there may one or more openings **430** extending through the foam that do not have a circular cross-section.

[0093] In some embodiments, the foam surface facing outward may be divided into quadrants. In some embodiments, each quadrant of the foam may include one or more openings **420**.

[0094] Referring to FIGS. 8A and 8B, a hub **450** can be seen, where the foam member **400** is shown in position within the hub. In some embodiments, a physician may puncture a valve **460** by inserting a needle through one of the openings **420**, and through valve **460**. In such embodiments, the one or more openings may be guides for aiding the physician in puncture the valve.

[0095] While various aspects described herein relate to sheath designs that are particularly suitable for simultaneous use with multiple medical devices (*e.g.*, via a single access technique), it should be appreciated that the presently disclosed sheath technology is not limited to uses with multiple medical devices, and that the presently disclosed sheath technology may provide advantages even when used with a single device (*e.g.*, when used only to provide access for an intravascular blood pump or other suitable medical device).

[0096] Those skilled in the art will recognize or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed by the following claims.

What is claimed is:

1. A device for insertion into a vasculature of a patient, the device comprising:
a primary tubular sheath body comprising a first material, the primary tubular sheath body extending from a proximal end to a distal end;
an intermediate tubular sheath body comprising a second material, the intermediate sheath body extending from a proximal end to a distal end, the distal end of the intermediate tubular sheath body connected to the proximal end of the primary tubular sheath body; and
a hub comprising a third material, the hub connected to a proximal portion of the intermediate sheath body and separated from the primary tubular sheath body by the intermediate tubular sheath body,
wherein the first material, second material, and third material are configured such that a theoretical interfacial bonding strength between the first and second material, and a theoretical interfacial bonding strength between the third material and the second material, are both greater than a theoretical interfacial bonding strength between the first material and the third material.
2. The device according to claim 1, wherein the intermediate tubular sheath body has a first inner diameter at the distal end, and a second inner diameter at an axial distance proximal to the distal end, the second inner diameter being greater than the first inner diameter.
3. The device according to claim 2, wherein the second inner diameter is between 5 mm and 6 mm.
4. The device according to any one of claims 1-3, wherein the first material comprises a polyether block amide (PEBA).
5. The device according to any one of claims 1-4, wherein the second material comprises a thermoplastic styrene-butadiene copolymer.
6. The device according to any one of claims 1-5, wherein the third material comprises acrylonitrile butadiene styrene.

7. The device according to any one of claims 1-6, wherein the primary tubular sheath body comprises a plurality of layers.
8. The device according to claim 7, wherein the plurality of layers comprises a frame layer and an outer jacket.
9. The device according to claim 8, wherein the frame layer comprises nitinol, and the outer jacket comprises a polyether block amide (PEBA).
10. The device according to any one of claims 1-9, further comprising a sideport extending from the hub.
11. The device according to any one of claims 1-10, further comprising a rotatable portion that is rotatable relative to the hub, the primary tubular sheath body, and the intermediate tubular sheath body, the rotatable portion being connected to a distal portion of the hub.
12. The device according to claim 11, wherein the rotatable portion is rotatable by at least 180 degrees.
13. The device according to claim 12, wherein the rotatable portion is rotatable by at least 360 degrees.
14. The device according to claim 11, wherein the rotatable portion is configured to allow a sideport extending from the hub to lie flat against a patient.
15. The device according to any one of claims 11-14, wherein the rotatable portion comprises a butterfly, a suture pad, or a combination thereof.
16. An apparatus comprising:
 - a hub including one or more threads extending partially around circumference of hub, each thread having a first locking portion that has a different axial thickness than a second, different portion of the thread;
 - a sheath having a tubular sheath body extending from a proximal end to a distal end, the proximal end operably coupled to the hub;
 - a dilator having a dilator body receivable through the tubular sheath body, the dilator comprising a dilator hub coupled to a proximal portion of the dilator body, the dilator hub

comprising a dilator cap and a dilator handle, the dilator cap including a groove or channel configured to receive the thread when the dilator is received through the sheath body, the groove or channel configured to have a ridge or depression adapted to engage with the locking portion of the thread.

17. The apparatus according to claim 16, wherein the groove or channel is configured to have a ridge and the locking portion has a smaller axial thickness than that a different portion of the thread.

18. The apparatus according to claim 16 or 17, wherein a height of the ridge or depression is the same as a difference in the axial thickness between the locking portion and the different portion.

19. The apparatus according to any one of claim 16-18, wherein the hub and the dilator cap each contain an indicator configured to convey when the groove or channel is aligned with the thread prior to being locked into position.

20. The apparatus according to any one of claims 16-19, wherein dilator cap defines an opening extending from a proximal surface to a distal surface along a central axis, the opening having a central circular portion and one or more spokes extending outward from the central circular portion, each spoke configured to align with a ridge on a distal surface of the dilator handle.

21. The apparatus according to any one of claims 16-20, wherein the apparatus is configured to provide an indicium to a user that the dilator is locked into place.

22. The apparatus according to claim 21, wherein the indicium comprises an auditory sound, a vibration through the dilator handle, or a combination thereof.

23. A hemostatic valve assembly, comprising:
a foam member configured to secure an elastomeric member at least partially within a housing and provide structural support against a proximal end of the elastomeric member, the foam member having a proximal surface defining a first opening extending along a longitudinal axis from the proximal surface to a distal surface of the foam member, and the

foam member having at least one visibly identifiable portion a predetermined distance from at least one edge of the first opening.

24. The hemostatic valve assembly according to claim 23, wherein the foam contains a silicone oil.
25. The hemostatic valve assembly according to claim 23 or 24, wherein the first opening is laser cut.
26. The hemostatic valve assembly according to any one of claims 23-25, wherein the at least one visibly identifiable portion comprises one or more additional openings extending at least partially from the proximal surface towards the distal surface.
27. The hemostatic valve assembly according to claim 26, wherein each of the one or more additional openings is equidistant from the at least one edge.
28. The hemostatic valve assembly according to claim 26 or 27, wherein each of the one or more additional openings have a diameter less than 0.5 mm.
29. The hemostatic valve assembly according to any one of claims 26-28, wherein the one or more additional openings comprises between 2 and 4 additional openings.
30. The hemostatic valve assembly according to any one of claims 23-25, wherein the at least one visible identifiable portion comprises a portion that is visibly darker or lighter than a different portion of the foam.