

A LOW DRAG SEPTUM STRUCTURE FOR A CATHETER

Technical Field

The present disclosure relates to a septum structure used in conjunction with a catheter to form a seal therein, which prevents potential unwanted or unintended fluid escape from the catheter. More specifically, the disclosed septum structure possesses features for facilitating simple and rapid orientation-specific insertion of the septum structure into the catheter, and/or features for reducing drag force generated and applied onto a needle passing through the septum structure without adversely affecting the septum structure's sealing properties.

Background

A catheter is common tool placed into hospitalized subjects or patients to facilitate fluid communication with the subject's body, such as intravenous fluid infusion. An infused fluid can be saline, or a nutrient or a medicine dissolved in a liquid carrier. Various types of catheters exist. In general, a catheter includes an extended or elongate main shaft or tube that is insertable into a subject's blood vessel, and a main fluid port connected to the main tube, such as by way of a catheter hub. Particularly, the main fluid port has a through opening aligned with a central lumen or passage of the main tube for receiving a needle to facilitate introduction of the main tube into a targeted vein. The catheter can also include a side port configured for fluid communication with the main tube, such as by way of transfusing a fluid into the main tube.

A given catheter is cooperatively designed with respect to a needle of a particular size. More specifically, the catheter is dimensioned to have its main tube tightly engage with and surround or enclose the needle, such that the distal sharp end of the needle can extend beyond the distal end of the catheter and prick through the subject's skin to reach a target blood vessel. Once the needle has penetrated into a blood vessel, the catheter tube can be slid forward and positioned in the vessel to remain therein for subsequent fluid infusion, and the needle can be withdrawn. To ascertain safe placement of the catheter, the needle can be fabricated with a notch or through aperture along its body to flash some blood sample back into the tube, which is commonly transparent or translucent, to provide a visual indication to the clinician or care giver (e.g., a physician or nurse) that the needle has indeed arrived in the

blood vessel. Retraction of the needle from the blood vessel is thus inevitably followed by a small volume of outflow blood, which can leak out of the catheter. This outflow blood can contain pathogens, which are transmittable to the clinician managing the patient. Even though the possibility of disease transmission is low as long the proper safety procedures are followed, it is preferred to eliminate such risk in practice.

For preventing undesired blood leakage from the catheter, a catheter seal, sealing member, or septum is commonly used together with the needle. The sealing member is typically manufactured from one or more elastic materials, and is inserted into the catheter's main fluid port by way of a compression fit, prior to the introduction of the needle into the catheter. The constant compression force generated from the sidewalls of the catheter's main fluid port against the sealing member interfacing therewith results in an elastic seal that increases the likelihood that the catheter's through opening or the passageway linked to the through opening is always tightly shut and rendered fluid impermeable upon withdrawal of the needle.

The use of such an elastic seal is widely accepted; however, some seal member designs can result in clinical complications. Specifically, the compression fit of the seal member against the inner sidewall the catheter's main fluid port results in a compression force that is distributed across the seal member's cross-sectional area. The seal member thus exerts a compression force upon a needle inserted therethrough. In some cases, the compression force that the seal member exerts upon a needle can be too great or too tight for the clinician to withdraw or remove the needle smoothly from the subject. Applying greater pulling force onto the needle generally increases the risk of dislodging the catheter tube from the subject. Once the catheter is dislodged, the clinician must perform the placement of catheter again. Additionally, uncontrolled pulling of the needle may end up injuring the clinician or someone standing nearby.

Furthermore, the engagement force of the needle against the sealing member can be sufficiently large that successful withdrawal of the needle results in removal of the sealing member together with the needle out of the catheter's main fluid port. Such accidental removal of the sealing member leads to spillage of blood from the main fluid port, defying the very need for having the sealing member in the first place. In some instances,

disengagement of the sealing member from the main fluid port during needle withdrawal can be attributed to a decrease in the sealing member elasticity as a result of a sealing member material aging process.

- 5 Certain existing sealing members, such as that described in US Patent No. 8,066,675, include a cavity therein that aids in reducing needle drag during needle withdrawal. Some sealing members of this type are formed as symmetric or mirror image sealing member halves defined between the proximal end and the distal end of the sealing member. The two mirror image halves are joined together by hinges disposed at predetermined proximal and distal
- 10 sites along the sealing member's length. Unfortunately, a sealing member having such a structure can be less effective with respect to forming a fluid impermeable seal within a catheter. Furthermore, a sealing member structured in this manner can undesirably complicate sealing member manufacturability.
- 15 Particular existing sealing members have a specific intended proximal end and a specific distal end with respect to their insertion direction into the catheter, such that the proximal end of the sealing member is intended to be oriented at or toward the proximal end of the catheter, and the distal end of the sealing member is intended to be oriented toward the distal end of the catheter. Unfortunately, it can be undesirably easy to insert an existing sealing member
- 20 into a catheter in an improper orientation, such that the sealing member's proximal end is oriented toward the catheter's distal end, and vice versa.

In view of the foregoing, a need exists for a sealing member for a catheter that is free from the abovementioned shortcomings, and which in particular is capable of reducing drag force

25 exerted onto a needle as the needle is withdrawn.

Summary

In accordance with an aspect of the present disclosure, a septum structure for a catheter or a catheter hub having an aperture and a main port structure includes: an elongate body

30 configured for insertion into the aperture and main port structure of the catheter or catheter hub, the body having a proximal end, a distal end, and a length between the proximal and distal ends, the length of the body parallel to a longitudinal axis of the body and/or the

septum structure. The body includes: a first longitudinal segment along the body length, the first longitudinal segment having a first inner surface; and a second longitudinal segment along at least a portion of the body length, the second longitudinal segment having a second inner surface configured to interface with the first inner surface when the septum structure is in a closed position. The first longitudinal segment and the second longitudinal segment have asymmetric shapes relative to each other about the longitudinal axis of the body, and are pivotably displaceable (openable / closable) relative to each other for transitioning the septum structure between the closed position and a set of open positions. Pivotal displacement of the first longitudinal segment relative to the second longitudinal segment occurs about a pivot axis that is perpendicular to the longitudinal axis of the body and parallel to the proximal end and/or the distal end of the body

The body includes a slit structure along at least portions of its length, wherein the slit structure defines a boundary between the first longitudinal segment and the second longitudinal segment when the septum structure is in a closed position. The slit structure defines a boundary between the first inner surface of the first longitudinal segment and the second inner surface of the second longitudinal segment when the septum structure is in the closed position. The slit structure can extend in a first plane parallel to the longitudinal axis of the body across a distance less than the length of the body.

The second longitudinal segment can have a different length than the first longitudinal segment across the length of the body. For instance, the first longitudinal segment can include a projection that transversely or perpendicularly extends away from the first inner surface of the first longitudinal segment. The projection includes a distal face against which a proximal face of the second longitudinal segment seats when the septum structure is in a closed position. The projection contributes or gives rise to the asymmetry between the first longitudinal segment and the second longitudinal segment, and aids the establishment and maintenance of a reliable fluid-impermeable elastic seal between outer portions of the septum structure corresponding to the projection and inner / internal surfaces of the catheter / catheter hub main port structure when the septum structure is disposed (e.g., by way of force fitting) therein.

The septum structure further includes an elongate cavity (e.g., at least one elongate cavity) carried by the body along a predetermined portion of the length of the body. A first portion of the elongate cavity is carried by the first longitudinal segment, and a second portion of the longitudinal cavity is carried by the second longitudinal segment. The elongate cavity is approximately bisected by a plane parallel to the longitudinal axis of the septum structure. A proximal boundary of the elongate cavity can be located closer to the proximal end of the body than a distal boundary of the elongate cavity is located relative to the distal end of the body.

10 The body includes a proximal portion and a distal portion. In multiple embodiments, the proximal portion and the distal portion are separated from each other by (a) different diameters, and/or (b) an indented region along a portion of the length of the body. For instance, the proximal portion and the distal portion can be separated from each other by different diameters, wherein a diameter of the proximal portion is smaller than a diameter of the distal portion. The body can also include a chamfered region adjacent to its distal end.

The septum structure can further include a housing into which the proximal portion is insertable, wherein the housing includes an opening that is centrally aligned relative to the longitudinal axis of the body and is configured for receiving a needle. The proximal portion is configured for insertion into and secure retention within the housing by way of a snug fit or an interference fit therein. The housing typically has an outer diameter equal or approximately equal to the outer diameter of the distal portion of the body.

25 The septum structure can further include a set of hinge elements coupled to each of the first longitudinal segment and the second longitudinal segment, where the set of hinge elements is configured for enabling pivotal displacement of the first longitudinal segment and the second longitudinal segment away from or toward each other about the pivot axis prior to septum structure insertion into the main port structure of the catheter or catheter hub. The set of hinge elements can be carried by the distal end of the body, such that the pivot axis is positioned at or very nearly at the distal end of the body. The set of hinge elements can include a first hinge structure and a second hinge structure disposed on opposite sides of the longitudinal axis of the body and separated from each other by a gap, wherein the

longitudinal axis of the body approximately bisects the gap. The body further can also include a recess defined within the gap.

In accordance with another aspect of the present disclosure, a kit (e.g., a medical procedure kit, or a septum sealable catheter kit) includes a catheter or catheter hub having a main port structure providing a main passage therein, wherein a longitudinal axis of the main port structure is definable along portions of the main passage, and the main passage terminates at an aperture at a proximal end of the catheter or catheter hub; and a septum structure having a longitudinal axis alignable with the longitudinal axis of the main port structure and insertable into the main passage of the main port structure by way of force fitting. The septum structure includes an elongate body configured for insertion into the aperture and main port structure of the catheter or catheter hub, wherein the body has a proximal end, a distal end, and a length between the proximal and distal ends that is parallel to a longitudinal axis of the septum structure. The body includes: a first longitudinal segment along the body length, the first longitudinal segment having a first inner surface; and a second longitudinal segment along at least a portion of the body length, the second longitudinal segment having a second inner surface configured to interface with the first inner surface when the septum structure is in a closed position. The first longitudinal segment and the second longitudinal segment have asymmetric shapes relative to each other about the longitudinal axis of the septum structure, and are pivotably displaceable relative to each other for transitioning the septum structure between the closed position and a set of open positions. Pivotal displacement of the first longitudinal segment relative to the second longitudinal segment occurs about a pivot axis that is perpendicular to the longitudinal axis of the septum structure and parallel to the proximal end and/or the distal end of the body.

In the kit, the septum structure can also include a set of hinge elements coupling the first longitudinal segment to the second longitudinal segment at a terminal end (e.g., the distal end) of the septum structure to define the pivot axis, wherein the set of hinge elements facilitates visual identification of a proper orientation of the septum structure relative to the main port structure prior to insertion of the septum structure into the main passage of the main port structure.

In accordance with an aspect of the present disclosure, a septum sealed catheter or catheter hub structure includes: a catheter or catheter hub having a main port structure providing a main passage therein, the main passage having an interior surface, wherein a longitudinal axis of the main port structure is definable along portions of the main passage; and a septum structure retained within the main passage of the main port structure by way of an interference fit between the interior surface of the main passage and an outer surface of the septum structure. The septum structure includes an elongate body having a proximal end, a distal end, and a length between the proximal and distal ends that is parallel to a longitudinal axis of the septum structure. The body includes: a first longitudinal segment along the body length, the first longitudinal segment having a first inner surface; and a second longitudinal segment along at least a portion of the body length, the second longitudinal segment having a second inner surface configured to interface with the first inner surface when the septum structure is in a closed position. The first longitudinal segment and the second longitudinal segment have asymmetric shapes relative to each other about the longitudinal axis of the septum structure, and are pivotably displaceable relative to each other for transitioning the septum structure between the closed position and a set of open positions. Pivotal displacement of the first longitudinal segment relative to the second longitudinal segment occurs about a pivot axis that is perpendicular to the longitudinal axis of the septum structure and parallel to the proximal end and/or the distal end of the body. The septum structure can also include a set of hinge elements coupling the first longitudinal segment to the second longitudinal segment at a terminal end (e.g., a distal end) of the septum structure to define the pivot axis, wherein the set of hinge elements has a predetermined orientation relative to a proximal aperture of the main port structure for indicating a proper orientation of the septum structure within the main passage of the main port structure.

Brief Description Of The Drawings

For the purpose of facilitating an understanding of the invention, there is illustrated in the accompanying drawings particular representative embodiments in accordance with the present disclosure.

FIG. 1 shows an embodiment of a septum structure including a septum member and a housing in accordance with an embodiment of the present disclosure, with dashed lines indicating internal structures of the septum structure;

- 5 FIG. 2 shows a septum member of the septum member of FIG. 1, in an open configuration exposing an elongate internal cavity thereof;

FIG. 3 shows a top view of the septum member of FIG. 1 in a closed configuration, with dashed lines indicating internal features of the septum member;

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FIG. 4 shows side cross-sectional view of the septum structure of FIG. 1 with the septum member in a closed configuration and inserted into the housing;

- 15 FIG. 5 shows a cross-sectional view of a catheter hub equipped with the septum structure of FIG. 1;

- FIGs. 6A and 6B illustrate engagement between a needle and (a) a conventional septum with full contact with the body of the needle and (b) an embodiment of the disclosed septum structure with significant decrease in contact with the needle as a result of an elongate cavity within the septum structure;
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FIG. 7 shows side view of another embodiment of the septum structure in accordance with an embodiment of the present disclosure, which can be used without a housing; and

- 25 FIG. 8 shows perspective view of the septum structure as illustrated in FIG. 7, in an open configuration.

Detailed Description

- Aspects of particular embodiments of the present disclosure address at least one aspect, problem, limitation, and/or disadvantage associated with existing sealing members, septa, or septum structures for catheters or catheter hubs. While features, aspects, and/or advantages associated with certain embodiments have been described in the disclosure, other
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embodiments may also exhibit such features, aspects, and/or advantages, and not all embodiments need necessarily exhibit such features, aspects, and/or advantages to fall within the scope of the disclosure. It will be appreciated by a person of ordinary skill in the art that several of the above-disclosed structures, components, or alternatives thereof, can be desirably combined into alternative structures, components, and/or applications. In addition, various modifications, alterations, and/or improvements may be made to various embodiments that are disclosed by a person of ordinary skill in the art within the scope of the present disclosure, which is limited only by the claims included herewith.

In the present disclosure, depiction of a given element or consideration or use of a particular element number in a particular FIG. or a reference thereto in corresponding descriptive material can encompass the same, an equivalent, or an analogous element or element number identified in another FIG. or descriptive material associated therewith. The use of “/” in a FIG. or associated text is understood to mean “and/or” unless otherwise indicated. The recitation of a particular numerical value or value range herein is understood to include or be a recitation of an approximate numerical value or value range, for instance, within +/- 20%, +/- 15%, +/- 10%, +/- 5%.

As used herein, the term “set” corresponds to or is defined as a non-empty finite organization of elements that mathematically exhibits a cardinality of at least 1 (i.e., a set as defined herein can correspond to a unit, singlet, or single element set, or a multiple element set), in accordance with known mathematical definitions (for instance, in a manner corresponding to that described in *An Introduction to Mathematical Reasoning: Numbers, Sets, and Functions*, “Chapter 11: Properties of Finite Sets” (e.g., as indicated on p. 140), by Peter J. Eccles, Cambridge University Press (1998)). In general, an element of a set can include or be a system, an apparatus, a device, a structure, an object, a process, a physical parameter, or a value depending upon the type of set under consideration.

The terms “septum,” “septum structure,” and “catheter septum structure” can be used interchangeably throughout the description herein unless indicated otherwise. Similarly, the terms “septum assembly” and “catheter septum assembly” can be used interchangeably unless indicated otherwise. Directional terms such as “vertical,” “longitudinal,” “lengthwise,” “parallel,” “side,” “perpendicular,” “distal,” and “proximal” as used herein generally refer to

the relative direction of the described embodiments with regard to the position of a clinician handling, deploying, or using a catheter or catheter hub and a septum structure in accordance with an embodiment of the present disclosure.

FIGs. 1 – 4 illustrate portions of a septum structure 100 for a catheter or a catheter hub in accordance with a representative embodiment of the present disclosure. More specifically, FIG. 1 illustrates aspects of a septum structure 100 that includes a body or body structure, which in this embodiment is formed as a septum member 140 providing or having a septum member body that is insertable into a housing 110. The septum structure 100 of FIG. 1 can also be referred to as a septum assembly 100. FIGs. 2 – 4 illustrate aspects of the septum member 140 in accordance with this embodiment of the present disclosure. Additionally, FIG. 5 illustrates a representative positioning of the septum structure 100 within a representative port structure 320, such as a main port structure 320, of a catheter or catheter hub 300 in accordance with an embodiment of the present disclosure.

With reference to FIG. 5, in various embodiments, the main port structure 320 forms a portion of a body or housing of the catheter / catheter hub 300, in a manner readily understood by an individual having ordinary skill in the relevant art. The main port structure 320 includes an aperture 322 located at a proximal end of a main passage 324 that is couplable or connected to an elongate catheter shaft or tube (not shown), in a manner readily understood by one having ordinary skill in the relevant art. A septum structure 100 in accordance with an embodiment of the present disclosure is insertable into the main port structure 320 such that the septum structure 100 occupies the internal cross-sectional area of the main port structure 320, and provides an elastic fluid impermeable seal against the main port structure's inner or interior surface or wall, as further detailed below. In various embodiments, such a seal occurs by way of an interference fit / friction fit / compression fit between outer surfaces of the septum structure 100 that interface with interior surfaces of the main port structure 320. A needle is insertable into the catheter, and hence into the catheter shaft, by way of the aperture 322 and the passage 324, in a manner also readily understood by one having ordinary skill in the relevant art. When the septum structure 100 resides within the main port structure 320, the needle can penetrate through the septum structure 100 during needle insertion into the catheter. When the needle is withdrawn from the catheter, the presence of the septum structure 100 within the main port structure 320 prevents fluid

leakage out of or from the main port structure's aperture 322, while simultaneously reducing drag force(s) upon the needle, as also described in detail below.

With associated reference to FIG. 1, in an embodiment the septum structure 100 includes a housing or housing member 110 and a septum member 140. In several embodiments, the housing 110 has a tubular or generally tubular shape. The housing 110 includes an outer cross-sectional area or diameter configured (e.g., shaped and dimensioned), which in several embodiments is configured for snug fitting or interference fitting into the main passage 324 of a catheter hub 320; and an inner cross-sectional area or diameter configured for receiving the septum member 140. When the septum member 140 has been inserted into the housing 110, the housing 110 can serve as a visual reference or guide with respect to an intended or proper septum structure orientation relative to septum structure insertion into the catheter hub's main port structure 320. More particularly, in various embodiments the housing 110 is intended to be further away from the proximal end of the main port structure 320 than a distal end or distal surface 131 of the septum structure 100 immediately prior to insertion of the septum structure 100 into the main port structure 320. In some embodiments, the housing 110 can have a distinctly different visual appearance than the septum member 140 (e.g., as a result of shape, marking, and/or colour differences) to further aid visual orientation of the septum structure 100 relative to the main port structure 320 prior to septum structure insertion into the main port structure 320.

In multiple embodiments, the housing 110 includes a first opening 112 at a distal border, boundary, or end 111; an abutment or lip structure 116 in which a second opening 114 is formed at a proximal end 115, where the second opening 114 typically has a smaller cross-sectional area or diameter than the first opening 112; and a receptacle or annular chamber 118 defined between the first and second openings 112, 114, which is configured for receiving or carrying portions of the septum member 140, as further detailed below. The housing's first opening 112 is configured for receiving or accommodating a portion of the septum member 140 in a snug-fit or an interference / friction / compression fit manner, and the housing's second opening 114 is configured for receiving a needle. The first opening 112 and the second opening 114 are coaxially aligned relative to a central or longitudinal axis of housing 110, where the housing's longitudinal axis can correspond to or form a portion of a longitudinal or lengthwise axis 150 of the septum structure 100. In a number of embodiments,

the housing 110 is produced from thermoplastic resin such as polypropylene, polycarbonate, or polystyrene to form a structure possessing good mechanical strength and rigidity.

As indicated in FIG. 1, the septum member 140 provides or includes a septum member body structure or body having or defined by a proximal portion 120 and a distal portion 130 of the septum member 140. The proximal portion 120 terminates at a proximal end 121 of the septum member 140; and the distal portion 130 correspondingly terminates at or on the distal end / distal surface 131 of the septum member 140. Thus, the septum member 140 has a septum member body length defined between its proximal end 121 and its distal end 131. The proximal portion 120 of the septum member 140 is configured for insertion into the housing's first opening 112, and can be further configured for fluid impermeable engagement with the housing's chamber 118. Thus, the diameter or cross-sectional area of the proximal portion 120 can be configured for snug fit or interference fit / friction fit / compression fit / mating engagement with the internal diameter or cross-sectional area of the housing's chamber 118. In various embodiments, the septum member 140 has a central, longitudinal, or lengthwise axis that corresponds to the longitudinal axis 150 of the septum structure 100, or forms a portion thereof when the septum member 140 is inserted into the housing's chamber 118. When the proximal portion 120 is fully inserted into the chamber 118, the proximal end 121 of the proximal portion 120 contacts or resides adjacent to an inner surface of the housing's lip structure 116, and overlays and blocks the housing's second opening 114.

The distal portion 130 is coupled to and extends distally away from the proximal portion 120, and has an outer diameter that is greater than that of the proximal portion 120. Thus, the septum member 140 shown in FIG. 1 includes two pieces or sections having different diameters or cross sectional areas (e.g., perpendicular to the septum structure's longitudinal axis 150), namely, a smaller diameter proximal portion 120 and a larger diameter distal portion 130. As a result, the distal portion 130 remains outside of and distal to the housing 110 when the proximal portion 120 is inserted into and engaged with the housing's chamber 118. In several embodiments, a proximal border or boundary 133 of the septum member's distal portion 130 abuts the distal border 113 of the housing 110 when the septum member's proximal portion 130 fully resides within the housing's chamber 118. In multiple embodiments, each of the proximal portion 120 and the distal portion 130 have a circular or generally circular diameter or cross-sectional area. The outer diameter of the housing 110

and the outer diameter of the septum member's distal portion 130 are typically equal, although in some embodiments they can slightly differ.

In a number of embodiments, the distal end 131 of the septum member includes a chamfered region or an oblique slope 133 thereon. Such a chamber or oblique slope 133 facilitates
5 initial registration of the septum structure 100 relative to the main port structure 320 of the catheter / catheter hub 300, and slidable insertion of the septum structure 100 therein. Depending upon embodiment details, the proximal portion 120 and the distal portion 130 can be made from one or more materials such as isoprene / polyisoprene rubber, polyurethane, thermoplastic elastomer (TPE), and/or other materials.

10 The septum member 140 is formed such that it includes at least one hollow region or cavity 160 therein, which facilitates reduced needle drag upon withdrawal of a needle that has been inserted into the aperture 322 and main passage 324 of the catheter hub 320 and into and through the septum member 140. In various embodiments, the septum member 140 includes an elongate cavity 160 that extends along a section of the septum member body length
15 between a first predetermined location within the proximal portion 120 to a second predetermined location within the distal portion 130. The elongate cavity 160 has a cross sectional area that is smaller than that of the septum member's proximal portion 120. In several embodiments, the elongate cavity 160 is centrally or axially aligned (e.g., coaxial) with respect to the central, longitudinal, or lengthwise axis of the septum member 140, where
20 this longitudinal axis of the septum member 140 can correspond to or form a portion of the longitudinal axis 150 of the septum structure 100. Thus, the elongate cavity 160 can be bisected or approximately bisected by a plane parallel to the longitudinal axis of the septum member 140. In some representative implementations, approximately 30% – 70% (e.g., about 40% – 60%, or about 50%, for instance, approximately 52%) of an overall length of the
25 elongate cavity 160 extends into the septum member's proximal portion 120, and correspondingly the remaining length of the elongate cavity 160 extends into the septum member's distal portion 120. Thus, a proximal boundary of the elongate cavity 160 can be located closer to the proximal end 121 of the septum member 140 than a distal boundary of the elongate cavity 160 is located relative to the distal end 131 of the septum member 140.
30 However, one having ordinary skill in the relevant art will understand that the elongate cavity 160 can have different relative portions of its overall length enclosed within the septum

member's proximal and distal portions 120, 130, depending upon embodiment and/or implementation details. Hence, in certain embodiments, a proximal boundary of the elongate cavity 160 can be located further from the proximal end 121 of the septum member 140 than a distal boundary of the elongate cavity 160 is located relative to the distal end 131 of the septum member 140.

As further indicated in FIG. 2, the septum member 140 is also formed such that it includes a first longitudinal or lengthwise section or segment 170a; and a second longitudinal or lengthwise section or segment 170b. The first longitudinal segment 170a and the second longitudinal segment 170b are formed such that they longitudinally or lengthwise partition or divide portions of the septum member body, that is, they longitudinally partition the septum member's elongate cavity 160, distal portion 130, and proximal portion 120 along a predetermined portion of the septum member body length. In a number of embodiments, such longitudinal or lengthwise partitioning of the septum member's elongate cavity 160, distal portion 130, and proximal portion 120 bisects or approximately bisects the elongate cavity 160, the distal portion 130, and a predetermined length of the proximal portion 120 with respect to the cross-sectional area of the elongate cavity 160, the distal portion 130, and the proximal portion 120, respectively.

In addition to the foregoing, the first longitudinal segment 170a and the second longitudinal segment 170b are pivotally displaceable or separable relative to each other about a pivot axis 152 that is transverse or perpendicular to the longitudinal axis 150 of the septum structure 100, or equivalently, transverse or perpendicular to the longitudinal axis of the septum member 140 or septum member body. In several embodiments, the first longitudinal segment 170a and the second longitudinal segment 170b are pivotally displaceable relative to each other at or proximate to the septum member's distal end 131. Thus, the pivot axis 152 in such embodiments is located or defined at or proximate to the septum member's distal end 131. However, in an alternate embodiment, the pivot axis 152 is located or defined at or proximate to the septum member's proximal end 121.

In several embodiments, the first longitudinal segment 170a and the second longitudinal segment 170b are pivotally displaceable away from or toward each other, and hence selectively separable from or contactable with / joinable to each other, or openable / closable relative to each other, by way of a set of hinge elements, members, or structures 180 carried

by the end of the septum member 140 at which the pivot axis 152 is located or defined, which in FIG. 1 is septum member's distal end 131. Thus, the set of hinge elements structurally couples or connects the distal end of the first longitudinal segment 170a to the distal end of the second longitudinal segment 170b. The pivot axis 152 can therefore be defined at or
5 extending along distal or distal-most portions of the set of hinge elements 180, for instance, in a manner indicated in FIGs. 1 and 3. However, in an alternate embodiment, the pivot axis 152 can be defined at or extending along proximal or proximal-most portions of the set of hinge elements 180.

In multiple embodiments, the set of hinge elements 180 includes a first hinge element and a
10 second hinge element laterally disposed on opposite sides of the septum member's distal end 131, such that a needle can exit the septum member's distal end 131 without intersecting either of the first and second hinge elements. Thus, the first and second hinge elements 180 are separated by a gap, which is typically bisected or approximately bisected by the longitudinal axis of the septum member body. In a number of embodiments, a recess or
15 depression 135 in the septum member's distal end 131 is centrally disposed in the gap between the first and second hinge elements. Such a recess 135 can further facilitate reduced needle drag upon withdrawal of a needle that has been inserted into the catheter / catheter hub 300 and through the septum member 140. Each hinge element 180 can include a pair of planar or generally planar projections that distally extend away from and which are coupled
20 together beyond the septum member's distal end 131. Furthermore, each hinge element 180 can have a triangular or generally triangular cross-section. Depending upon embodiment details, each hinge element 180 can be made from one or more materials such as polyisoprene, polyurethane, TPE, and/or other materials. In a number of embodiments, an overall length of the septum member 140 can be defined as a sum of the septum member body length plus a
25 longitudinal or lengthwise distance across which the set of hinge elements 180 extends.

In accordance with the foregoing, the first longitudinal segment 170a and the second longitudinal segment 170b are pivotally displaceable between a closed position as illustrated in FIG. 1, in which the first and second longitudinal segments 170a,b contact, directly interface, or reside directly adjacent to each other; and a range of open positions, such as a
30 representative open position illustrated in FIG. 2, in which the first and second longitudinal segments 170a,b have been pivotally displaced apart from each other, except at or near the set

of hinge elements 180 where they remain coupled or joined. Thus, the septum member 100 is selectively openable or closable by way of displacement of the first longitudinal segment 170a away from or toward the second longitudinal segment 170b, respectively.

5 The first longitudinal segment 170a includes a first inner surface 172a, and the second longitudinal segment 170b includes a corresponding second inner surface 172b. The first and second inner surfaces 172a,b contact, interfaces with, or reside directly adjacent to each other when the septum member 140 is in a closed position (e.g., as illustrated in FIG. 1). An angle between the first and second inner surfaces 172a,b progressively increases, for instance, from approximately 0 degrees to significantly greater than 0 degrees, such as between
10 approximately 90 - 180 degrees, as the first and second longitudinal segments 170a,b are progressively displaced apart or away from each other by way of the set of hinge elements 180.

Depending upon embodiment, implementation, clinical situation details, while the septum member 140 is in the open position, a biocompatible lubricating gel and/or an antiseptic agent
15 can be introduced or disposed in the elongate cavity 160, after which the septum member 140 can be transitioned to the closed position. When the septum member 140 is in the closed position, the proximal portion 120 thereof can be inserted into the housing's chamber 118. The septum structure 100 can then be inserted or force fit into the main port 320 of the catheter / catheter hub 300 to provide a fluid impermeable seal therein, as previously
20 described.

Thus, in view of the foregoing, prior to each of (a) insertion of the septum structure 100 into the main port 320 of the catheter / catheter hub 300, and (b) insertion of the septum member 140 into the housing 110, the septum member's proximal portion 120 is external to the housing's chamber 118, and the septum member 140 can be opened by way of pivotable
25 displacement of the first and second longitudinal segments 172a,b away from each other; and closed by way of pivotable displacement of the first and second longitudinal segments 172a,b toward each other until they come into contact. Once the septum member 140 is in the closed position, it can be inserted or force fit into the chamber 118 of the housing 110, after which the entire septum structure 100 can be inserted or force fit into the main port 320 of the
30 catheter / catheter hub 300.

As indicated in FIGs. 1 and 2, the length of the first longitudinal segment 170a is different than that of the second longitudinal segment 170b. For instance, the length of the first longitudinal segment 170a in various embodiments is greater than that of the second longitudinal segment 170b. More particularly, in such embodiments, the first longitudinal segment 170a has a length equal to the septum member body length; and the second longitudinal segment 170b has a length less than the septum member body length. Still more particularly, a proximal section or region of the first longitudinal segment 170a includes a pane, panel, or projection 174, which in several embodiments has a hemispherical profile or shape relative to the septum member's longitudinal axis. The projection 174 outwardly, radially, transversely, or perpendicularly extends away from the first inner surface 172a and/or the lengthwise axis 150 of the septum structure 100, such that the proximal end 121 of the septum member 140 exhibits or defines a cross sectional area (e.g., an elliptical or circular cross sectional area) that is shape-matched to the interior of the housing's chamber 118 (e.g., corresponding to the shape of the periphery of the projection 174 and the periphery of the first longitudinal segment 170a). When the septum member 140 is in a closed position, a proximal face 175 of the second longitudinal segment 170b seats against a corresponding distal face 176 of this projection 174. Thus, when the septum member 140 is in the closed position, the second inner surface 172b of the second longitudinal segment 170b is configured to rest or press against the first inner surface 172a of the first longitudinal segment 170a, and the proximal face 175 of the second longitudinal segment 170b is configured to rest or press against the distal face 176 of the projection 174.

In view of the foregoing and as indicated in FIGs. 1 and 4, when the septum member 140 is in the closed position, in various embodiments the first longitudinal segment 170a and the second longitudinal segment 170b are separated or delineated from each other by a slit structure or through cut structure. The slit structure can extend in a plane parallel to the longitudinal axis of the septum member 140 across at least a portion of the septum member's length (e.g., a distance less than the septum member's length). In a number of embodiments, the slit structure is L-shaped or a generally L-shaped. For instance, in the embodiment shown, when the septum member 140 is in the closed position, a first or longest portion 178 of the slit structure or L-shaped slit corresponds to or is defined by a distance across which the first inner surface 172a and the second inner surface 172b contact each other; and a second or shortest portion 179 of the slit structure or L-shaped slit corresponds to or is defined by a

distance across which the proximal face 175 of the second longitudinal segment 170b seats against or contacts the distal face 176 of the first longitudinal segment's projection 174. While the first and second portions 178, 179 of the L-shaped slit are illustrated as being offset from each other by an angle of approximately 90 degrees, one having ordinary skill in the relevant art will understand that the first and second portions 178, 179 can be offset by an angle other than approximately 90 degrees (e.g., approximately 75 degrees), depending upon embodiment details.

An individual having ordinary skill in the art will recognize that a septum member 140 in accordance with an alternate embodiment of the present disclosure can have a first longitudinal segment 170a and a second longitudinal segment 170b which, when the septum member 140 is in a closed position, are separated or delineated from each other by a slit or through-cut structure having another type of shape. For instance, the slit structure could be generally V-shaped or generally U-shaped, rather than L-shaped or generally L-shaped.

As indicated in FIGs. 1 – 4, in various embodiments the first or longest portion 178 of the slit structure is shorter than the entire longitudinal extent or length of the first longitudinal segment 170a. As a result, the slit structure 178, 179 does not extend or cut through the projection 174. Thus, the first and second longitudinal segments 170a,b have asymmetric shapes relative to each other along the septum member's length or the longitudinal axis 150, i.e., the first and second longitudinal segments 170a,b are not symmetric or mirror images halves with respect to each other. More particularly, across a terminal or proximal portion, region, section, or segment 142 of the septum member 140, the septum member 140 remains a unitary, contiguous, or undivided structure across its entire diameter (e.g., proximal end diameter), which aids in effectively and/or reliably establishing and maintaining a fluid impermeable seal between portions of the septum member 140 (e.g., the proximal segment 142) and the chamber 118 of the housing 110, thereby aiding or enhancing the sealing effectiveness and/or reliability between the septum structure 100 and inner / internal surfaces of a catheter / catheter hub main port structure 320 in which the septum structure 100 resides. In several embodiments, the proximal segment 142 of the septum member 140 extends across a lengthwise or longitudinal distance (e.g., parallel to the longitudinal axis 150) defined between the proximal end 121 of the septum member 140 and the distal face 176 of the projection 174.

With reference to FIGs. 3 and 4, the housing 110 has an outer diameter that is similar, essentially identical, or identical to the outer diameter of the septum member's distal portion 130. Full engagement or insertion of the septum member's proximal portion 120 in the housing's chamber 118 results in the formation of the septum structure 100, as indicated in
5 FIGs. 3 and 4, which in various embodiments has a substantially uniform outer surface and cross-sectional area. The proximal portion 120 of the septum member 140 can be force fit or compression fit into the housing's chamber 118, such that the inner surface of the chamber 118 persistently radially compresses the septum member's proximal portion 120 (which can exert a resilient expansion force against the inner surface of the chamber 118). Once the
10 septum member 140 has been inserted (e.g., fully inserted) into the housing 118, the proximal end 121 of the septum member 140 contacts the housing's lip structure 116 and blocks the housing's second opening 114 such that fluid transfer through the second opening 114 cannot occur. The presence of the set of hinge elements 180 at the septum member's distal end can facilitate rapid determination of a proper or intended orientation of the septum member 140
15 relative to the housing 118 as well as a proper or intended orientation of the septum structure 100 relative to a catheter's main port structure 320 into which the septum structure 100 is to be inserted.

FIG. 5 illustrates engagement of the septum structure 100 and the main port structure 320 of the catheter or catheter hub 300. As indicated in FIG. 5, the main passage 324 extends
20 lengthwise through the catheter / catheter hub 300, and is axially aligned relative to a central, longitudinal, or lengthwise axis 350 of the catheter / catheter hub 300 and/or the main port structure 320. One having ordinary skill in the relevant art will understand that a catheter shaft or tube (not shown) distally extends away from the main port structure 320. When the septum structure 100 resides within the main passage 324, the septum structure's longitudinal
25 axis 150 is parallel to, coaxially aligned, or approximately coaxially aligned with the main port structure's longitudinal axis 350, or can form a portion thereof. In some embodiments the main port structure 320 can include a fluid conduit that encloses a side passage that merges into the main passage 324, in a manner readily understood by one having ordinary skill in the relevant art. The main passage 324 and the side passage in such embodiments
30 form a generally Y-shaped fluid junction or pathway within the main port structure 320.

The septum structure 100 can be inserted (e.g., slidably force-fit) into the main passage 324 of the main port structure 320 to establish an interference fit between the septum structure 100 and the main passage 324 in which the septum structure 100 resides, such that the exterior or outer surfaces of the septum structure 100 are compressed against the interior or inner surface of the main port structure's main passage 324. As a result, the interface between the outer surfaces of the septum structure 100 and the inner surface of the main passage 324 is fluid impermeable, and the cross sectional area of the septum structure 100 that occupies the cross sectional area of the main passage 324 blocks the passage of fluid through the passage 324. Thus, the presence of the septum structure 100 within the passage 328 ensures that fluid leakage from the catheter / catheter hub 300 does not occur. The septum member's distal portion 130 has an outer cross sectional area or diameter slightly greater than the inner cross sectional area or diameter of the main passage 324, which facilitates or enables force-fit insertion of the septum structure 100 into the main passage 324, and sufficient radial compression of the septum structure's outer surfaces by the inner surface of the main passage 324 that the septum structure 100 seals the main passage 324 with respect to fluid transfer into or out of the main port structure's aperture 322.

The septum structure 100 can be inserted or force fit into the catheter hub's main passage 324 by way of cooperative alignment of the septum structure's longitudinal axis 150 and the catheter hub's longitudinal axis 350, followed by the application of an insertion force to the septum structure 100 along a proximal to distal direction. The septum structure 100 can be inserted into and displaced along a depth of the main passage 324 until the insertion force applied to the septum structure 100 along a proximal to distal direction fails to further distally displace the septum structure 100 along the main passage 324. Thus, the septum structure 100 is insertable into the main passage 324 to a depth or distance within the main passage 324 at or approximately at which the frictional forces resulting from the interference fit between the inner surfaces of the main passage 324 and the peripheral surfaces of septum member 140 or septum structure 100 are equal to or greater than the proximal to distal insertion force applied to the septum structure 100.

Once the septum structure 100 has been inserted to a suitable, intended, target or maximum depth or distance within the main passage 324 of the main port structure 320 such that a fluid impermeable interference fit between the septum structure 100 and the main passage 324

exists, a needle can be progressively inserted into the catheter hub's aperture 322 and main passage 324, such that the needle penetrates and travels through the septum structure 100 and into the catheter shaft. When the needle is withdrawn from the catheter, the fluid impermeable barrier and seal provided by the septum structure 100 relative to the main passage 324 prevents fluid leakage from the catheter hub's aperture 322. During withdrawal of the needle, the persistent radial compressive force exerted by the inner surface of the main passage 324 of the catheter / catheter hub 300 against portions of the periphery of the septum structure 100 (e.g., the septum member 140) results in nearly immediate and persistent sealing of a potential fluid passage within the septum member 140 that could exist along a path internal to the septum member 140 where the needle previously resided, corresponding to a trajectory along which the needle had been inserted into and through the septum member 140.

When the septum structure 100 resides within the main port structure 320, the septum structure's elements are cooperatively aligned (e.g., coaxially aligned) relative to each other in a manner that facilitates reliable low drag needle insertion into and withdrawal from the catheter / catheter hub 300. Thus, the cross sectional areas of each portion of the septum structure 100 through which the needle passes during insertion or withdrawal are coaxially aligned. More particularly, the cross sectional area of the chamber's second aperture 114 is coaxially aligned relative to the cross sectional area of first and second portions 120, 130 of the septum member 140, the cross sectional area of the elongate cavity 160, and the cross sectional area of the recess 135 carried by the septum member's distal end 131. Because of the presence of the elongate cavity 160, and possibly additionally the presence of the recess 135 at the septum member's distal end 131, the amount of physical material that a needle inserted into or withdrawn from a catheter / catheter hub 300 into which the septum structure 100 has been inserted is reduced or minimized, thereby reducing or minimizing drag force upon the needle. Such drag force is reduced or minimized without compromising the fluid barrier provided by the septum structure 100 within the catheter hub's main port structure 320.

Ideally, the aforementioned needle insertion and withdrawal is intended to occur parallel or substantially parallel to or along the septum structure's longitudinal axis 150. In order to facilitate reliable low drag needle insertion and withdrawal, in several embodiments, the size of the chamber's second opening 114 is slightly to moderately larger than the diameter of the

needle to facilitate needle insertion into and withdrawal from the septum structure 100 in a direction along or approximately parallel to the septum structure's longitudinal axis 150. Additionally, in some embodiments, the second opening 114 can have a diameter that is smaller or significantly smaller than the diameter of the elongate cavity 160 in order to increase the likelihood that the needle traverses an intended low trajectory during needle insertion or withdrawal.

FIG. 6A illustrates a conventional septum sealing member disposed within a catheter / catheter hub 300, where the conventional septum sealing member lacks an internal cavity; and FIG. 6B illustrates a septum structure 100 in accordance with an embodiment of the present disclosure disposed within a catheter / catheter hub 300. Due to the absence of an internal cavity, the conventional septum sealing member exerts an undesirably high drag force upon a needle 5 across the entire length of the conventional septum sealing member. In contrast, the elongate cavity 160 provided by a septum member 140 in accordance with an embodiment of the present disclosure provides an internal region along or within a predetermined portion of the septum member's body length, across which reduced or no friction, and hence reduced or no drag force, is exerted upon a needle 5. As also indicated in FIG. 6B, the housing's second opening 114 is configured to inherently or automatically guide the needle 5 during needle insertion into the septum structure 100 such that it traverses through the elongate chamber 160, thus facilitating consistent and reliable low drag needle insertion and withdrawal, without requiring additional effort on the part of the clinician.

In multiple embodiments the septum structure 100 has a cylindrical or generally cylindrical shape; however, in certain embodiments the septum structure 100 has a tapered shape along one or more portions of its length (e.g., in a direction parallel to the septum structure's longitudinal axis 150), such that the outer diameter of the septum structure 100 perpendicular to its longitudinal axis varies along one or more portions of the septum structure body length. Such tapering can facilitate or enhance the formation of an interference fit between interior surfaces of a catheter hub's main port structure 320 and outer surfaces of the septum structure 100 that interface therewith.

While septum structure embodiments described above include the housing 110, various embodiments in accordance with the present disclosure also provide for septum structures

that exclude / lack or need not include such a housing 110. Notwithstanding the exclusion or lack of a housing 110, several structural and functional aspects of septum structures that do not include the housing 110 are analogous, essentially identical, or identical to structural and functional aspects of septum structure embodiments described above, as further detailed hereafter.

FIGs. 7 and 8 illustrate a septum structure 200 that lacks or need not include a housing 110 in accordance with an embodiment of the disclosure. The septum structure 200 includes a body having proximal portion 220 that is coupled or connected to a distal portion 230, and an elongate cavity 260 enclosed therein. The proximal portion 220 terminates at a proximal end 221 of the septum structure 200, and the distal portion 230 terminates at a distal end or distal surface 231 of the septum structure 200. The septum structure 200 has a septum structure body length defined between its proximal and distal ends 221, 231. A central, longitudinal, or lengthwise axis 250 can be defined that extends through and which bisects or approximately bisects each of the proximal portion 220, the distal portion, 230, and the elongate cavity 260. Thus, the elongate cavity 260 is coaxially aligned with respect to the septum structure's longitudinal axis 250, in order to provide a reduced, low, or no drag pathway with respect to needle insertion or withdrawal along a portion of the septum structure's body length.

In some embodiments, an outer diameter (e.g., a largest or maximum outer diameter) of the proximal portion 220 and an outer diameter (e.g., a largest or maximum outer diameter) of the distal portion 230 are equal or approximately equal. However, in certain embodiments, the outer diameters of the proximal and distal portions 220, 230 can be slightly different. In various embodiments, each of the proximal portion and the distal portion 220, 230 is generally shape matched or shape matched with respect to the main passage 324 of a catheter hub's main port structure 320. Hence, in several embodiments the proximal and distal portions 320, 330 have a cylindrical or generally cylindrical shape. In a number of embodiments, the septum structure 200 has a tapered shape along one or more portions of the length of the septum structure body (e.g., in a direction parallel to the longitudinal axis 250), such that the outer diameter of the septum structure 200 perpendicular to its longitudinal axis 250 varies along one or more portions of the septum structure body length.

The distal end 231 of the distal portion 230 of the septum structure 200 can include a chamfered region or an oblique slope 233 thereon. Such a chamfered region or oblique slope 233 facilitates initial registration of the septum structure 200 relative to the main port structure 320 of the catheter / catheter hub 300, and slidable insertion of the septum structure 200 therein. The chamfered region / oblique slope 233 can additionally provide a visual cue or clue with respect to an intended or proper orientation of the septum structure 200 relative to a catheter / catheter hub 300, prior or immediately prior to insertion of the septum structure 200 into the main passage 328 of the catheter hub's main port structure 320.

Depending upon embodiment details, a length of the proximal portion 220 and a length of the distal portion 230 can be approximately equal, equal, or at least slightly different. In a number of embodiments, the septum structure 200 includes an indented region or indentation 245 disposed between (e.g., approximately midway between) the proximal and distal portions 220, 230, along or across a predetermined portion of the septum member body length. The indentation 245 can be annular or ring shaped, and can indicate or demarcate an interface region or boundary between the septum structure's proximal portion 220 and its distal portion 230.

In a manner analogous to that described above, the septum structure's elongate cavity 260 extends longitudinally or lengthwise between a predetermined location within the proximal portion 220 and a predetermined location within the distal portion 230. In a representative implementation, approximately 30% - 70% (e.g., about 40% - 60%, or about 50%, or approximately 52%) of an overall length of the elongate cavity 260 resides within septum structure's proximal portion 220, and the remaining length of the elongate cavity 260 resides within the septum structure's distal portion 230. One having ordinary skill in the relevant art will understand that the elongate cavity 260 can have different relative portions of its overall length enclosed within the septum structure's proximal and distal portions 220, 230, depending upon embodiment and/or implementation details.

In a manner also analogous to that described above, the septum structure 200 includes a first longitudinal segment 270a and a second longitudinal segment 270b, which are formed such

that they longitudinally or lengthwise divide the septum structure's elongate cavity 260, distal portion 230 and proximal portion 220 along a predetermined portion of the septum structure body length. Such longitudinal or lengthwise partitioning of the septum structure's elongate cavity 260, distal portion 230, and proximal portion 220 can bisect or approximately bisect the elongate cavity 260, the distal portion 230, and a predetermined length of the proximal portion 220 with respect to the cross-sectional area of the elongate cavity 260, the distal portion 230, and the proximal portion 220, respectively.

In a manner essentially identical or analogous to that previously described, the first and second longitudinal segments 270a,b are pivotally displaceable relative to each other about a pivot axis 252, for instance, at or proximate to the septum structure's distal end 231, such as by way of a set of hinge elements 280 that structurally couple or connect the first and second longitudinal segments 270a,b. As a result, the first and second longitudinal segments 270a,b can be positioned such that the septum structure 200 is in a closed position or one or more open positions, in a manner also analogous to that previously described. The set of hinge elements 280 can include a first hinge element and a second hinge element laterally disposed on opposite sides of the septum structure distal end 231 and separated by a gap, such that a needle can exit the septum structure's distal end 231 without intersecting either of the first and second hinge elements. A recess or depression 235 can be formed in the septum structure's distal end 231, centrally disposed between the first and second hinge elements 280. Each hinge element 280 can have a structure that is generally analogous, analogous, or essentially identical to that described above. An overall length of the septum structure 200 can be defined as a sum of the septum structure body length plus a longitudinal or lengthwise distance across which the set of hinge elements 280 extends.

The set of hinge elements 280 can provide a visual cue or clue with respect to an intended or proper septum structure orientation relative to insertion of the septum structure 200 into a catheter hub's main port structure 320. In particular, the set of hinge elements 280 should be positioned closest to the main port structure's aperture 322, and hence oriented toward a distal section of the main port structure 320 or the catheter shaft, immediately prior to insertion of the septum structure 200 into the main port structure's main passage 324.

The first longitudinal segment 270a includes a first inner surface 272a, and the second longitudinal segment 280b includes a corresponding second inner surface 272b, which contact, interface with, or reside directly adjacent each other when the septum structure 200 is in a closed position. Prior to insertion of the septum structure 200 into a catheter hub's main port structure 320, the first longitudinal segment 270a and the second longitudinal segment 280b can be pivotally displaced away from each other to position the septum structure 200 in one or more open positions. As the first and second longitudinal segments 270a,b are progressively pivotally displaced further from each other by way of the set of hinge elements 280, an angle between the first and second inner surfaces 272a,b progressively increases (e.g., from approximately 0 degrees to significantly greater than 0 degrees, such as between approximately 90 - 180 degrees).

The length of the first longitudinal segment 270a is equal to the septum structure body length; and the length of the second longitudinal segment 270b is less than the septum structure body length. A proximal section or region of the first longitudinal segment 270a includes a hemispherical projection 274 that outwardly or radially extends away from the first inner surface 272a, such that the proximal end 221 of the septum structure 200 has a circular cross sectional area that is approximately shape-matched or shape-matched to at least portions of the interior of the main passage 324 of the catheter hub's main port structure 320 within which the septum structure 200 is intended to reside. When the septum structure 200 is in a closed position, a proximal face 275 of the second longitudinal segment 270b seats against a corresponding distal face 276 of the projection 274. Thus, the second inner surface 272b of the second longitudinal segment 270b is configured to rest or press against the first inner surface 272a of the first longitudinal segment 270a, and the proximal face 275 of the second longitudinal segment 270b is configured to rest or press against the distal face 276 of the projection 276 when the septum structure 200 is closed.

When the septum structure 200 is in the closed position, in multiple embodiments the first longitudinal segment 270a and the second longitudinal segment 270b are separated or delineated from each other by a slit structure, such as an L-shaped or generally L-shaped slit. A first or longest portion 278 of the slit structure or L-shaped slit corresponds to or is defined by a distance across which the first inner surface 272a and the second inner surface 272b contact each other; and a second or shortest portion 279 of the slit structure or L-shaped slit

corresponds to or is defined by a distance across which the proximal face 275 of the second longitudinal segment 270b seats against or contacts the distal face 276 of the first longitudinal segment's projection 274. The first and second portions 278, 279 of the L-shaped slit can be offset from each other by an angle of approximately 90 degrees, or an angle other than approximately 90 degrees depending upon embodiment details. An individual having ordinary skill in the art will recognize that a septum structure 200 in accordance with an alternate embodiment can have a first longitudinal segment 270a and a second longitudinal segment 270b which, when the septum structure 200 is in a closed position, are separated or delineated from each other by a slit or through-cut structure having another type of shape. For instance, the slit structure could be generally V-shaped or generally U-shaped, rather than L-shaped or generally L-shaped.

In various embodiments the first or longest portion 278 of the slit structure is shorter than the entire longitudinal extent or length of the first longitudinal segment 270a. As a result, the slit structure 278, 279 does not extend or cut through the projection 274. Thus, the first and second longitudinal segments 270a,b have asymmetric shapes relative to each other along the septum structure's length or longitudinal axis 250, i.e., the first and second longitudinal segments 270a,b are not symmetric or mirror images halves with respect to each other along the septum structure's length or longitudinal axis. More particularly, across a terminal or proximal portion, region, section, or segment 242 of the septum structure 200, the septum structure 200 remains unitary, contiguous, or undivided across its entire diameter (e.g., its proximal end diameter), which aids in effectively and/or reliably establishing and maintaining a fluid impermeable seal between the septum structure 200 and the main passage 324 of a main port structure 320 of a catheter / catheter hub 300. In several embodiments, the proximal segment 242 of the septum structure 200 extends across a lengthwise or longitudinal distance (e.g., parallel to the longitudinal axis 250) defined between the proximal end 221 of the septum structure 200 and the distal face 276 of the projection 274.

With respect to the insertion of the septum structure 200 into the main passage 324 of a main port structure 320 of a catheter / catheter hub 300, when the septum structure 200 is in the closed position, the septum structure's axis 250 can be cooperatively aligned relative to the main port structure's axis 350. The septum structure 200 can then be inserted by way of force fitting into the aperture 322 and main passage 324 of the main port structure 320 to

establish an interference / friction / compression fit between interior surfaces of the main passage 324 and peripheral surfaces of the septum structure 200 in contact therewith, in a manner analogous to that described above.

Each of the proximal and distal portions 220, 230 of the septum structure 200 typically have
5 an outer cross sectional area (e.g., perpendicular to the septum structure's longitudinal axis 250) or diameter slightly greater than the cross sectional area or diameter of the main passage 324 to realize force fitting of the septum structure 200 into the main passage 324, secure retention of the septum structure 200 therein, and the creation and maintenance of a fluid impermeable interference / friction / compression fit between the septum structure 200 and
10 the main passage 324. After the septum structure 200 has been inserted into or disposed within the catheter hub's main passage 324, each of the proximal portion 220 and the distal portion 230 are subjected to a radial compression force exerted by the inner surface of the main passage 324. Such a radial compression force against the distal and proximal portions 230 of the septum structure 200 leads to persistent and almost immediate sealing of a fluid
15 pathway that can be formed in the septum structure 200 as a result of withdrawal of a needle from a needle insertion trajectory through the septum structure 200.

Aspects of particular embodiments of the present disclosure address at least one aspect, problem, limitation, and/or disadvantage associated with exiting septum sealing structures for
20 catheters. While features, aspects, and/or advantages associated with certain embodiments have been described in the disclosure, other embodiments may also exhibit such features, aspects, and/or advantages, and not all embodiments need necessarily exhibit such features, aspects, and/or advantages to fall within the scope of the disclosure. It will be appreciated by a person of ordinary skill in the art that several of the above-disclosed systems, devices,
25 structures, components, processes, or alternatives thereof, may be desirably combined into other different systems, devices, structures, components, processes, and/or applications. In addition, various modifications, alterations, and/or improvements may be made to various embodiments that are disclosed by a person of ordinary skill in the art within the scope of the present disclosure.

Claims

1. A septum structure for a catheter or a catheter hub having an aperture and a main port structure, the septum structure comprising:

an elongate body configured for insertion into the aperture and main port structure of the catheter or catheter hub, the body having a proximal end, a distal end, and a length between the proximal and distal ends, the length of the body parallel to a longitudinal axis of the body, the body comprising:

a first longitudinal segment along the body length, the first longitudinal segment having a first inner surface; and

a second longitudinal segment along at least a portion of the body length, the second longitudinal segment having a second inner surface configured to interface with the first inner surface when the septum structure is in a closed position,

wherein the first longitudinal segment and the second longitudinal segment have asymmetric shapes relative to each other about the longitudinal axis of the body, and are pivotably displaceable relative to each other for transitioning the septum structure between the closed position and a set of open positions, and wherein pivotal displacement of the first longitudinal segment relative to the second longitudinal segment occurs about a pivot axis that is perpendicular to the longitudinal axis of the body and parallel to the proximal end and/or the distal end of the body.

2. The septum structure of claim 1, wherein the body includes a slit structure along at least portions of its length, wherein the slit structure defines a boundary between the first longitudinal segment and the second longitudinal segment when the septum structure is in a closed position.

3. The septum structure of claim 2, wherein the slit structure defines a boundary between the first inner surface of the first longitudinal segment and the second inner surface of the second longitudinal segment when the septum structure is in a closed position.

4. The septum structure of claim 2, wherein the slit structure extends in a first plane parallel to the longitudinal axis of the body across a distance less than the length of the body.

5. The septum structure of any one of claims 1 – 4, wherein the second longitudinal segment has a different length than the first longitudinal segment across the length of the body.

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6. The septum structure of claim 5, wherein the first longitudinal segment includes a projection that transversely or perpendicularly extends away from the first inner surface of the first longitudinal segment.

10 7. The septum structure of claim 6, wherein the projection includes a distal face against which a proximal face of the second longitudinal segment seats when the septum structure is in a closed position.

8. The septum structure of any one of claims 1 – 6, further comprising an elongate cavity carried by the body along a predetermined portion of the length of the body.

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9. The septum structure of claim 8, wherein a first portion of the elongate cavity is carried by the first longitudinal segment, and a second portion of the longitudinal cavity is carried by the second longitudinal segment.

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10. The septum structure of claim 9, wherein the elongate cavity is approximately bisected by a plane parallel to the longitudinal axis of the septum structure.

11. The septum structure of any one of claims 8 – 10, wherein a proximal boundary of the elongate cavity is located closer to the proximal end of the body than a distal boundary of the elongate cavity is located relative to the distal end of the body.

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12. The septum structure of any one of claims 1 – 11, wherein the body includes a chamfered region adjacent to its distal end.

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13. The septum structure of any one of claims 1 – 12, wherein the body further comprises a proximal portion and a distal portion, and wherein the proximal portion and the distal

portion are separated from each other by (a) different diameters, or (b) an indented region along a portion of the length of the body.

14. The septum structure of claim 13, wherein the proximal portion and the distal portion are separated from each other by different diameters, and wherein a diameter of the proximal portion is smaller than a diameter of the distal portion.

15. The septum structure of claim 13 or 14, further comprising a housing into which the proximal portion is insertable, wherein the housing includes an opening that is centrally aligned relative to the longitudinal axis of the body and is configured for receiving a needle.

16. The septum structure of claim 15, wherein the proximal portion is configured for insertion into and secure retention within the housing by way of a snug-fit or an interference fit therein.

17. The septum structure of claim 15 or 16, wherein the housing has an outer diameter approximately equal to the outer diameter of the distal portion of the body.

18. The septum structure of any one of claims 1 – 17, further comprising a set of hinge elements coupled to each of the first longitudinal segment and the second longitudinal segment, the set of hinge elements configured for enabling pivotal displacement of the first longitudinal segment and the second longitudinal segment away from or toward each other about the pivot axis prior to septum structure insertion into the main port of the catheter or catheter hub.

19. The septum structure of claim 18, wherein the set of hinge elements is carried by the distal end of the body.

20. The septum structure of claim 18 or 19, wherein the set of hinge elements includes a first hinge structure and a second hinge structure disposed on opposite sides of the longitudinal axis of the body and separated from each other by a gap, and wherein the longitudinal axis of the body approximately bisects the gap.

21. The septum structure of claim 20, wherein the body further comprises a recess defined within the gap.

22. The septum structure of any one of claims 1 – 21, wherein the septum structure is configured for an interference fit into and retention by the main port structure of the catheter or catheter hub.

23. A kit comprising:

a catheter or catheter hub having a main port structure providing a main passage therein, wherein a longitudinal axis of the main port structure is definable along portions of the main passage and the main passage terminates at an aperture at a proximal end of the catheter or catheter hub; and

a septum structure having a longitudinal axis alignable with the longitudinal axis of the main port structure and insertable into the main passage of the main port structure by way of force fitting, wherein the septum structure comprises an elongate body configured for insertion into the aperture and main port structure of the catheter or catheter hub, the body having a proximal end, a distal end, and a length between the proximal and distal ends, the length of the body parallel to the longitudinal axis of the septum structure, and wherein the body comprises:

a first longitudinal segment along the body length, the first longitudinal segment having a first inner surface; and

a second longitudinal segment along at least a portion of the body length, the second longitudinal segment having a second inner surface configured to interface with the first inner surface when the septum structure is in a closed position,

wherein the first longitudinal segment and the second longitudinal segment have asymmetric shapes relative to each other about the longitudinal axis of the septum structure, and are pivotably displaceable relative to each other for transitioning the septum structure between the closed position and a set of open positions, and wherein pivotal displacement of the first longitudinal segment relative to the second longitudinal segment occurs about a pivot axis

that is perpendicular to the longitudinal axis of the septum structure and parallel to the proximal end and/or the distal end of the body.

24. The kit of claim 23, wherein the septum structure further comprises a set of hinge elements coupling the first longitudinal segment to the second longitudinal segment at a terminal end of the septum structure to define the pivot axis, and wherein the set of hinge elements facilitates visual identification of a proper orientation of the septum structure relative to the main port structure prior to insertion of the septum structure into the main passage of the main port structure.

25. The kit of claim 24, wherein the set of hinge elements is carried by a distal end of the septum structure.

26. A septum sealed catheter or catheter hub structure comprising:

a catheter or catheter having a main port structure providing a main passage therein, the main passage having an interior surface, wherein a longitudinal axis of the main passage is definable within the main port structure along portions of the main passage, and the main passage terminates at an aperture at a proximal end of the catheter or catheter hub; and

a septum structure retained within the main passage of the main port structure by way of an interference fit between the interior surface of the main passage and an outer surface of the septum structure, wherein the septum structure comprises an elongate body having a proximal end, a distal end, and a length between the proximal and distal ends, wherein the length of the body is parallel to a longitudinal axis of the septum structure, and wherein the body comprises:

a first longitudinal segment along the body length, the first longitudinal segment having a first inner surface; and

a second longitudinal segment along at least a portion of the body length, the second longitudinal segment having a second inner surface configured to interface with the first inner surface when the septum structure is in a closed position,

wherein the first longitudinal segment and the second longitudinal segment have asymmetric shapes relative to each other about the longitudinal axis of the septum structure, and are pivotably displaceable relative to each other for transitioning the septum structure between the closed position and a set of open positions, and wherein pivotal displacement of the first longitudinal segment relative to the second longitudinal segment occurs about a pivot axis that is perpendicular to the longitudinal axis of the septum structure and parallel to the proximal end and/or the distal end of the body.

27. The catheter or catheter hub structure of claim 26, wherein the septum structure further comprises a set of hinge elements coupling the first longitudinal segment to the second longitudinal segment at a terminal end of the septum structure to define the pivot axis, and wherein the set of hinge elements has a predetermined orientation relative to a proximal aperture of the main port structure for indicating a proper orientation of the septum structure within the main passage of the main port structure.

28. The catheter or catheter hub structure of claim 27, wherein the set of hinge elements is carried by a distal end of the septum structure.