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STORAGE JAR ASSEMBLY FOR A PROSTHETIC HEART VALVE

Abstract

A storage jar assembly for use with a prosthetic heart valve is disclosed in several embodiments. As one example, a storage jar assembly can include a jar having an open end and configured to receive a prosthetic heart valve. The storage jay assembly also includes a lid configured to cover the open end of the jar. The storage jar assembly can include a valve holder having a base, a column connected to and extending axially away from the base, and a plurality of circumferentially spaced valve retention members mounted on the base. The valve holder can be configured to hold the prosthetic heart valve in a partially compressed state within the jar.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application is a divisional of U.S. patent application Ser. No. 18/139,794, filed on Apr. 26, 2023, which is a continuation of PCT Application No. PCT/US2021/062690, filed on Dec. 9, 2021, which claims the benefit of U.S. Provisional Patent Application No. 63/199,331, filed on Dec. 18, 2020, all of which applications are incorporated herein by reference in their entirety.

FIELD

[0002] The present disclosure relates to a storage jar assembly that is configured to receive a prosthetic heart valve.

BACKGROUND

[0003] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require repair of the native valve or replacement of the native valve with an artificial valve. Transcatheter prosthetic heart valves are designed with an expandable frame and a valvular structure (e.g., one or more prosthetic leaflets) attached to the frame. This configuration allows the prosthetic heart valve to be inserted in a patient while compressed or partially compressed, and then to be expanded to fit the diameter of the native heart valve being replaced.

[0004] In some cases, the prosthetic leaflets, typically made of pericardial tissues, require hydration when they are stored prior to use. The prosthetic heart valve must also be protected from physical damage during shipping and storage. This is generally accomplished by the use of a valve storage jar assembly containing a hydrating fluid, such as glutaraldehyde, allowing the storage jar assembly to both physically protect and hydrate the leaflets of the prosthetic heart valve before it is installed in a patient.

[0005] Typically, a prosthetic heart valve is placed loose in a jar and therefore can be exposed to potential damage during storage, shipping and handling through contact between the prosthetic heart valve and the inner surfaces of the jar. Additionally, during device preparation, removal of the prosthetic heart valve from the jar can be awkward or difficult to accomplish because the clinician must reach into the jar with a sterile tool, such as forceps or tweezers, while avoiding contact the sides of the jar and avoiding pinching or tearing of the soft components of the prosthetic heart valve.

[0006] Known storage jar assemblies have included a valve holding mechanism for holding a prosthetic valve within a jar. The valve holding mechanism requires the placement of sutures for securing the prosthetic valve to the valve holding mechanism during the assembly process. As can be appreciated, this increases the complexity and length of the assembly process. Moreover, special tools may be required to remove the valve holding mechanism and the prosthetic valve from the jar as well as to remove the prosthetic valve from the valve holding mechanism.

[0007] Another issue concerning storage jar assemblies is that prosthetic heart valves come in various sizes. A storage jar assembly designed for a prosthetic heart valve of one specific size may not be suitable for use with a similar valve of a different size.

[0008] Therefore, there is a need for storage jars assemblies for prosthetic heart valves that overcome one or more disadvantages of the prior art.

SUMMARY

[0009] Disclosed herein are prosthetic heart valves, storage jar assemblies for use with various prosthetic heart valves, as well as securing devices for securing or holding prosthetic heart valves inside storage jar assemblies during shipping, storage, and subsequent handling. The securing

devices can be used to partially compress prosthetic heart valves so that they may be contained in the storage jar assemblies disclosed herein. In some embodiments, the securing device is attached to or incorporated in a lid of the storage jar assembly. In other embodiments, the securing device may be a holder that can be inserted into the storage jar assembly.

[0010] Certain embodiments of the disclosure concern a storage jar assembly including a jar having an open end and configured to receive a prosthetic heart valve. Such embodiments also include a lid configured to cover the open end of the jar. The lid can include a plurality of valve attachment features configured to be releasably attached to corresponding features of the prosthetic heart valve.

[0011] Certain embodiments of the disclosure concern another storage jar assembly including a jar having an open end and configured to receive a prosthetic heart valve. Such embodiments also include a lid configured to cover the open end of the jar. Such embodiments also include a valve securement mechanism coupled to the lid and comprising a plurality of notches configured to be releasably attached to corresponding features of the prosthetic heart valve and hold one end of the prosthetic heart valve in at least a partially radially compressed state.

[0012] Certain embodiments of the disclosure concern another storage jar assembly including a jar having an open end and configured to receive a prosthetic heart valve. Such embodiments also include a lid configured to cover the open end of the jar and a valve holder. The valve holder can comprise a base, a column, and plurality of valve retention members. The column can have a lower end coupled to the base, an upper end, and can extend axially from the base. The plurality of valve retention members can extend upwardly from the base and can be configured to contact an outer surface of the prosthetic heart valve.

[0013] Certain embodiments of the disclosure concern another storage jar assembly including a jar having an open end and configured to receive a prosthetic heart valve. Such embodiments also include a lid configured to cover the open end of the jar and a valve holder configured to hold the prosthetic heart valve in a partially compressed state within the jar.

[0014] Certain embodiments of the disclosure concern a lid, configured to cover an open end of a jar to form a storage jar assembly. The lid also includes an upper portion, a side wall depending from the upper portion, and a valve attachment feature coupled to the lid. The valve attachment feature can be configured to releasably hold corresponding features of a prosthetic heart valve. The lid can also include a valve release mechanism configured to detach the prosthetic heart valve from the valve attachment feature.

[0015] Certain embodiments of the disclosure concern a storage jar assembly, comprising a jar having an open end and configured to receive a prosthetic heart valve and a lid, configured to cover an open end of the jar. The lid may include an upper portion, a side wall depending from the upper portion, and a valve attachment feature coupled to the lid. The valve attachment mechanism may be configured to releasably hold corresponding features of a prosthetic heart valve. Such embodiments can also include a valve release mechanism configured to detach the prosthetic heart valve from the valve attachment feature.

[0016] The foregoing and other objects, features, and advantages of the invention will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. **1** is a perspective view of a prosthetic heart valve, according to one embodiment.

[0018] FIG. **2** is a cross sectional schematic view of the frame and valvular structure of the prosthetic heart valve of FIG. **1**.

[0019] FIG. **3** is a perspective view of a prosthetic heart valve, according to another embodiment.

[0020] FIG. **4** is a side elevation view of the inner frame of the prosthetic heart valve of FIG. **3**.
[0021] FIG. **5** is a side elevation view of the outer frame of the prosthetic heart valve of FIG. **3**.
[0022] FIG. **6** is a side elevation view of a storage jar assembly containing a prosthetic heart valve attached to a lid of the storage jar assembly, according to one embodiment.
[0023] FIG. **7** is a plan view of the bottom of the lid of FIG. **6** showing the outer frame of the prosthetic heart valve attached to the lid.
[0024] FIG. **8** is a side elevation view of the lid and outer frame shown in FIG. **7**.
[0025] FIG. **9** is a perspective view of the lid shown in FIG. **6**.
[0026] FIG. **9**A is an enlarged view of a portion of the lid shown in FIG. **9**.
[0027] FIG. **10** is a perspective view of the lid and the outer frame of FIG. **7**.
[0028] FIG. **11** is a schematic depiction of an alternative mechanism for attaching the lid and the jar to each other.
[0029] FIG. **12** is a side elevation view of an alternative embodiment of a storage jar assembly.
[0030] FIG. **13** is a perspective view of a storage jar assembly having a valve holder, according to another embodiment.
[0031] FIG. **14** is a perspective view of the valve holder depicted in FIG. **13**.
[0032] FIG. **15** is a perspective view of the valve holder depicted in FIG. **14** showing a representative outer frame of a prosthetic heart valve disposed within the valve holder.
[0033] FIG. **16** is a schematic side view of a valve retention member of the valve holder of FIGS. **13-15** shown in contact with struts of a representative outer frame of a prosthetic heart valve.
[0034] FIG. **17** is a perspective view of a lid for use with a storage jar assembly, having a valve release button, showing an exemplary prosthetic heart valve attached to the lid.
[0035] FIG. **18** is a cutaway schematic view of a portion the lid and a portion of the frame of the prosthetic heart valve of FIG. **17**.

DETAILED DESCRIPTION

[0036] Disclosed herein are storage jar assemblies comprising securing mechanisms for prosthetic heart valves. Storage jar assemblies disclosed herein generally comprise a jar and a removable lid. The jar is configured to receive a prosthetic heart valve. The prosthetic heart valve rests within the jar when it is being stored and is removed from the jar prior to use. In particular embodiments, the securing mechanisms can hold a prosthetic heart valve in at least a partially-compressed state to permit use of a relatively smaller jar and/or to better secure the prosthetic heart valve within the jar during shipping and storage.
[0037] The storage jar assemblies disclosed herein may be used with various embodiments of prosthetic heart valves. Prosthetic heart valves for use with the presently disclosed storage jar assemblies can have a frame assembly comprising at least one radially compressible and expandable frame and a valvular structure supported within the frame assembly. Additionally, the prosthetic heart valves may have a plurality of anchoring structures for securing the prosthetic heart valve to native tissue of a patient. In some embodiments, the frame assembly can comprise an inner frame and an outer frame.
[0038] For example, FIGS. **1** and **2** depict one embodiment of a prosthetic heart valve **10** that can be used with the storage jar assemblies disclosed herein. The prosthetic heart valve **10** comprises a frame assembly **12** and a valvular structure **14** supported by the frame assembly **12**. The frame assembly **12** defines an inlet end **22** and an outlet end **20** of the prosthetic heart valve **10**. As best shown in FIG. **2**, the frame assembly **12** in the illustrated embodiment includes an inner frame **15** and an outer frame **16**. The inner and outer frames **15**, **16** can comprises a plurality of interconnected struts **18** arranged in a lattice or diamond pattern.
[0039] The inner frame **15** can include an annular inner frame body **24**. The inner frame body **24** can have a generally cylindrical shape such that it has a substantially constant diameter from an upper end (inlet end) to a lower end (outlet end) of the inner frame body **24**. However, it is to be understood that in alternative embodiments, the diameter of the inner frame body **24** can vary along

its length. Although inner frame body **24** is described as generally having a cylindrical shape, it is understood that all or a portion of the inner frame body **24** can have a non-circular cross-section such as, but not limited to, a D-shape.

[0040] The outer frame **16** can include an annular outer frame body **26** and an outer frame anchoring feature **28**. The outer frame body **26** can have an upper region **30**, an intermediate region **32**, and a lower region **34**. In some situations, such as those in which the prosthetic heart valve **10** is positioned within a native mitral valve, the upper region **30** can be generally positioned supra-annularly, the intermediate region **32** can be generally positioned intra-annularly, and the lower region **34** can be positioned sub-annularly. However, it is to be understood that in some situations, the positioning of the outer frame **16** relative to the annulus can differ. Moreover, it is to be understood that in some embodiments, the outer frame **16** can omit one or more of the upper region **30**, the intermediate region **32**, and/or the lower region **34**.

[0041] The outer frame **16** can include a plurality of angularly spaced outer posts **36** extending from the respective apices **56** of the upper region **30** at the inlet end **22** of the prosthetic heart valve. In the illustrated embodiment, FIG. **1** shows the outer frame **16** has ten such posts **36**, although a greater or lesser number of posts may be used. As best shown in FIG. **2**, the inner frame **15** similarly may include a plurality of angularly spaced inner posts **38**, each of which can be circumferentially aligned with a corresponding post **36** of the outer frame **16** to form a plurality of pairs of posts **36**, **38** angularly spaced from each other along the inlet end **22**. The inner and outer posts **36**, **38** of each pair can be connected to each other with a suture and/or a fabric. The outer posts **38** and/or the inner posts **38** can be used to form a releasable connection with a delivery apparatus for securing the prosthetic heart valve **10** to the delivery apparatus when the prosthetic heart valve and the delivery apparatus are advanced through a patient's vasculature to a desired implantation site (e.g., the native mitral valve). The outer posts **38** and/or the inner posts **38** can also be used to form a releasable connection with a securement mechanism of a storage jar assembly, as further described below.

[0042] The frame assembly **12** may further include a plurality of angularly spaced anchoring features **40** (which can also be referred to as “anchoring legs” or “ventricular anchors”). The anchoring features **40** can extend from an outflow end of the inner frame body **24**. As illustrated in FIG. **1**, the anchoring features **40** may extend generally downwardly and radially outwardly from the outlet end of the inner frame body **24**. When implanted in a native valve (e.g., a native mitral or tricuspid valve), the anchoring features **40** can extend behind and/or engage native tissue, such as the native leaflets and/or chordae tendineae, within a ventricle of a heart. As shown in FIG. **1**, the anchoring features **40** can be covered or wrapped by respective covers **42**, which can be formed from a relatively soft material, such as a fabric or natural tissue. In alternative embodiments, the anchoring features **40** can be components of the outer frame **16**. For example, the anchoring features **40** can extend from an outlet end of the outer frame main body **26**. In alternative embodiments, similar anchoring features can be provided at the inlet of the inner frame **15** or the outer frame **16** for engaging tissue within an atrium of a heart.

[0043] The prosthetic heart valve **10** can include one or more skirts for sealing against native tissue surrounding the prosthetic heart valve once implanted, for attaching other components (e.g., leaflets) to the frame assembly and/or for blocking the flow of blood through the open cells of the frame. As shown in FIG. **1**, the prosthetic heart valve **10** can have an inner skirt **44** and an outer skirt **46**. The inner skirt **44** can be disposed between the inner frame **15** and the outer frame **16** and can be attached to the outer frame **16** by sutures **48**. The outer skirt **46** can be disposed around the outer frame **16** and can be attached to the outer frame by sutures **48**. In some embodiments, the inner skirt **44** and the outer skirt **46** can be formed from a single piece of material that is folded at one end. In other embodiments, the inner skirt **44** and the outer skirt **46** can be formed from separate pieces of material. The skirts **44**, **46** can be made of any of various suitable materials, including synthetic fabrics, such as polyethylene terephthalate (PET) fabric, or natural tissue (e.g.,

pericardial tissue).
[0044] As shown in FIG. **2**, the valvular structure **14** may comprise a leaflet assembly comprising a plurality of leaflets **50** disposed within a lumen of the inner frame **15**. In particular embodiments, the leaflet assembly comprises three leaflets **50**, although a greater or fewer number of leaflets may be used in other embodiments. The leaflets **50** are configured to permit flow from the inlet end **22** of the prosthetic heart valve **10** to the outlet end **20**, but to prohibit flow from the outlet end **20** of the prosthetic heart valve **10** to the inlet end. The leaflets **50** can be made of pericardial tissue (e.g., bovine pericardial tissue), biocompatible synthetic materials, or various other suitable natural or synthetic materials as known in the art.
[0045] The leaflet assembly can further include a liner **52**. The liner **52** can be used to assist with fluid flow through and/or around the prosthetic heart valve **10**, such as through the inner frame **15** and the valve leaflets **50**. The liner **52** can surround at least a portion of the valve leaflets **50** and be connected to one or more of the valve leaflets **50**. For example, as shown in the illustrated embodiment, the one or more valve leaflets **50** can be attached to the liner **52** (e.g., by sutures) along an arcuate or fixed edge of the valve leaflets **50**. The liner **52** can extend from the arcuate or fixed edge of each leaflet **50** and extend upwardly towards an upper end of the inner frame **15**. The liner **52** in turn can be attached to the inner frame **15**, such as by sutures.
[0046] The outer frame **16** can be attached to the inner frame **15** at one or more attachment points. The outer frame **16** can be tautly attached to the inner frame **15** such that little to no relative movement between the inner frame **15** and the outer frame **16** occurs at the one or more attachment points. In other embodiments, the outer frame **16** and the inner frame **15** can be loosely attached such that some relative movement between the inner frame **15** and the outer frame **16** can occur at the one or more attachment points. Although the outer frame **16** and inner frame **15** are illustrated as separate components in FIG. **2**, it is to be understood that outer frame **16** and inner frame **15** can be unitarily or monolithically formed. For example, the entire frame assembly **12** can be formed (e.g., laser cut) from a single piece of material.
[0047] In alternative embodiments, the prosthetic heart valve **10** can have a single frame, which can be formed with the outer posts **36**, anchoring features **40**, and/or other features described above in connection with frames **15** and **16**. Examples of a prosthetic heart valve having a single frame are disclosed in Publication No. US 2016/0317301 and U.S. Pat. No. 10,350,062, which are incorporated herein by reference.
[0048] In particular embodiments, the frames **15**, **16** are made of a self-expandable material, such as Nitinol. When constructed of a self-expandable material, the frames **15**, **16** (and thus the prosthetic heart valve **10**) can be crimped to a radially compressed state and restrained in the compressed state by insertion into a sheath or equivalent mechanism of a delivery catheter. Once inside the body at the desired implantation site (e.g., the native mitral valve), the prosthetic heart valve can be advanced from the delivery sheath, which allows the prosthetic heart valve to expand from the radially compressed state to a radially expanded state corresponding to its functional size.
[0049] In other embodiments, the frames **15**, **16** can be made of any suitable plastically-expandable materials, such as stainless steel or a nickel-based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy), polymers, or combinations thereof. When constructed of a plastically-expandable material, the frames **15**, **16** (and thus the prosthetic heart valve **10**) can be crimped to a radially compressed state on a delivery catheter, such as on or adjacent an inflatable balloon or equivalent expansion mechanism. Once inside the body at the desired implantation site (e.g., the native mitral valve), the prosthetic can be expanded from the radially compressed state to a radially expanded state corresponding to its functional size by the inflatable balloon or the equivalent expansion mechanism.
[0050] Exemplary delivery apparatuses that can be used to implant the prosthetic heart valves disclosed herein are disclosed in Publication Nos. US 2016/0317301 and 2019/0008640, which are incorporated herein by reference.

[0051] FIG. **3** depicts an alternative embodiment of a prosthetic heart valve **100** that can be used with the storage jar assemblies disclosed herein. The prosthetic heart valve **100** comprises a frame assembly **102** and a valvular structure **104** supported by the frame **102**. The frame assembly **102** defines an inlet end **106** and an outlet end **108** of the prosthetic heart valve **100**. As illustrated in FIGS. **4** and **5**, the frame assembly **102** in the illustrated embodiment includes an outer frame **110** and an inner frame **112**. The outer and inner frames **110**, **112** can comprise a plurality of interconnected struts **114** arranged in a lattice or diamond pattern. As shown in FIG. **3**, the prosthetic heart valve **100** can also comprise an inner skirt **116** and an outer skirt **118**. The skirts **116**, **118** may be attached to the frame assembly **102**.
[0052] As best illustrated in FIG. **4** the outer frame **110** can include an annular outer frame body **120**. The outer frame body **120** can have an upper region **122**, an intermediate region **124**, and a lower region **126**. In some situations, such as those in which the prosthetic heart valve **100** is placed within a native mitral valve, the upper region **122** can be generally positioned supra-annularly, the intermediate region **124** can be generally positioned intra-annularly, and the lower region **126** can be generally positioned sub-annularly. However, it is to be understood that in some embodiments, the outer frame **110** can omit one or more of the upper region **122**, the intermediate region **124**, or the lower region **126**.
[0053] As best illustrated in FIG. **5**, the inner frame **112** can include an annular inner frame body **128** and anchoring features **130**. The inner frame body **128** can have a generally cylindrical shape such that it has a substantially constant diameter from an upper end (inlet end) to a lower end (outlet end) of the inner frame body. However, it is to be understood that, in alternative embodiments, the diameter of the inner frame body **128** can vary along its length. Although inner frame body **128** is described as generally having a cylindrical shape, it is understood that all or a portion of the inner frame body **128** may have a non-circular cross-section such as, but not limited to, a D-shaped cross-section.
[0054] The outer frame **110** can include a plurality of angularly spaced outer posts **132** extending from respective apices **134** at the upper region **122** near the inlet end **106** of the prosthetic heart valve **100**. In one illustrated embodiment, as shown in FIG. **3**, the outer frame **110** has eleven such outer posts **132**, but a greater or lesser number of posts may be used. As best shown in FIG. **5**, inner frame **112** may similarly include a plurality of angularly spaced inner posts **136** along the inlet end **106** of the prosthetic heart valve **100**. Each of the angularly spaced inner posts **136** can be circumferentially aligned with a corresponding outer post **132** of the outer frame **110** to form a plurality of pairs of posts **132**, **136** angularly spaced from each other along the inlet end **106**. The posts **132**, **136** of each pair can be connected to each other with a suture and/or a fabric. The outer posts **132** and/or the inner posts **136** can be used to form a rescalable connection with a delivery apparatus for securing the prosthetic heart valve **100** to the delivery apparatus when the prosthetic heart valve and delivery apparatus are advanced through a patient's vasculature to a desired implantation site (e.g., the native mitral valve). The outer posts **132** and/or inner posts **136** can also be used to form a releasable connection with a securement mechanism of the storage jar assemblies described herein.
[0055] The frame assembly **102** may further include a plurality of angularly spaced anchoring features **130** (which can also be referred to as “anchoring legs” or “ventricular anchors”). The anchoring features **130** can extend from an outflow end of the inner frame body **128**. As illustrated in FIG. **3**, the anchoring features **130** may extend generally downwardly and radially outwardly from the inner frame body **128**. When implanted in a native valve (e.g., a native mitral or tricuspid valve), the anchoring features **130** can extend behind and/or engage native tissue, such as the native leaflets and/or chordae tendineae, within a ventricle of a heart. As shown in FIG. **3**, the anchoring features **130** can be covered or wrapped by respective covers **138**, which can be formed from a relatively soft material such as fabric or natural tissue. In alternative embodiments, the anchoring features **130** can be components of the outer frame **110**. For example, the anchoring features **130**

can extend from the lower region **126** of the outer frame body **120**. In alternative embodiments, similar anchoring features can be provided at the inlet end of inner frame body **128** or outer frame body **120** for engaging tissue with an atrium of a heart.

[0056] The prosthetic heart valve **100** can include one or more skirts for sealing against native tissue surrounding the prosthetic heart valve once implanted, for attaching other components (such as leaflets) to the frame assembly, and/or for blocking the flow of blood through the open cells of the frame. As shown in FIG. **3**, the prosthetic heart valve **100** can have an inner skirt **116** and an outer skirt **118**. The inner skirt **116** can be disposed between the inner frame **112** and the outer frame **110** and can be attached to the outer frame **110** with sutures or any other suitable attachment mechanism. The outer skirt **118** can be disposed around the outer side of outer frame **110** and can be attached to the outer frame **110** with sutures or any other suitable attachment mechanism. In some embodiments, the inner skirt **116** and outer skirt **118** may be formed from a single piece of material that is folded at one end. In other embodiments, the inner skirt **116** and the outer skirt **118** can be formed from separate pieces of material. The skirts **116**, **118** can be made of any suitable materials, including synthetic fabrics or natural tissue.

[0057] As shown in FIG. **3**, the valvular structure **104** may comprise a plurality of leaflets **140** disposed within a lumen of the inner frame **112**. In some embodiments, the valvular structure comprises three leaflets **140**, although a greater or fewer number of leaflets may be used in other embodiments. The leaflets **140** are configured to permit flow from inlet end **106** of the prosthetic heart valve **100** to outlet end **108**, but to prohibit flow from the outlet end of the prosthetic heart valve **100** to the inlet end **106**. The leaflets **140** can be made of pericardial tissue, biocompatible synthetic materials, or synthetic materials as known in the art.

[0058] The outer frame **110** can be attached to inner frame **112** at one or more attachment points. The outer frame **110** can be tautly attached to inner frame **112** such that little to no relative movement between the outer frame **110** and the inner frame **112** at the one or more attachment points. In other embodiments, the outer frame **110** and the inner frame **112** can be loosely attached, such that some relative movement between the outer frame **110** and the inner frame **112** can occur at the one or more attachment points. Although the outer frame **110** and the inner frame **112** are illustrated as separate components in FIGS. **4** and **5**, it is to be understood that the outer frame **110** and the inner frame **112** can be unitarily or monolithically formed. For example, the entire frame assembly **102** can be formed (e.g., laser cut) from a single piece of material or additively manufactured.

[0059] In particular embodiments, the frames **110**, **112** are made of a self-expandable material, such as Nitinol. When constructed of a self-expandable material, frames **110**, **112** (and thus the prosthetic heart valve **100**) can be crimped to a radially compressed state and restrained in the compressed state by insertion into a sheath or equivalent mechanism of a delivery catheter. Once inside the body at the desired implementation site (e.g., the native mitral valve), the prosthetic heart valve can be advanced from the delivery sheath, which allows the prosthetic heart valve to expand from the radially compressed state to a radially expanded state corresponding to its functional size.

[0060] In other embodiments, the frames **110**, **112** can be made of any suitable plastically-expandable materials, such as stainless steel or a nickel-based alloy (e.g., a cobalt-chromium or a nickel-cobalt-chromium alloy), polymers, or combinations thereof. When constructed of a plastically-expandable material, frames **110**, **112** (and thus the prosthetic heart valve **100**) can be crimped to a radially compressed state on a delivery catheter, such as on or adjacent to an inflatable balloon or equivalent expansion mechanism. Once inside the body at the desired implantation site (e.g., the native mitral valve), the prosthetic can be expanded from the radially compressed state to a radially expanded state corresponding to its functional size by the inflatable balloon or the equivalent expansion mechanism.

[0061] Further details of the prosthetic heart valve **10** of FIGS. **1-2**, the prosthetic heart valve **100** of FIGS. **3-5**, and other prosthetic heart valves that can be used with the storage jar assemblies of

the present disclosure are disclosed in Publication Nos. US 2016/0317301, US 2018/0055629 and US 2019/0262129, and U.S. Pat. No. 10,350,062, which are incorporated herein by reference.
[0062] In some embodiments, the storage jar assemblies disclosed herein may incorporate a lid having a valve securement mechanism. The valve securement mechanism can have a plurality of valve attachment features configured to releasably attach to corresponding features on a prosthetic heart valve, such as the outer posts **36**. In some embodiments, the valve attachment features may be configured to hold the prosthetic heart valve in a partially compressed state. The lid may further comprise a lid attachment mechanism configured to releasably attach to corresponding features on a jar.
[0063] Referring now to the storage jar assembly embodiment shown in FIG. **6**, a storage jar assembly **200** can include a jar **202**. The jar **202** generally comprises a base **204**, an upstanding side wall **206** extending upwardly from the base **204**. The upper end portion of the wall **206** can form a mouth defining an opening at the upper end of jar **202**. The jar **202** can be configured to receive a prosthetic heart valve, such as prosthetic heart valve **10**. Although the following description of the storage jar assembly **200** proceeds with reference to the prosthetic heart valve **10**, it should be understood that other prosthetic heart valves (e.g., prosthetic heart valve **100** or any of those disclosed in Publication Nos. US 2016/0317301, US 2018/0055629 and US 2019/0262129, and U.S. Pat. No. 10,350,062) can be used with the storage jar assembly **200**.
[0064] The storage jar assembly **200** may also have a lid **208** that can be configured to be releasably attachable to the jar **202** and to a prosthetic heart valve **210**. The lid **208** may also be configured to hold prosthetic heart valve **210** in a partially-compressed state. In the illustrated embodiment, the jar **202** has a cylindrical wall **206** defining a circular cross-sectional profile (in a plane perpendicular to a central longitudinal axis of the jar). In other embodiments, jar **202** can have plural wall segments that define other cross-sectional profiles (in a plane perpendicular to a central longitudinal axis of the jar), such as square, hexagonal etc.
[0065] Referring to FIGS. **7**-**10**, the lid **208** can have an upper portion **212** and a downwardly depending side wall **214**. The inner surface of the lid comprises a plurality of valve attachment features, which are configured to releasably attach to corresponding features on the frame a prosthetic heart valve. The inner surface of the lid can also comprise a lid attachment mechanism, which is configured to releasably attach to corresponding features on the jar. In FIGS. **7**, **8** and **10**, only the outer frame **16** of the prosthetic heart valve **10** is shown and the other components of the prosthetic heart valve are omitted for purposes of illustrating the attachment between the outer frame **16** and the lid **208**.
[0066] As best shown in FIGS. **9** and **9**A, an inner surface **216** of the upper portion **212** comprises a valve securement mechanism in the form of an annular projection or ring **218** (also referred to as an annular lip) having an inner peripheral edge **220** and an outer peripheral edge **222**. The annular ring **218** can be formed with a plurality of valve attachment features in the form of a plurality of slots or notches **224** that are configured to receive the outer posts **38** of the outer frame **16** of the prosthetic heart valve **10**. The notches **224** are circumferentially spaced from each other along an imaginary circle coincident with a circumference of the inner peripheral edge **220** of the annular ring **218**. Each notch **224** can extend in a radial direction from the inner peripheral edge **220** partially through the ring **218** and can have a closed end **226** spaced inwardly from the outer peripheral edge **222**. The inner peripheral edge **220** and the notches **224** can be slightly spaced from a central inner surface portion **228** of the lid to form a receiving space that accommodates tip portions of the outer posts **38**, as further described below.
[0067] In alternative embodiments, the notches **224** can extend completely through the annular ring **218** from the inner peripheral edge **220** to the outer peripheral edge **222**. In other embodiments, the notches **224** can extend from the outer peripheral edge **222** (i.e., the notches are open at the outer peripheral edge) partially through the annular ring **218** and have closed ends that are spaced from the inner peripheral edge **220**.

[0068] The annular ring **218** in the illustrated embodiment is circular in shape, but it is to be understood that the ring may have other shapes, such as elliptical, D-shaped, or any other shape sufficient to accommodate the shape of the outer frame **16**.
[0069] FIG. **10** shows the outer posts **38** disposed in the notches **224**, which is effective to securely hold the prosthetic heart valve **10** relative to the lid **208**. To attach the outer frame **16** to the lid **208**, the outer posts **38** and/or the outflow end of the prosthetic heart valve **10** can be compressed or pinched a sufficient amount to allow the outer posts **38** to be inserted inside of the annular ring **218**. Each outer post **36** can be aligned with a corresponding notch **224**, after which the compression force on the outer posts **38** can be released to allow the posts to slide into the notches under the resiliency of the frame. Tip portions **58** of the outer posts **38** can be located in the space between the annular ring **218** and the adjacent surface portion **228** of the inner surface of the lid. The tip portions **58** have a width that is greater than the width of the notches **224**, which prevents the prosthetic heart valve **10** from being pulled away from the lid in an axial direction while the outer posts **38** are positioned in the notches **224**. Removal of the outer posts **38** from the notches **224** can be accomplished by compressing the prosthetic heart valve or just the inlet end of the prosthetic heart valve a sufficient amount to move the outer posts **38** radially inwardly until they are removed from the notches. Thereafter, the prosthetic heart valve **10** can be separated from the lid.
[0070] While the illustrated embodiment shows the outer posts **38** of the outer frame **16** secured within the notches **224**, it should be noted that other components of the prosthetic heart valve can be secured within the notches. For example, in some embodiments, both the outer posts **38** of the outer frame **16** and the inner posts **38** of the inner frame **15** can be secured within the notches **224**. In other embodiments, only the inner posts **38** of the inner frame **15** can be secured within the notches **224**.
[0071] In some embodiments, the annular ring **218** and the notches **224** are sized such that the outer frame **16** (and the prosthetic heart valve) is not held in a state of compression once the outer posts **38** are placed within the notches **224**. That is, after aligning the outer posts **38** with the notches **224** and releasing the compression force on the frame, the end of the outer frame **16** with the outer posts **38** can fully expand and the outer posts **38** are retained within the notches by the engagement of the tip portions **58** with the annular ring **218**.
[0072] In other embodiments, the annular ring **218** and the notches **224** can be sized and/or shaped to retain the outer frame **16** (and the prosthetic heart valve **10**) in a compressed or partially compressed state. The amount of compression under which the outer frame **16** (and the prosthetic heart valve **10**) is retained can vary depending on the diameter of an imaginary circle coincident with the close ends **226** of the notches **224**. Thus, when the outer posts **38** are placed within the notches **224**, the outer posts **38** can expand radially outwardly to contact the closed ends **226**, but prevent the posts from fully expanding, effectively retaining that end of the frame in a partially compressed state. The outer posts **38** therefore can exert an outward bias against the closed ends **226**, which assists in retaining the posts within the notches and further increases the attachment force between the frame and the lid.
[0073] When the frame is formed from a self-expandable material (e.g., Nitinol), the inherent resiliency of the frame causes the outer posts **38** to expand within the notches **224**. If the frame is formed from a plastically-expandable material (e.g., stainless steel), the outer posts **38** can still exhibit sufficient resiliency to self-expand after being compressed and then released within the notches **224** if the posts are not initially compressed to such an extent that causes plastic deformation of the outer posts **38**. Thus, it should be understood that the lid **208** can be used to retain self-expanding frames and plastically-expandable frames. Although less desirable, in some embodiments, the frame can undergo at least some amount of plastic deformation when placing the outer posts **38** within the notches **224** and then re-expanded via an outside force (e.g., a manual force applied to the frame or the posts).
[0074] With continued reference to FIG. **9**, the inner surface of the side wall **214** of the lid **208** may

further comprise a storage jar attachment region **230**. The storage jar attachment region may contain one or more storage jar attachment features configured to releasably attach to corresponding features on the exterior of the upper end portion of the wall **206** of the storage jar **202**. In some embodiments, as illustrated in FIG. **9**, the one or more storage jar attachment features may include helical threads **232** (also referred to as screw threads), which configured to engage with corresponding helical threads **232** on the upper end portion of the wall **206** of the storage jar **202**.

[0075] While FIGS. **9** and **10** depict a lid configured to attach to a jar with helical threads, other storage jar attachment mechanisms can be used. For example, as illustrated in FIG. **11**, the one or more jar attachment features disposed on jar attachment region **230** may comprise one or more features for forming a press-fit or snap-fit connection with the jar. For example, the jar attachment region **230** of the lid can comprise an annular ridge **252**, and the upper end portion of the jar side wall **206** can comprise an annular lip **254** on the exterior of jar **202**. The ridge **252** is configured to releasably engage with lip **254** when lid **208** is pressed onto the upper end portion of the jar side wall **206 202**. While the embodiment illustrated in FIG. **11** shows a ridge **252** with a generally triangular or sloped cross-section and a lip **254** with a generally rectangular cross-section, it is to be understood that the geometries of the ridge and the lip may have other configurations, such as a rectangular ridge **252** and a triangular or sloped lip **254**, a configuration wherein one or both of the ridge and the lip have a cross-section that is a segment of a cylinder or sphere, or any other geometries suitable for a releasable engagement between the ridge and the lip.

[0076] FIG. **6** shows the fully assembled storage jar assembly **200** with the prosthetic heart valve **10** attached to the lid **208** and the lid **208** attached to the jar **202**. During assembly (such as at the manufacturing site of the prosthetic heart valve), the assembler can attach the prosthetic heart valve **10** to the lid **208** as previously described, fill the jar with a hydrating solution (e.g., glutaraldehyde), and then place the lid on top of the jar and secure it place (e.g., by screwing the lid onto the jar). Desirably, a sufficient volume of hydrating solution is placed in the jar so as to fully immerse the leaflets **50** of the prosthetic heart valve.

[0077] In some embodiments, the leaflets **50** can be made of a material or chemically treated such that they can be stored without a hydrating solution within the jar. In such embodiments, the storage jar assembly **200** can comprise a prosthetic heart valve (e.g., prosthetic heart valve **10**) attached to the lid **208** and stored inside the jar **202**, which can be free of any liquids except for any moisture retained by the leaflets following a tissue treatment process. Methods for treating tissue leaflets for so-called dry storage are disclosed in U.S. Pat. No. 8,007,992 and U.S. Patent Publication No. 2009/0164005, filed Dec. 18, 2008, both of which documents are incorporated herein by reference.

[0078] In the fully assembled state, the assembly **200** can be shipped to end users (e.g., hospitals) and stored until the prosthetic heart valve is used in a heart valve replacement procedure. Prior to implantation, the user (e.g., a physician) can remove the lid from the jar and then remove the prosthetic heart valve from the lid, as previously described. Advantageously, the lid **208** securely retains the prosthetic heart valve in place relative to the lid to prevent or minimize damage to the prosthetic heart valve during shipping and storage. Further, removal of the prosthetic heart valve from the jar and the lid is relatively simple and easy compared to known storage assemblies, does not require any special tools, and avoids or minimizes contact and possible damage to the leaflets **50**.

[0079] In alternative embodiments of the storage jar assembly disclosed herein, the lid may further comprise a valve holder or valve securement mechanism that is spaced below the side wall of the lid to position the prosthetic heart valve closer to the bottom of the jar. This may be done, for example, to enable a prosthetic heart valve to be fully-immersed in a hydrating fluid when stored inside the jar (or to fully immerse the prosthetic heart valve using a relatively smaller volume of a hydrating fluid, or to facilitate detachment of the prosthetic heart valve from the lid of the storage

jar assembly). In these alternative embodiments, the prosthetic heart valve may be stored in a partially compressed state as previously described.

[0080] In an exemplary embodiment shown in FIG. **12**, a storage jar assembly **300** can comprise a jar **302** and a lid **308**. The jar **302** comprises a base **304** and a wall **306** defining an opening for the jar at an upper end thereof. The jar **302** can have the same configuration and features as described above for the jar **202** and therefore is not described further. The lid **308** can comprise an upper portion **312** and a side wall **314**. The lid **308** can have the same configuration as the lid **308** described above except that it includes a securement mechanism for a prosthetic heart valve that is offset from the inner surface of the lid, and more specifically, spaced below a side wall **314** of the lid **308**.

[0081] Although the following description of the storage jar assembly **300** proceeds with reference to the prosthetic heart valve **10**, it should be understood that other prosthetic heart valves (e.g., prosthetic heart valve **100** or any of those disclosed in Publication Nos. US2016/0317301, US 2018/0055629 and US 2019/0262129, and U.S. Pat. No. 10,350,062) can be used with the storage jar assembly **300**.

[0082] The valve securement mechanism (also referred to as an "attachment structure") can comprise an annular ring **318** and one or more struts or posts **320**. Similar to the annular ring **218**, the ring **318** can be configured to be releasably attachable to the prosthetic heart valve **10**. The annular lip **318** can have a thickness in the radial direction defined by an inner peripheral edge (not visible in FIG. **12**) and an outer peripheral edge. Each of the one or more struts **320** has a lower end connected to the annular ring **318** and an upper end connected to an inner surface of the lid **308**.

[0083] With continued reference to FIG. **12**, the annular ring **318** may further comprise a plurality of valve attachment features in the form of notches **324**. In some embodiments, as shown in FIG. **12**, the notches **324** can extend from the inner peripheral edge of annular ring **318** partially through the annular ring, similar to the notches **224** shown in FIGS. **9** and **9**A. In other alternative embodiments, the notches **324** can extend completely through the annular ring **318** from its inner peripheral edge to its outer peripheral edge **322**. In other embodiments, the notches **324** can extend from the outer peripheral edge **322** partially through the annular ring **318**. Similar to the notches **224**, the notches **324** are configured to releasably attach to corresponding features of the prosthetic heart valve **10**. For example, the notches **324** can be configured to receive the outer posts **38** of the outer frame **16** as shown, the inner posts **38** of the inner frame **15**, the outer posts **38** and the inner posts **38**, or other components of the frame assembly **12**.

[0084] The prosthetic heart valve **10** can be attached to and removed from the annular ring **318** of the lid **308** in the same manner as described for the embodiment of FIGS. **6-10**. Moreover, the annular ring **318** and the notches **324** can be configured to retain the prosthetic heart valve **10** in a fully expanded state, or in a partially compressed state, as previously described for the embodiment of FIGS. **6-10**. As shown in FIG. **12**, when the storage jar assembly **300** is in the fully assembled state with the prosthetic heart valve **10** attached to the annular ring **318** and the lid **308** is attached to the jar, the prosthetic heart valve is held closer to the bottom of the jar and is spaced from the side wall **314** of the lid. This can allow the prosthetic heart valve **10** to be fully immersed in a hydrating fluid using a relatively smaller volume of fluid as compared to the embodiment of FIG. **6**. Also, by holding the prosthetic heart valve **10** outside of the space defined by the side wall **314** of the lid, it may be relatively easier to remove the prosthetic heart valve from the annular ring.

[0085] Referring now to FIG. **13**, a storage jar assembly **400** according to another embodiment is shown. The storage jar assembly **400** includes a jar **402**. The jar **402** generally comprises a base **404** and an upstanding side wall **406** extending upwardly from the base **404**. The upper end portion of the wall **406** can form a mouth defining an opening at the upper end of the jar **402**. The jar **402** can be configured to receive a prosthetic heart valve, such as prosthetic heart valve **10**. The storage jar assembly can also include a lid **408**, configured to releasably attach to the jar **402**. Although the following description of the storage jar assembly **400** proceeds with reference to the prosthetic

heart valve **10**, it should be understood that other prosthetic heart valves, (e.g., prosthetic heart valve **100** or any of those discussed in Publication Nos. US2016/0317301, US2018/0055629 and US2019/0262129, and U.S. Pat. No. 10,350,062) can be used with the storage jar assembly **400**.
[0086] The storage jar assembly **400** may also have a valve securement mechanism or valve holder **410** that can be configured to be received by the jar **402** and to receive the prosthetic heart valve **10** or the frame assembly **12** of the prosthetic heart valve **10**. The valve holder **410** may be configured to hold the prosthetic heart valve **10** and/or the frame assembly **12** in a compressed or partially compressed state. As shown in FIGS. **13-15**, in some embodiments, the valve holder **410** can have a plurality of valve retention members **412** and a base **414**. In FIGS. **13** and **15**, only the inner frame **15** of the prosthetic heart valve **10** is shown, and the other components of the prosthetic heart valve are omitted for the purpose of illustrating the interaction of the valve holder **410** and the inner frame **15** of the prosthetic heart valve **10**.
[0087] In some embodiments, the base **414** has a circular cross-sectional profile as shown. The base **414** has an upper surface **416**, a lower surface **417**, and an outer peripheral edge **418** extending between the upper surface **416** and the lower surface **417**. The diameter of the base **414** can be less than the diameter of the opening defined by the mouth at the upper end of the jar **402** and allow for the valve holder **410** to pass through the mouth at the upper end of the jar **402** as the valve holder is inserted into or removed from the jar. While the base **414** illustrated in FIGS. **13-15** is shown as having a circular cross-sectional profile, it is to be understood that base **414** may, in some embodiments, have a square cross-section, a hexagonal-cross section, a D-shaped cross-section, or any cross-section suitable for receiving the inner frame **15** of prosthetic heart valve **10**.
[0088] Referring to FIGS. **13-15**, the valve holder **410** may also have a plurality of valve retention members **412**. The valve retention members **412** may be disposed on the upper surface **416** of the base **414** of the valve holder **410**. In some embodiments, the valve retention members **412** may be positioned along the outer peripheral edge **418** of the base **414** of the valve holder **410**. In alternative embodiments, valve retention members **412** may be inset from the outer peripheral edge **418** of the base **414** towards the center of the base.
[0089] In some embodiments, the positioning of valve retention members **412** relative to the outer peripheral edge **418** and the center of the base **414** of the valve holder **410** may be adjustable. In one embodiment best illustrated in FIG. **14**, the base **414** further comprises a plurality of slots **420** angularly spaced from one another and extending from the outer peripheral edge **418** of the base **414** towards the center of the base, and each valve retention member **412** further comprises a projection **422**. The slots **420** on the base **414** may be configured to receive the projections **422** of the valve retention members **412** and to permit the positioning of valve retention members **412** to be adjustable by sliding the projections **422** along the length of the slots **420**. While FIG. **14** depicts the slots **420** disposed on the base **414** and the projections **422** disposed on the valve retention members **412**, it is to be appreciated that in alternative embodiments, the projections might be disposed on the base **414** and the slots might be disposed on the valve retention members **412**.
[0090] The valve retention members **412** can be secured to the base **414** by a plurality of fasteners, such as the illustrated screws **419**. Each screw **419** can extend through a corresponding slot **420** and into a corresponding threaded bore in a valve retention member **412**. Loosening the screws **419** allows the valve retention members **412** to be slid radially inwardly and outwardly along the upper surface of the base **414**. Tightening the screws **419** fixes the positions of the valve retention members **412** relative to the base **414**. The positions of the valve retention members **412** can be adjusted to adjust the amount of retention force that is applied to the prosthetic heart valve **10**, as further described below, and/or accommodate prosthetic heart valves of different sizes.
[0091] The valve retention members **412** may be configured to contact a corresponding inner frame anchoring feature **40** of the inner frame **15** of prosthetic heart valve **10**. As best illustrated in FIG. **16**, the valve retention members **412** may be configured to hold the frame assembly **12** (and thus the prosthetic heart valve **10**) in a compressed or partially compressed state. The degree of

compression imparted on the prosthetic heart valve **10** may be determined by the positioning of the valve retention members **412** relative to the outer peripheral edge **418** of the base **414**. In the illustrated embodiment, the contact between the valve retention members **412** and the inner frame anchoring features **40** pushes the inner frame anchoring features **40** towards the center of the base **414** and against the outer frame **16**. In this fashion, both the inner frame **15** and outer frame **16**, and therefore the entire frame assembly **12** of prosthetic heart valve **10** are at least partially compressed by the valve retention members **412**. In other embodiments, the amount of compression can be selected to partially compress the tip portions of the anchoring features, but otherwise may not cause any corresponding compression of the outer frame **16**.

[0092] While FIGS. **13**, **15**, and **16** show valve retention members **412** configured to contact corresponding inner frame anchoring features **40** of prosthetic heart valve **10**, it is to be understood that in other embodiments, the valve retention members **412** can be configured to contact other portions of the frame assembly, such as the outer frame body **26**, the anchoring features **28** of the outer frame **16**, and/or the inner frame body **24**.

[0093] The compressive strain imparted on the frame assembly **12** desirably is great enough that the outermost diameter of the prosthetic heart valve **10** is less than the inner diameter of the jar **402** (to allow the prosthetic heart valve to be easily inserted into and removed from the jar), and small enough that the prosthetic heart valve **10** may be kept under the imparted strain for the entire storage life of the prosthetic heart valve **10** without damaging the frame assembly or other components of the prosthetic heart valve. In particular embodiments, the compressive strain can be less than 6%, such as 3% or less or 1% or less.

[0094] In certain alternative embodiments, valve retention members can be configured to contact the corresponding inner frame anchoring feature **40** or other portions of the frame assembly without imparting a compressive strain to the frame assembly **12** while still retaining the prosthetic heart valve relative to the valve holder during shipping and storage. For example, in some embodiments, each valve retention member **412** can include a recessed portion **440** on the inner radially facing surface of the valve retention member **412**. Each recessed portion **440** can receive a respective anchoring feature **40** or another portion of the frame assembly. When the prosthetic heart valve is positioned on the valve holder **410**, the anchoring features **40** can be aligned with and at least partially inserted into the recessed portions **440** (see FIG. **15**). Moreover, in lieu of or in addition to the recessed portions **440**, portions of the anchoring features **40** can be positioned within the slots **420** (see FIG. **15**). In some embodiments, the positioning of the anchoring features **40** in the recessed portions **440** and/or the slots **420** can retain the prosthetic heart valve relative to the valve holder without imparting any compressive stain on the frame assembly.

[0095] When the frame assembly **12** is formed from a self-expandable material (e.g., Nitinol), the inherent resilience of the frame causes the inner frame anchoring features **40** to press against the valve retention members **412** to cause the compressive strain on the prosthetic heart valve. If the frame is formed from plastically-expandable material (e.g., stainless steel, polymer), the inner frame anchoring features **40** can still exhibit sufficient resiliency to self-expand after being compressed and released within the valve holder **410**, if the frame is not initially compressed to such an extent that causes plastic deformation of the anchoring features **40** or other components of the frame assembly. Thus, it should be understood that the valve holder **410** can be used to retain self-expanding frames and plastically-expandable frames. Although less desirable, in some embodiments the anchoring features **40** and/or other components of the frame assembly can undergo at least some amount of plastic deformation when retained by valve retention members **412**, and then be re-expanded via an outside force (e.g., a manual force applied to the frame or the anchoring features).

[0096] As shown in FIGS. **13-15**, the valve holder **410** may also have a column or shaft **424**. The column **424** has a lower end portion **428** and an upper end portion **430**. The lower end portion **428** may contact or be connected to the upper surface **416** of the base **414** of the valve holder **410**. The

column **424** may project away from the base **414** of the valve holder **410** in an axial direction such that, when the valve holder **410** is within the jar **402**, the column **424** extends towards the mouth of the jar **402**, as best illustrated in FIG. **13**. While FIGS. **13-15** show the column **424** positioned at the center of the base **414**, it is to be understood that, in some embodiments, the column **424** may be positioned at a different location on the base **414**, such as between the peripheral edge **418** and the center of the base, or at the peripheral edge **418**.

[0097] In certain embodiments, the column **424** may extend such that, when the valve holder **410** is within the jar **402**, the upper end portion **430** of the column **424** may be placed at or near the mouth of the jar **402**, as best seen in FIG. **13**. In some embodiments, the upper end portion **430** of the column **424** is configured to come into contact with an inner surface of the lid **408** when the valve holder **410** is within the jar **402** and the lid **408** is attached to the jar **402**. It is to be appreciated that these embodiments offer several advantages, such as facilitating the removal of the valve holder **410** from the jar **402** by a user or providing additional stability to the valve holder **410** during storage and transport of the storage jar assembly.

[0098] In some embodiments, best illustrated in FIG. **15**, the column **424** can be configured to pass through the center of the frame assembly **12** of the prosthetic heart valve **10**, such as through the center of the inner frame **15** and/or the outer frame **16** when the prosthetic heart valve is received by valve holder **410**. However, it is to be understood that, in alternative embodiments, the column **424** may not pass through the center or any other portion of the frames **15**, **16** of the prosthetic heart valve **10**.

[0099] In some embodiments, as illustrated in FIG. **14**, the column **424** can be cylindrical with a uniform circular cross-section. However, it is to be understood that column may have alternative geometries, such as a cross-section that varies along its length, or the column may have a different cross-sectional shape such as a square cross-section, a hexagonal cross-section, a D-shaped cross-section, or any other cross-section suitable for passing through the frames **15**, **16** of the prosthetic heart valve **10** and/or facilitating the removal of the valve holder **410** from the jar **402**.

[0100] Returning to FIG. **13**, the storage jar assembly **400** may further include a lid **408** that can have an upper portion **432** and a downwardly depending side wall **434**. The inner surface of the lid **408** can further comprise a storage jar attachment mechanism, which is configured to releasably attach to corresponding features on the jar **402**. It is to be understood that the storage jar attachment mechanism of lid **408** may include any of the storage attachment features previously described, such as helical threads, screw threads, press-fit, or snap-fit attachment features.

[0101] In some embodiments, an inner surface of the upper portion **432** of the lid **408** may further comprise a column securing feature configured to receive upper end portion **430** of column **424** when the valve holder **410** is within the jar **402** and the lid **408** is attached to the jar **402**. The column securing feature may be, for example, a recess or indent formed in the inner surface of the upper portion **432** with a geometry suitable for receiving the upper end **430** of a corresponding column **424**.

[0102] In some embodiments, the upper end portion **430** of the column **424** can be connected to the upper portion **432** of the lid **408**, which allows the valve holder **410** and a prosthetic heart valve **10** retained by the valve holder to be inserted into and removed from the jar **402** by manipulating the lid **408**. In some embodiments, the upper end portion **430** of the column can be removably attached to the lid **408**. This allows the valve holder to be disconnected from the lid after removing the valve holder and the prosthetic heart valve from the jar, which can facilitate removal of the prosthetic heart valve from the valve holder.

[0103] FIG. **13** shows the fully-assembled storage jar assembly **400**, with the valve holder **410** placed within jar **402** and retaining the prosthetic heart valve **10**. During assembly (such as at the manufacturing site of the prosthetic heart valve), the assembler can place the prosthetic heart valve **10** within the valve holder **410** as previously described, place the valve holder **410** and the prosthetic heart valve within jar **402**, fill the jar with a hydrating solution (e.g., glutaraldehyde),

place the lid on top of the jar, and then secure it in place (e.g., by screwing the lid onto the jar). Desirably, a sufficient volume of hydrating solution can be placed in the jar so as to fully immerse the leaflets **50** of the prosthetic heart valve.

[0104] In some embodiments, the leaflets **50** can be made of a material or chemically treated such that they can be stored without hydrating solution within the jar. In such embodiments, the storage jar assembly **400** can comprise a prosthetic heart valve held by valve holder **410** and stored within jar **402**, which can be free of any liquids except for any moisture retained by the leaflets following a tissue treatment process. Methods for treating tissue leaflets for so-called dry storage are disclosed in U.S. Pat. No. 8,007,992 and U.S. Patent Publication No. 2009/0164005, filed Dec. 18, 2008, both of which documents are incorporated herein by reference.

[0105] In the fully assembled state, the storage jar assembly **400** can be shipped to end users (e.g., hospitals) and stored until the prosthetic heart valve is used in a heart valve replacement procedure. Prior to implementation, the user (e.g., a physician) can remove the lid from the jar, withdraw the valve holder from the jar, and then remove the prosthetic heart valve from the valve holder. The valve holder **410** securely retains the prosthetic heart valve **10** in place within the jar **402** to prevent or minimize damage to the prosthetic heart valve during shipping and storage. Further, the column **424** of the valve holder **410** facilitates the removal of the prosthetic heart valve **10** from the jar **402**, as it is relatively easier to reach and grasp compared to known storage assemblies, does not require any specialized tools, and avoids or minimizes direct contact to the prosthetic heart valve **10**, the leaflets **50**, or the frame assembly **12**.

[0106] Referring now to FIGS. **17-18**, a lid **500** for a storage jar assembly according to another embodiment is shown. The lid **500** can include an upper portion **502** and a downwardly depending wall **504**. The lid **500** can be configured to receive a prosthetic heart valve such as prosthetic heart valve **10**. The lid **500** can further be configured to releasably attach to a valve storage jar (not shown) configured to receive the prosthetic heart valve **10**, such as the jars previously disclosed, to form a storage jar assembly. Although the following description of the lid **500** proceeds with reference to the prosthetic heart valve **10**, it should be understood that other prosthetic heart valves (e.g., prosthetic heart valve **100** or any of those discussed in Publication Nos. US 2016/0317301, US2018/0055629 and US 2019/0262129, and U.S. Pat. No. 10,350,062) can be used with the lid **500**.

[0107] As shown in FIG. **17**, the lid **500** may further comprise a valve release mechanism, such as a button **506** disposed on and/or within the upper portion **502** of the lid. As best illustrated in FIG. **18**, the button **506** may be formed from a separate body set within an opening of the upper portion **502** of lid **500**, forming a lid-button interface **508**. The button **506** may be configured to slidably engage with the upper portion **502** of lid **500** along the lid-button interface **508**. The slidable engagement of button **506** and upper portion **502** may allow the button **506** a range of movement with relation to the upper portion having both an upper limit and a lower limit. In some embodiments, the lower limit of the movement range is defined at a point when a lower surface **510** of the button **506** is flush with or lower than a lower surface **512** of the upper portion **502**, and the upper limit of the movement range is defined at a point where the lower surface **510** of the button **506** is above the lower surface **512** of the upper portion **502** and/or where an upper surface **514** of the button **506** is elevated above an upper surface **516** of the upper portion **502**.

[0108] The button **506** and the upper portion **502** of the lid may further be configured such that they form the valve attachment feature **518** on the inner surface of the upper portion **502** of the lid **500**, beneath the button **506**. In some embodiments, best illustrated in FIG. **18**, the valve attachment feature **518** is a circular recession defined by the lower surface **510** of the button **506** and the lid-button interface. The valve attachment feature **518** may be configured to receive corresponding features of a frame **12** of a prosthetic heart valve **10**, such as the angularly spaced outer posts **36** shown in FIG. **1**. In some embodiments, the diameter of attachment feature **518** may be configured to be less than the diameter defined by the angularly spaced outer posts **36** in a fully-

expanded state. In this way, the compressive forces exerted on angularly outer spaced posts **36** may cause interference forces sufficient to retain the prosthetic heart valve **10** in the valve attachment feature.

[0109] While the valve attachment feature **518** has been described as a circular recession, it is to be understood that any feature geometry suitable for retaining the angularly spaced outer posts **36** or other portions of the frame **12** of the prosthetic heart valve **10** may be used, such as an annular recession or groove, a polygonal recession, or a plurality of notches or indentations formed in the inner surface **512** of the upper portion **502** and/or the lower surface **510** of the button **506**. In one embodiment, for example, notches or recesses (similar to notches **224**) sized for receiving the outer posts **38** or other portions of the frame can be formed on the lower surface **512** and/or an inner surface of the upper portion **502** at the interface **508**, and the button **506** can be configured to push the frame downwardly relative to the lid to push the outer posts **36** out of the notches. In some embodiments, the button **506** can be shaped to push the outer posts **38** radially inwardly away from the interface **508** and out of the notches as the button **506** is pressed downwardly relative to the upper portion **502** of the lid. In other embodiments, the outer posts **38** or other portions of the frame can be retained against the inner surface of the upper portion **502** at the interface **508** by the radial outward expansion of those portions of the frame against the adjacent inner surface of the upper portion **502**.

[0110] Returning to FIG. **17**, the inner surface of the lid **500** can further comprise a storage jar attachment mechanism (not shown), which is disposed on depending wall **504** and configured to releasably attach to corresponding features on the jar (not shown in FIGS. **17-18**). It is to be understood that the storage jar attachment mechanism of lid **500** may include any of the storage attachment features previously described, such as helical threads, screw threads, press-fit, or snap-fit attachment features.

[0111] During assembly of a jar assembly comprising, in part, the lid **500** (such as at the manufacturing site of the prosthetic heart valve), the assembler can attach the prosthetic heart valve **10** to the lid **500** as previously described, fill the jar with a hydrating solution (e.g., glutaraldehyde), and then place the lid on top of the jar and secure it place (e.g., by screwing the lid onto the jar). Desirably, a sufficient volume of hydrating solution is placed in the jar so as to fully immerse the leaflets **50** of the prosthetic heart valve.

[0112] In a fully-assembled storage state, partially illustrated in FIG. **17**, the lid **500** may be configured such that corresponding features of the prosthetic heart valve **10**, such as the angularly spaced outer posts **36** or other elements of the frame **12** rest within the valve attachment feature **518**. The prosthetic heart valve **10** thus may depend from the lid **500** and be contained within the valve storage jar in the fully-assembled storage state. In possible embodiment, when a jar assembly including the lid **500** is in the fully-assembled storage state, the button **506** may be near the upper limit of movement relative to upper portion **502** of lid **500**.

[0113] In the fully-assembled storage state, the storage jar assembly including the lid **500** can be shipped to end users (e.g., hospitals) and stored until the prosthetic heart valve is used in a heart valve replacement procedure. Prior to implementation, the user (e.g., a physician) can press the button **506**, moving the button **506** downwards relative to both the upper portion **502** of the lid **500** and the prosthetic heart valve **10**, in the direction of arrow **520** in FIG. **18**, causing the frame **12** or the angularly spaced outer posts **36** of the prosthetic heart valve **10** to be pushed or ejected from the valve attachment feature **518**. In some embodiments, the prosthetic heart valve can be released prior to removing the lid from the jar, which causes the prosthetic heart valve **10** to detach from the lid **500** and become submerged or partially submerged in the hydrating solution (e.g., glutaraldehyde). Thereafter, the user can remove the prosthetic heart valve from jar just prior to loading the prosthetic heart valve onto the delivery device.

[0114] In other embodiments, the lid **500** can be removed from the jar while the prosthetic heart valve is still attached to the lid, after which the user can push the button **506** to release the

prosthetic heart valve from the lid. Advantageously, this configuration allows a user to detach the prosthetic heart valve from the lid **500** while minimizing direct contact with the prosthetic heart valve and without requiring any tools, thereby facilitating the removal of the prosthetic heart valve from the storage jar assembly, and preventing or minimizing damage to the prosthetic heart valve.

[0115] In some embodiments, the lid **500** can include a locking feature or locking element that prevents inadvertent movement of the button **506** during shipping, storage and handling of the assembly prior to intended removal of prosthetic heart valve from the lid. The locking feature can be moved between a locked position and an unlocked position. In the locked position, the locking feature can contact and resist movement of the button **506**. In the unlocked position, the locking feature is removed from contact with the button **506** and allows it to pushed relative to the upper portion **502** in order to release the prosthetic heart valve from the lid.

[0116] In some embodiments, the lid **500** can include a biasing element, such as a spring (e.g., a coil spring), configured to resiliently bias the button **506** to its upper limit of travel. When releasing the prosthetic heart valve from the lid, the user can press the button downwardly against the bias of the biasing element.

General Considerations

[0117] For purposes of this description, certain aspects, advantages, and novel features of the embodiments of this disclosure are described herein. The described methods, systems, and apparatus should not be construed as limiting in any way. Instead, the present disclosure is directed toward all novel and non-obvious features and aspects of the various disclosed embodiments, alone and in various combinations and sub-combinations with one another. The disclosed methods, systems, and apparatus are not limited to any specific aspect, feature, or combination thereof, nor do the disclosed methods, systems, and apparatus require that any one or more specific advantages be present, or problems be solved.

[0118] Features, integers, characteristics, compounds, chemical moieties, or groups described in conjunction with a particular aspect, embodiment or example of the disclosure are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract, and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The disclosure is not restricted to the details of any foregoing embodiments. The disclosure extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract, and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0119] Although the operations of some of the disclosed methods are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods, systems, and apparatus can be used in conjunction with other systems, methods, and apparatus.

[0120] As used herein, the terms “a,” “an,” and “at least one” encompass one or more of the specified element. That is, if two of a particular element are present, one of these elements is also present and thus “an” element is present. The terms “a plurality of” and “plural” mean two or more of the specified element.

[0121] As used herein, the term “and/or” used between the last two of a list of elements means any one or more of the listed elements. For example, the phrase “A, B, and/or C” means “A,” “B,” “C,” “A and B,” “A and C,” “B and C,” or “A, B, and C.”

[0122] As used herein, the term “coupled” generally means physically coupled or linked and does not exclude the presence of intermediate elements between the coupled items absent specific

contrary language.
[0123] Directions and other relative references (e.g., inner, outer, upper, lower, etc.) may be used to facilitate discussion of the drawings and principles herein, but are not intended to be limiting. For example, certain terms may be used such as “inside,” “outside,”, “top,” “down,” “interior,” “exterior,” and the like. Such terms are used, where applicable, to provide some clarity of description when dealing with relative relationships, particularly with respect to the illustrated embodiments. Such terms are not, however, intended to imply absolute relationships, positions, and/or orientations. For example, with respect to an object, an “upper” part can become a “lower” part simply by turning the object over. Nevertheless, it is still the same part and the object remains the same. As used herein, “and/or” means “and” or “or,” as well as “and” and “or.”
[0124] In the context of the present application, the terms “lower” and “upper” are used interchangeably with the term's “outlet” and “inlet”, respectively. Thus, for example, the lower end of the valve is its outlet end and the upper end of the valve is its inlet end.
[0125] As used herein, with reference to the prosthetic medical device (e.g., heart valve), capsule, and the delivery apparatus, “proximal” refers to a position, direction, or portion of a component that is closer to the user and/or a handle of the delivery apparatus that is outside the patient, while “distal” refers to a position, direction, or portion of a component that is further away from the user and/or the handle of the delivery apparatus and closer to the implantation site. The terms “longitudinal” and “axial” refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined. Further, the term “radial” refers to a direction that is arranged perpendicular to the axis and points along a radius from a center of an object (where the axis is positioned at the center, such as the longitudinal axis of the prosthetic heart valve).
[0126] In some of the illustrations previously discussed of the various embodiments of storage jar assemblies and the features thereof, only the frame, or only a part of the frame of prosthetic heart valves intended for use with the present invention are shown. This is done to assist with the clarity of the illustrations, and should be not be taken as limiting the scope of the invention.
Additional Examples of the Disclosed Technology
[0127] In view of the above-described implementations of the disclosed subject matter, this application discloses the additional examples enumerated below. It should be noted that one feature of an example in isolation or more than one feature of the example taken in combination and, optionally, in combination with one or more features of one or more further examples are further examples also falling within the disclosure of this application.
[0128] Example 1. A storage jar assembly, comprising: a jar having an open end and configured to receive a prosthetic heart valve; and a lid configured to cover the open end of the jar, the lid comprising a plurality of valve attachment features configured to be releasably attached to corresponding features of the prosthetic heart valve.
[0129] Example 2. The storage jar assembly of any example herein, particularly example 1, wherein the plurality of valve attachment features comprise notches formed on an inner surface of the lid, the notches configured to receive portions of a frame of the prosthetic heart valve.
[0130] Example 3. The storage jar assembly of any example herein, particularly example 2, wherein the inner surface of the lid comprises an annular lip, wherein the notches are formed on an inner peripheral edge of the annular lip.
[0131] Example 4. The storage jar assembly of any example herein, particularly example 2, wherein the inner surface of the lid comprises an annular lip, wherein the notches are formed on an outer peripheral edge of the annular lip.
[0132] Example 5. The storage jar assembly of any example herein, particularly examples 1˜4 wherein the plurality of valve attachment features of the lid is configured to hold one end of the frame in a partially compressed state.
[0133] Example 6. The storage jar assembly of any of any example herein, particularly examples 1-5, wherein the plurality of valve attachment features is circumferentially spaced from each other

along an imaginary circle centered around an axis extending through the lid.
[0134] Example 7. The storage jar assembly of any example herein, particularly example 6, wherein a diameter of the imaginary circle is selected to impart a desired holding force on the prosthetic heart valve.
[0135] Example 8. The storage jar assembly of any example herein, particularly examples 1-7, wherein the plurality of valve attachment features extends away from an interior surface of the lid.
[0136] Example 9. The storage jar assembly of any example herein, particularly examples 1-8, wherein the jar contains a hydrating fluid and a prosthetic heart valve.
[0137] Example 10. The storage jar assembly of any example herein, particularly example 9, wherein the hydrating fluid is glutaraldehyde.
[0138] Example 11. The storage jar assembly of any example herein, particularly examples 8-9, wherein the valve attachment features are configured to fully submerge the prosthetic heart valve in the hydrating fluid when the lid is attached to a jar.
[0139] Example 12. The storage jar assembly of any example herein, particularly examples 1-11, wherein the lid comprises a lid attachment mechanism configured to releasably attach to the jar near the open end.
[0140] Example 13. The storage jar assembly of any example herein, particularly example 12, wherein the lid attachment mechanism comprises a screw thread configured to engage a corresponding screw thread on the jar.
[0141] Example 14. The storage jar assembly of any example herein, particularly example 12, wherein the lid attachment mechanism comprises a ridge on the inside of the lid configured to releasably engage with a lip disposed on an exterior of the jar near the open end.
[0142] Example 15. A storage jar assembly, comprising: a jar having an open end and configured to receive a prosthetic heart valve; a lid configured to cover the open end of the jar; and a valve securement mechanism coupled to the lid and comprising a plurality of notches configured to be releasably attached to corresponding features of the prosthetic heart valve and hold one end of the prosthetic heart valve in at least a partially radially compressed state.
[0143] Example 16. The storage jar assembly of any example herein, particularly example 15, wherein the valve securement mechanism comprises an annular ring, wherein the notches are formed in the annular ring.
[0144] Example 17. The storage jar assembly of any example herein, particularly example 16, wherein the notches are formed in an inner peripheral edge of the annular ring.
[0145] Example 18. The storage jar assembly of any example herein, particularly example 16, wherein the notches are formed in an outer peripheral edge of the annular ring.
[0146] Example 19. The storage jar assembly of any example herein, particularly examples 16-18, wherein the annular ring is positioned below the lid.
[0147] Example 20. The storage jar assembly of any example herein, particularly example 19, wherein the valve securement mechanism comprises one or more struts interconnecting the annular ring to the lid.
[0148] Example 21. The storage jar assembly of any example herein, particularly examples 15-20, wherein the lid comprises a screw thread configured to engage a corresponding screw thread on the jar.
[0149] Example 22. The storage jar assembly of any example herein, particularly examples 15-20, wherein the lid comprises a ridge on the inside of the lid configured to releasably engage with a lip disposed on an exterior of the jar near the open end.
[0150] Example 23. The storage jar assembly of any example herein, particularly examples 15-20, wherein the jar contains a hydrating fluid and a prosthetic heart valve.
[0151] Example 24. The storage jar assembly of any example herein, particularly example 23, wherein the hydrating fluid is glutaraldehyde.
[0152] Example 25. The storage jar assembly of any example herein, particularly examples 23-24,

wherein the valve securement mechanism is configured to fully submerge the prosthetic heart valve in the hydrating fluid when the lid is attached to a jar.

[0153] Example 26. A storage jar assembly, comprising a jar having an open end and configured to receive a prosthetic heart valve; a lid configured to cover the open end of the jar; and a valve holder comprising a base, a column, and plurality of valve retention members, wherein the column has a lower end portion coupled to the base, an upper end portion, and extends axially from the base; and the plurality of valve retention members extend upwardly from the base and are configured to contact an outer surface of the prosthetic heart valve.

[0154] Example 27. The storage jar assembly of any example herein, particularly example 26, wherein the plurality of valve retention members are disposed at circumferentially spaced locations on the base of the valve holder.

[0155] Example 28. The storage jar assembly of any example herein, particularly examples 26-27, wherein a position of the plurality of valve retention members is adjustable radially inwardly and outwardly relative to a central axis of the base.

[0156] Example 29. The storage jar assembly of any example herein, particularly examples 26-28, wherein the base comprises plurality of slots and each of the valve retention members comprises a projection that extends into a corresponding slot.

[0157] Example 30. The storage jar assembly of any example herein, particularly examples 26-28, wherein the base comprises plurality of projections and each of the valve retention members comprises a slot that receives a corresponding projection.

[0158] Example 31. The storage jar assembly of any example herein, particularly examples 26-30, wherein the plurality of valve retention members are configured to hold the prosthetic heart valve under a radial compressive strain.

[0159] Example 32. The storage jar assembly of any example herein, particularly example 31, wherein the radial compressive strain is less than 6%.

[0160] Example 33. The storage jar assembly of any example herein, particularly example 31, wherein the radial compressive strain is less than 3%.

[0161] Example 34. The storage jar assembly of any example herein, particularly example 31, wherein the radial compressive strain is less than 1%.

[0162] Example 35. The storage jar assembly of any example herein, particularly examples 26-34, wherein an inner diameter of the jar is less than an outer diameter of the prosthetic heart valve in its fully expanded state.

[0163] Example 36. The storage jar assembly of any example herein, particularly examples 26-35, wherein the upper end portion of the column comprises a handle to assist in withdrawing the valve holder from the jar.

[0164] Example 37. The storage jar assembly of any example herein, particularly examples 26-36, wherein the valve holder is configured to support the prosthetic heart valve within the jar for sterilization, shipping, and handling.

[0165] Example 38. The storage jar assembly of any example herein, particularly examples 26-37, wherein the base of the valve holder has an outer diameter that is less than 55 mm.

[0166] Example 39. The storage jar assembly of any example herein, particularly examples 26-38, wherein the lid comprises a lid attachment mechanism configured to be releasably attached to the jar near the open end.

[0167] Example 40. The storage jar assembly of any example herein, particularly example 39, wherein the lid attachment mechanism is a screw thread configured to engage a corresponding screw thread on the jar.

[0168] Example 41. The storage jar assembly of any example herein, particularly example 39, wherein the lid attachment mechanism comprises a ridge on the inside of the lid configured to releasably engage with a lip disposed on an exterior of the jar near the open end.

[0169] Example 42. The storage jar assembly of any example herein, particularly examples 26-41,

wherein lid attached to the upper end portion of the column.
[0170] Example 43. The storage jar assembly of any example herein, particularly examples 26-41, wherein the lid is configured to be removably attached to the upper end portion of the column.
[0171] Example 44. The storage jar assembly of any example herein, particularly examples 26-43, wherein the jar contains a hydrating fluid and a prosthetic heart valve.
[0172] Example 45. The storage jar assembly of any example herein, particularly example 44, wherein the hydrating fluid is glutaraldehyde.
[0173] Example 46. A storage jar assembly, comprising a jar having an open end and configured to receive a prosthetic heart valve; a lid configured to cover the open end of the jar; and a valve holder configured to hold the prosthetic heart valve in a partially compressed state within the jar.
[0174] Example 47. The storage jar assembly of any example herein, particularly example 46, wherein the valve holder comprises a plurality of valve retention members.
[0175] Example 48. The storage jar assembly of any example herein, particularly example 47, wherein the position of the plurality of valve retention members is radially adjustable inwardly and outwardly relative to an outer circumference of the valve holder.
[0176] Example 49. The storage jar assembly of any example herein, particularly examples 46-48, wherein the valve holder comprises a base and a column having a lower end portion connected to the base and extending axially away from the base.
[0177] Example 50. The storage jar assembly of any example herein, particularly example 49, wherein the plurality of valve retention members is disposed along a surface of the base.
[0178] Example 51. The storage jar assembly of any example herein, particularly examples 49-50, wherein the base comprises a plurality of slots and each of the valve retention members comprises a projection that extends into a corresponding slot.
[0179] Example 52. The storage jar assembly of any example herein, particularly examples 49-50, wherein the base comprises one or more projections and each of the valve retention members comprises a slot that receives a corresponding projection.
[0180] Example 53. The storage jar assembly of any example herein, particularly examples 46-52, wherein the valve retention members are circumferentially spaced from each other.
[0181] Example 54. The storage jar assembly of any example herein, particularly examples 46-52, wherein the plurality of valve retention members are configured to hold the prosthetic heart valve under a radial compressive strain.
[0182] Example 55. The storage jar assembly of any example herein, particularly example 54, wherein the radial compressive strain is less than 6%.
[0183] Example 56. The storage jar assembly of any example herein, particularly example 54, wherein the radial compressive strain is less than 3%.
[0184] Example 57. The storage jar assembly of any example herein, particularly example 54, wherein the radial compressive strain is less than 1%.
[0185] Example 58. The storage jar assembly of any example herein, particularly examples 49-52, wherein the lid is configured to receive and secure an upper end portion of the column.
[0186] Example 59. The storage jar assembly of any example herein, particularly examples 46-58, wherein an inner diameter of the jar is less than an outer diameter of the prosthetic heart valve in its fully expanded state.
[0187] Example 60. The storage jar assembly of any example herein, particularly examples 46-59, wherein the lid comprises a lid attachment mechanism configured to releasably attach to the jar near the open end.
[0188] Example 61. The storage jar assembly of any example herein, particularly example 60, wherein the lid attachment mechanism is a screw thread configured to engage a corresponding screw thread on the jar.
[0189] Example 62. The storage jar assembly of any example herein, particularly example 60, wherein the lid attachment mechanism comprises a lip on the inside of the lid configured to

releasably engage with a ridge disposed on the exterior of the jar near the open end.
[0190] Example 63. The storage jar assembly of any example herein, particularly examples 47-62, wherein the jar contains a hydrating fluid and a prosthetic heart valve.
[0191] Example 64. The storage jar assembly of any example herein, particularly example 63, wherein the hydrating fluid is glutaraldehyde.
[0192] Example 65. A lid, configured to cover an open end of a jar, comprising: an upper portion; a side wall depending from the upper portion; a valve attachment feature coupled to the lid and configured to releasably hold corresponding features of a prosthetic heart valve; and a valve release mechanism configured to detach the prosthetic heart valve from the valve attachment feature.
[0193] Example 66. The lid of any example herein, particularly example 65, wherein the valve release mechanism is a button.
[0194] Example 67. The lid of any example herein, particularly example 66, wherein the button is set in the upper portion of the lid and is configured to slide axially relative to the upper portion of the lid.
[0195] Example 68. The lid of example herein, particularly examples 65-67, wherein the valve attachment feature is a circular recession in the lid.
[0196] Example 69. The lid of any example herein, particularly examples 65-67, wherein the valve attachment feature is an annular recession formed in the lid.
[0197] Example 70. The lid of any example herein, particularly examples 65-67, wherein the valve attachment feature is a plurality of notches formed in the lid and circumferentially spaced from one another.
[0198] Example 71. The lid of any example herein, particularly examples 65-70, wherein the valve attachment feature is at least partially defined by the button.
[0199] Example 72. The lid of any example herein, particularly examples 65-71, wherein the prosthetic heart valve is retained in the valve attachment feature by an interference fit.
[0200] Example 73. The lid of any example herein, particularly examples 65-72, wherein the valve release mechanism is configured to press on the prosthetic heart valve and detach it from the valve attachment feature.
[0201] Example 74. The lid of any example herein, particularly examples 65-73, wherein the lid comprises a lid attachment mechanism configured to releasably attach to the jar near the open end.
[0202] Example 75. The lid of any example herein, particularly examples 65-74, wherein the lid attachment mechanism is a screw thread configured to engage a corresponding screw thread on the jar.
[0203] Example 76. The lid of any example herein, particularly examples 65-75, wherein the lid attachment mechanism comprises a lip on the inside of the lid configured to releasably engage with a ridge disposed on the exterior of the jar near the open end.
[0204] Example 77. A storage jar assembly, comprising: a jar having an open end and configured to receive a prosthetic heart valve; a lid, configured to cover an open end of the jar, comprising: an upper portion; a side wall depending from the upper portion; a valve attachment feature coupled to the lid and configured to releasably hold corresponding features of a prosthetic heart valve; and a valve release mechanism configured to detach the prosthetic heart valve from the valve attachment feature.
[0205] Example 78. The storage jar assembly of any example herein, particularly example 77, wherein the valve release mechanism is a button.
[0206] Example 79. The storage jar assembly any example herein, particularly example 78, wherein the button is set in the upper portion of the lid and is configured to slide axially relative to the upper portion of the lid.
[0207] Example 80. The storage jar assembly of any example herein, particularly examples 77-79, wherein the valve attachment feature is a circular recession in the lid.
[0208] Example 81. The storage jar assembly of any example herein, particularly examples 77-79,

wherein the valve attachment feature is an annular recession formed in the lid.
[0209] Example 82. The storage jar assembly of any example herein, particularly examples 77-79, wherein the valve attachment feature is a plurality of notches formed in the lid and circumferentially spaced from one another.
[0210] Example 83. The storage jar assembly of any example herein, particularly examples 77-82, wherein the valve attachment feature is at least partially defined by the button.
[0211] Example 84. The storage jar assembly of any example herein, particularly examples 77-83, wherein the prosthetic heart valve is retained in the valve attachment feature by an interference fit.
[0212] Example 85. The storage jar assembly of any example herein, particularly examples 77-84, wherein the valve release mechanism is configured to press on the prosthetic heart valve and detach it from the valve attachment feature.
[0213] Example 86. The storage jar assembly of any example herein, particularly examples 77-85, wherein the lid comprises a lid attachment mechanism configured to releasably attach to the jar near the open end.
[0214] Example 87. The storage jar assembly of any example herein, particularly example 86, wherein the lid attachment mechanism is a screw thread configured to engage a corresponding screw thread on the jar.
[0215] Example 88. The storage jar assembly of any example herein, particularly example 87, wherein the lid attachment mechanism comprises a lip on the inside of the lid configured to releasably engage with a ridge disposed on the exterior of the jar near the open end.
[0216] Example 89. The storage jar assembly of any example herein, particularly examples 77-88, wherein the jar contains a hydrating fluid and a prosthetic heart valve.
[0217] Example 90. The storage jar assembly of any example herein, particularly example 89, wherein the hydrating fluid is glutaraldehyde.
[0218] Example 91. The storage jar assembly of any example herein, particularly example 90, wherein the valve release mechanism is configured to release the prosthetic heart valve into the hydrating fluid when used.
[0219] In view of the many possible embodiments to which the principles of the disclosed invention may be applied, it should be recognized that the illustrated embodiments are only preferred examples of the invention and should not be taken as limiting the scope of the invention. Rather, the scope of the invention is defined by the following claims. We therefore claim as our invention all that comes within the scope and spirit of these claims.

Claims

1. An assembly, comprising: a jar having an open end and configured to receive a valve holder; a lid configured to cover the open end of the jar; and a valve holder comprising a base, a column connected to and extending axially away from the base, and a plurality of circumferentially spaced valve retention members mounted on the base, wherein the valve holder is configured to receive a prosthetic heart valve and to hold the prosthetic heart valve in a partially compressed state within the jar.
2. The assembly of claim 1, wherein the plurality of circumferentially spaced valve retention members are configured to hold the prosthetic heart valve under a radial compressive strain.
3. The assembly of claim 2, wherein the radial compressive strain is less than 6%.
4. The assembly of claim 1, wherein a position of the plurality of circumferentially spaced valve retention members is radially adjustable inwardly and outwardly relative to an outer circumference of the base.
5. The assembly of claim 4, wherein the base comprises plurality of radially extending slots and each of the valve retention members comprises a projection that extends into a corresponding slot such that the projection is slidable within the slot to adjust the position of the valve retention

member on the base.
6. The assembly of claim 1, wherein the column has an upper end portion connected to the lid.
7. The assembly of claim 1, wherein the column has an upper end portion removably attached to the lid.
8. An assembly, comprising: a jar having an open end and configured to receive a prosthetic heart valve; a lid configured to cover the open end of the jar; and a valve holder configured to hold the prosthetic heart valve in a partially compressed state within the jar, wherein when the lid covers the open end of the jar, the lid is configured to retain a hydrating fluid inside the jar.
9. The assembly of claim 8, wherein the valve holder comprises a plurality of valve retention members configured to engage portions of the prosthetic heart valve.
10. The assembly of claim 9, wherein the valve holder comprises a base and a column having a lower end portion connected to the base and extending axially away from the base, wherein the valve retention members are positioned on an upper surface of the base.
11. The assembly of claim 10, wherein the base comprises a plurality of slots and each of the valve retention members comprises a projection that extends into a corresponding slot.
12. The assembly of claim 11, wherein each slot is sized to receive a portion of a frame of the prosthetic heart valve.
13. The assembly of claim 9, wherein the valve retention members are circumferentially spaced from each other.
14. The assembly of claim 9, wherein the valve retention members are configured to hold the prosthetic heart valve under a radial compressive strain.
15. The assembly of claim 9, wherein each valve retention member comprises a radially facing recess configured to receive a portion of a frame of the prosthetic heart valve.
16. The assembly of claim 10, wherein the column comprises an upper end portion and wherein the lid is releasably attached to the upper end portion of the column.
17. The assembly of claim 8, wherein the lid comprises a lid attachment mechanism configured to releasably attach to the jar near the open end.
18. The assembly of claim 17, wherein the lid attachment mechanism is a screw thread configured to engage a corresponding screw thread on the jar.
19. A lid configured to cover an open end of a jar, the lid comprising: an upper portion; a side wall depending from the upper portion; a valve attachment feature coupled to the lid and configured to releasably hold corresponding features of a prosthetic heart valve; and a valve release mechanism configured to detach the prosthetic heart valve from the valve attachment feature.
20. The lid of claim 19, wherein the valve attachment feature is configured to retain at least one end of the prosthetic heart valve in a radially compressed state.