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(54) **FLEXIBLE HEART VALVE WITH ARM ATTACHMENT TO OUTSIDE STRUCTURE**

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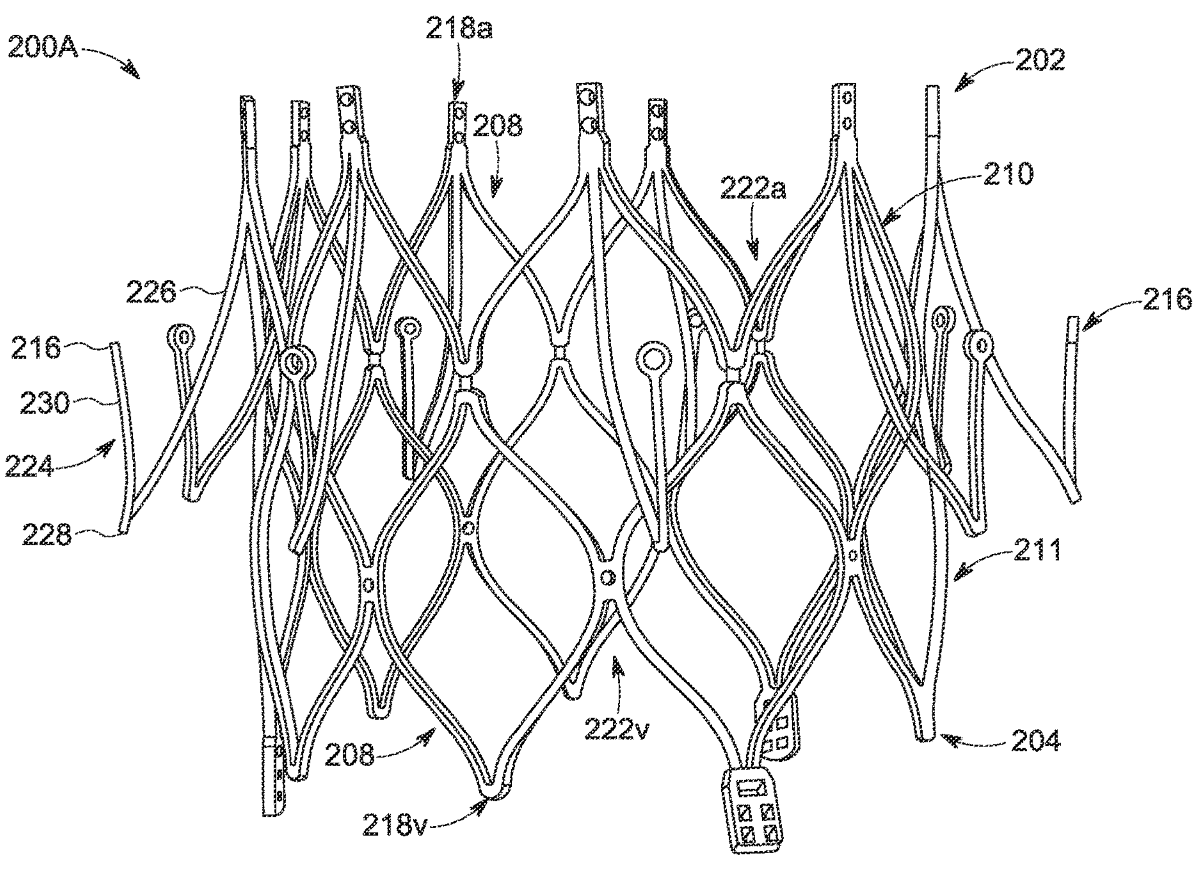
(57) **ABSTRACT**

The present disclosure provides replacement heart valves that include an outer frame, an inner frame, and arms extending therebetween. The outer frame and inner frame may be formed by a plurality of cells, such as diamond shaped cells. The arms may extend from an apex of a diamond shaped cell on the inner frame and be fastened to an apex where adjacent cells of the outer frame adjoin. The arms may include one or more bends. For example, the arms may extend in a first direction for a predefined length, have a bend point, and then extend in a second direction opposite the first. The arms may isolate the inner frame from the outer frame such that forces exerted on the outer frame are absorbed by the arms and do not deform the inner frame.



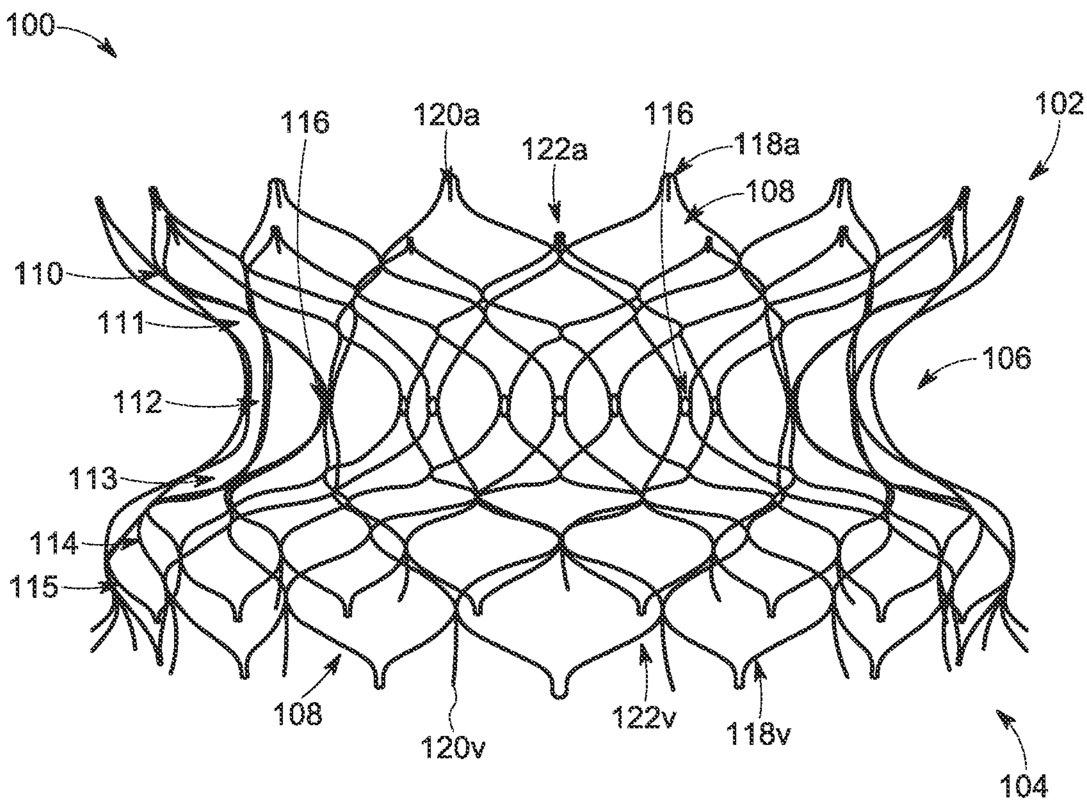

100
116
120a
122a
116
118a
102
108
110
111
106
112
113
114
115
108
120v
122v
118v
104

FIG. 1

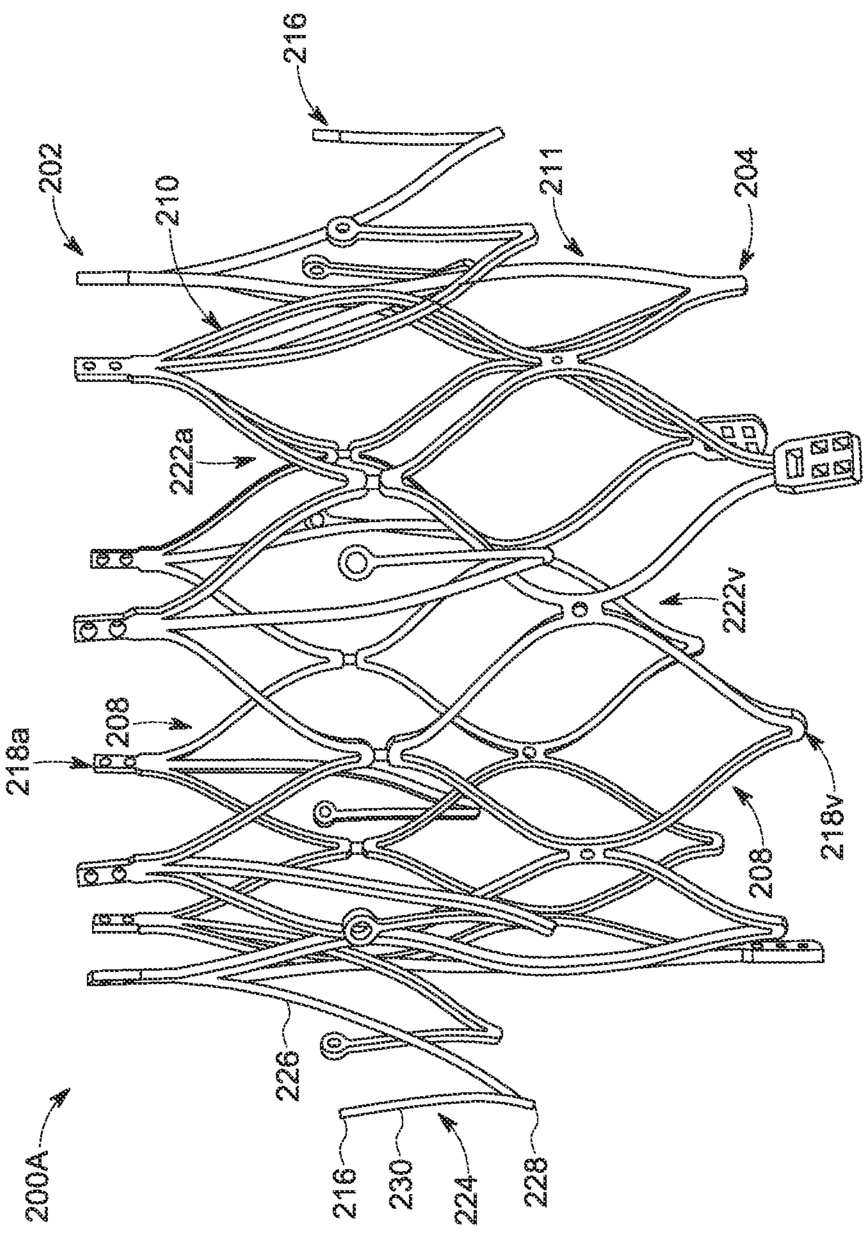

202
210
211
204
216
222a
222v
218a
208
208
218v
200A
226
216
230
224
228

FIG. 2A

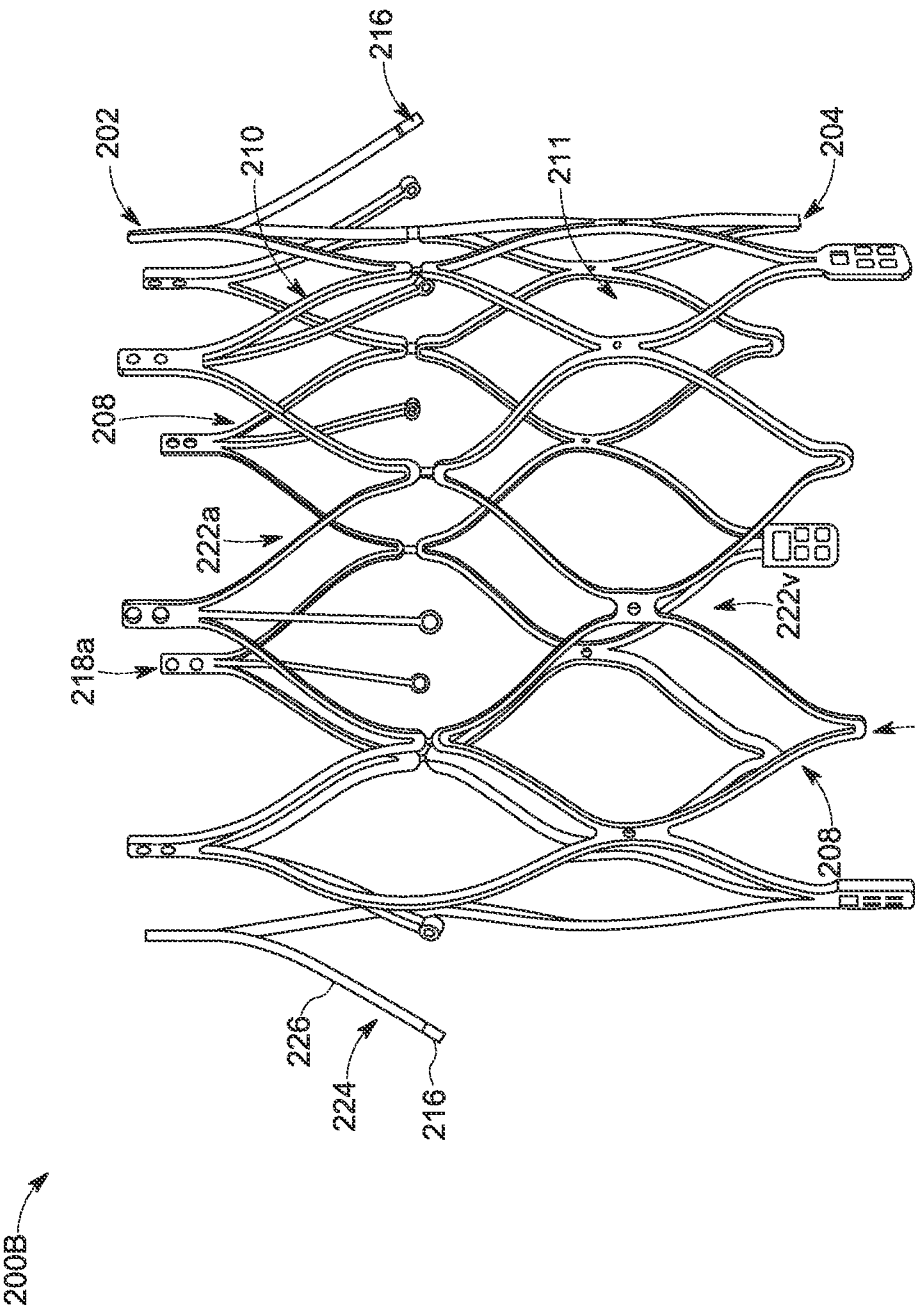

202
216
210
211
204
208
222a
222v
218a
218v
208
226
224
216
200B

FIG. 2B

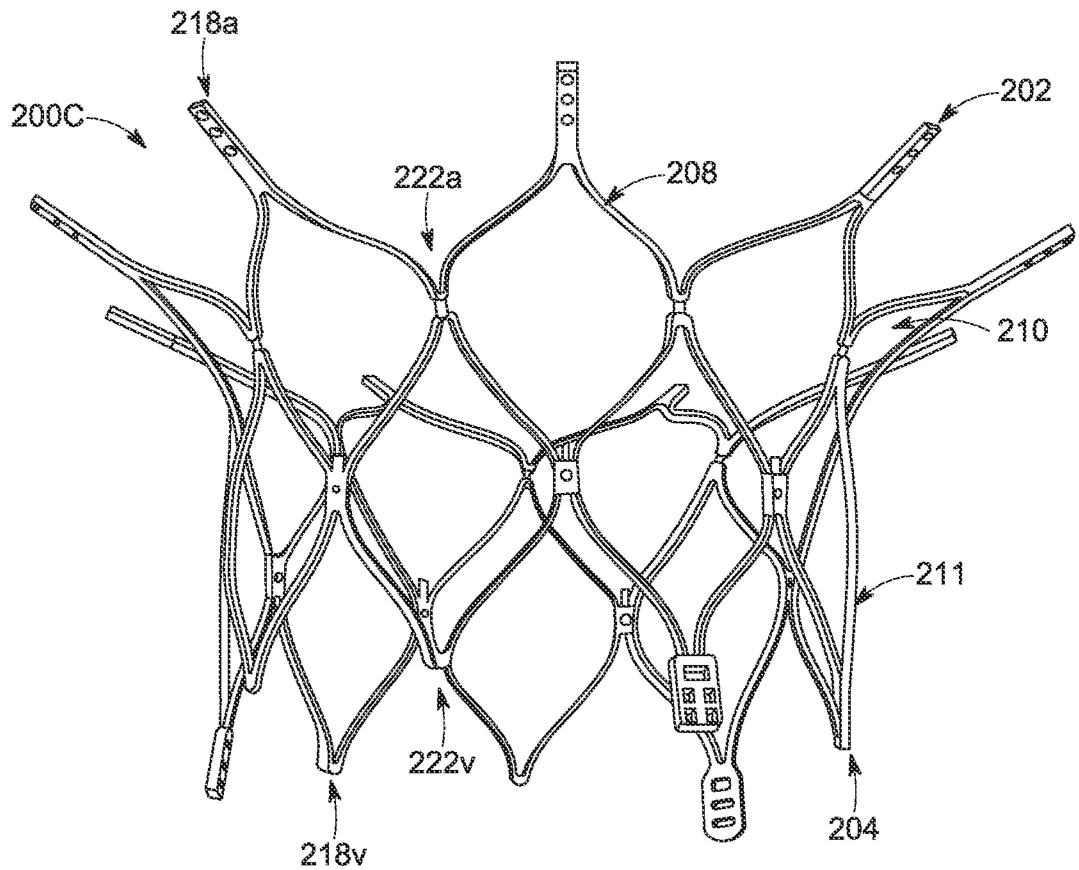


FIG. 2C

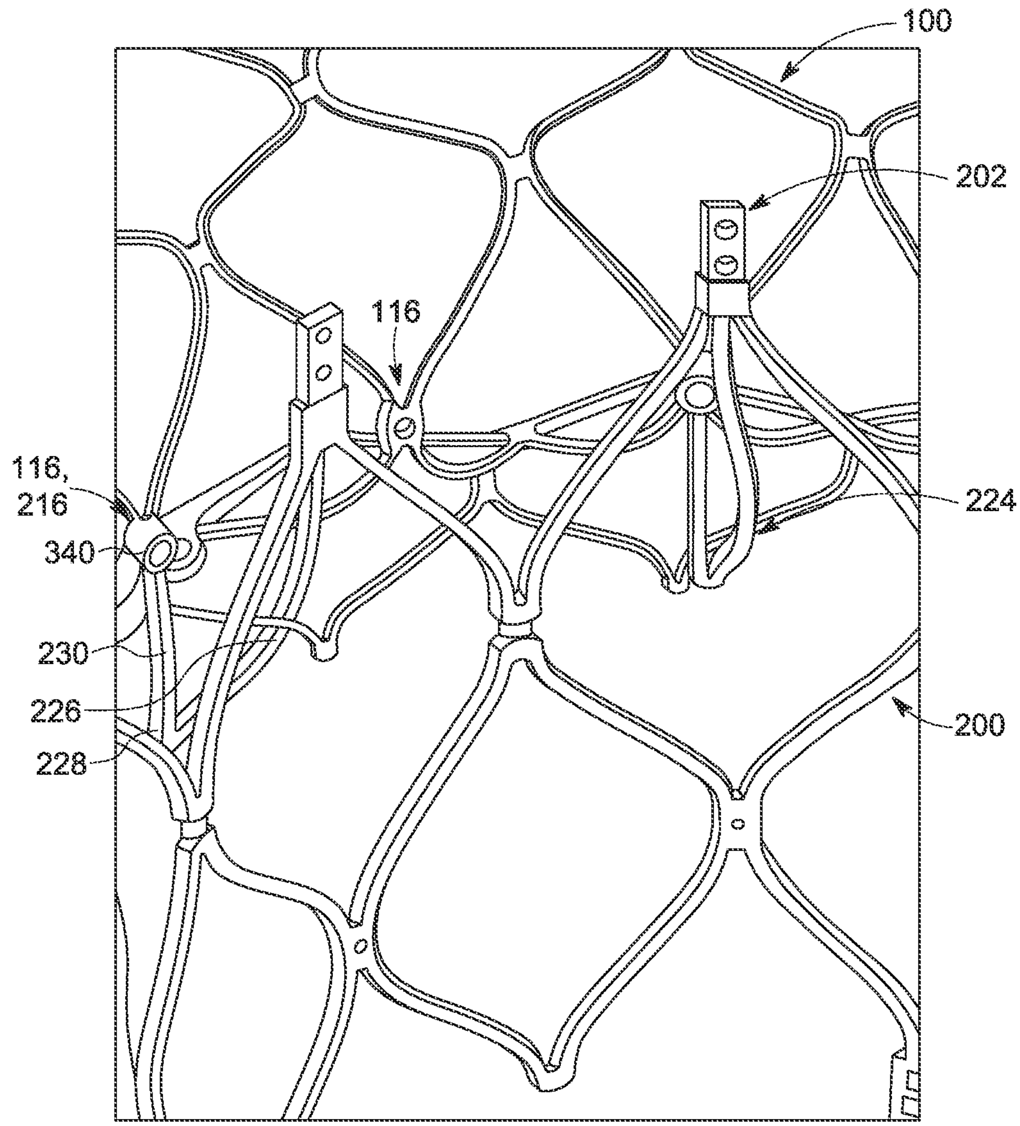


FIG. 3

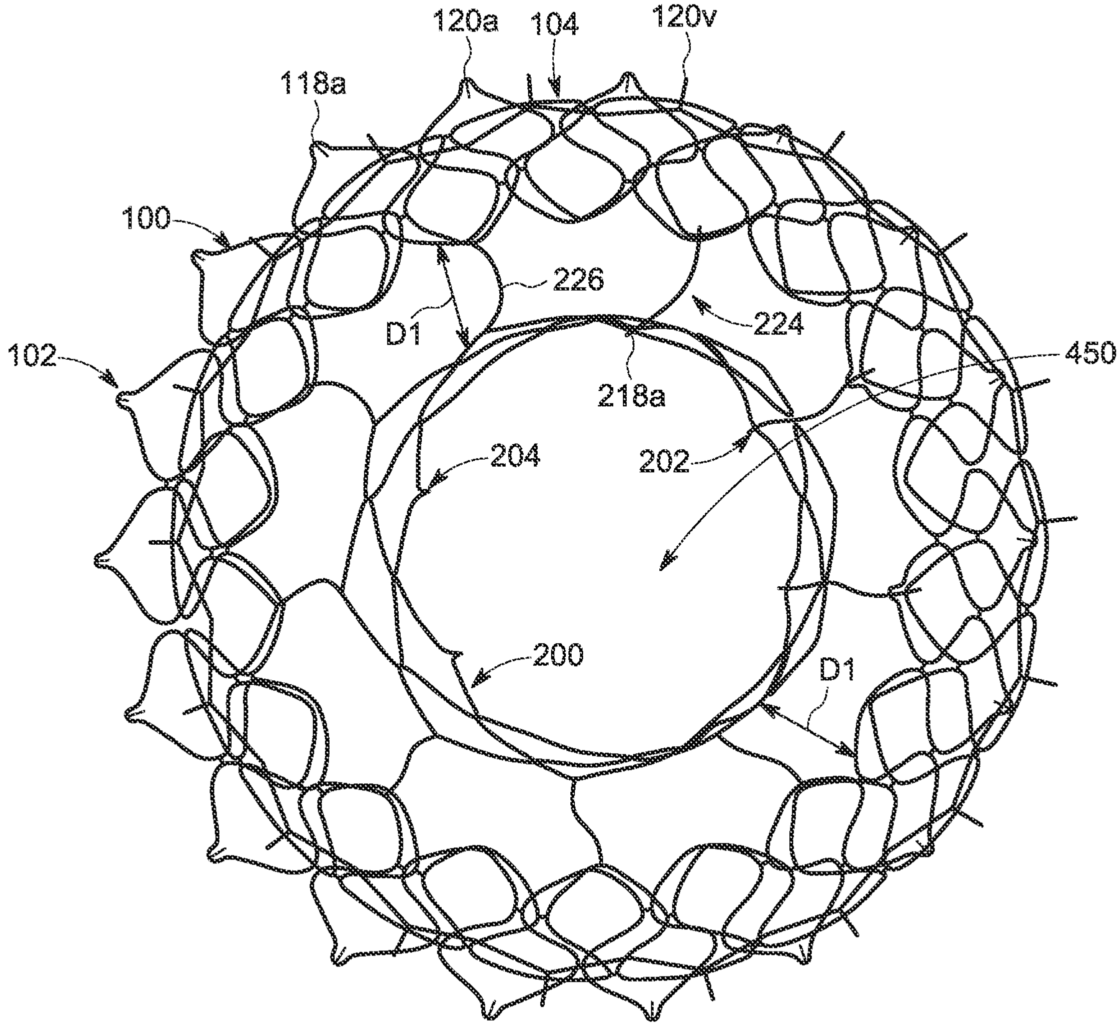


FIG. 4

FLEXIBLE HEART VALVE WITH ARM ATTACHMENT TO OUTSIDE STRUCTURE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to the filing date of U.S. Provisional Patent Application No. 63/304,830, filed Jan. 31, 2022, the disclosure of which is hereby incorporated by reference herein.

BACKGROUND OF THE DISCLOSURE

[0002] Replacement heart valves may include two frames, such as an outer frame and an inner frame. The outer frame is used to anchor the structure while the inner frame is used to hold the leaflets. The size of the inner frame may relate, or correspond, to the effective orifice area ("EOA"). The EOA and, therefore, the size of the inner frame often remains constant even when the annulus is dilated to a different size. For example, a replacement mitral valve can have an outer frame between 32 mm and 48 mm. The inner frame and, therefore, the valve, is to be kept at a constant size, such as 27 mm or 29 mm, regardless of the size of the outer frame. The larger the size of the inner frame the lower the pressure gradient should be.

[0003] A larger size inner frame provides a greater possibility to perform a valve in valve procedure when the replacement heart valve begins to deteriorate. A larger inner frame and, therefore, larger valve size, results in a greater amount of stress on the leaflets as compared to a smaller inner frame and valve. Physicians expect that a valve in valve procedure has to be performed at least once and as many as three times, if not more. Therefore, it is necessary to balance valve leaflet durability, EOA, and the ability to perform valve in valve procedures.

[0004] The outer and inner frames of the replacement valve may be rigid and/or manufactured as a single structure. This may prevent the physician from being able to select a combination of sizes of an outer frame and an inner frame. Moreover, with a rigid outer and inner frame, the inner frame may be deformed by any force exerted on the external frame. Thus, the inner frame may not maintain its shape.

BRIEF SUMMARY

[0005] The disclosure is generally directed to a replacement heart valve having an outer frame, an inner frame, and a plurality of arms therebetween. The outer frame may be configured to engage the dilated heart annular area and the inner frame may be configured to carry the heart valve tissue and sealing fabrics. Each of the outer frame and inner frame may include a plurality of cells. In some examples, the cells may be diamond shaped cells. The arms may extend from the inner frame and fasten to the outer frame, such that the arms couple, or connect, the outer and inner frame. According to some examples, the arms may extend from the apex of a cell of the inner frame and be coupled to an apex where adjacent cells of the outer frame adjoin. In some examples, the arms may have more than one portion such that a first portion of the arm extends in a first direction and a second section of the arm extends in a second direction opposite the first with a hinge, or a bend, between the first section and the section portion. For example, a first section of the arm may extend from an apex of a cell on the atrial end of the inner frame towards the ventricular end, a second section of the arm may extend back towards the atrial end, and there is a hinge, or a bend point between the first section and the second section such that the arms form a "zig-zag" shape. In some examples, there may be more than one bend point, such that the arms form a "zig-zag-zig" shape. In other examples, there may not be a bend in the arm, such that the arms are straight. The length of the arm, the number of bend points, the thickness of the material forming the arm, etc. may determine how much force the arms can absorb. For example, an increase in the number of bend points in each of the arms may increase the independence of the inner frame from the outer frame. Independence of the inner frame from the outer frame may prevent the inner frame from deformation such that the valve remains circular even when the outer frame is deformed.

[0006] The arms may absorb forces exerted on the outer frame to prevent or alleviate the force from being exerted on the inner frame. That is, the arms may isolate the inner frame such that a force exerted on the outer frame is absorbed (including being partially absorbed) by the outer frame and/or arms rather than the inner frame. This may allow for the inner frame to maintain its circular shape (or ovalize less) regardless of the force exerted on the outer frame of the replacement heart valve. In some examples, the arms may allow for both lateral and axial movement of the inner frame during a heart cycle to be isolated.

[0007] One aspect of the disclosure is directed to a replacement cardiac valve, comprising an outer frame configured to expand from a collapsed configuration to an expanded configuration, an inner frame configured to expand from a collapsed configuration to an expanded configuration, and one or more arms extending between the inner frame and the outer frame, wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed (including being partially absorbed) by the outer frame and the one or more arms.

[0008] The one or more arms may extend from the inner frame and may be coupled to the outer frame. The outer frame may include a first plurality of diamond shaped cells and the inner frame may include a second plurality of diamond shaped cells such that each of the one or more arms extends from an apex of the second plurality of cells to a connection point between adjacent cells of the first plurality of cells. Each of the one or more arms may be coupled to the outer frame by a rivet, a suture, a polymer, or an interlocking system.

[0009] The one or more arms may have at least one hinge point. Each of the at least one hinge points may correspond to a change in direction of the arms. The one or more arms may be a tether. A circumference of the outer frame may include a first number of cells and a circumference of the inner frame may include a second number of cells. The first number of cells may be a multiple (i.e. a whole-number multiple) of the second number of cells.

[0010] Another aspect of the disclosure is a replacement cardiac valve comprising an outer frame having a first plurality of diamond shaped cells, the outer frame configured to expand from a collapsed configuration to an expanded configuration, an inner frame having a second plurality of diamond shaped cells, the inner frame configured to expand from a collapsed configuration to an expanded configuration, and one or more arms extending from the inner frame to the outer frame, wherein each of the one or more arms extends from an apex of the second plurality of diamond shapes cells and is coupled to an apex of the first plurality of diamond shaped cells.

[0011] Yet another aspect of the disclosure is a replacement cardiac valve comprising an outer frame configured to expand from a collapsed configuration to an expanded configuration, an inner frame configured to expand from a collapsed configuration to an expanded configuration, and one or more arms extending from the inner frame and coupled to the outer frame, wherein each of the one or more arms has a bend point corresponding to a change in direction of each of the one or more anchoring mechanisms, and wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed (including being partially absorbed) by the outer frame and the one or more arms.

[0012] Yet another aspect of the disclosure is a replacement valve comprising an outer frame having a first plurality of diamond shaped cells, the outer frame configured to expand from a collapsed configuration to an expanded configuration, an inner frame having a second plurality of diamond shaped cells, the inner frame configured to expand from a collapsed configuration to an expanded configuration, and one or more arms extending from an apex of the second plurality of cells to a connection point between adjacent cells of the first plurality of cells, wherein each of the one or more arms includes one or more portions, a first portion of each of the one or more arms extending in a first direction and a second portion of each of the one or more arms extending in a second direction opposite the first direction, wherein each of the one or more arms has a bend point between the first portion and the second portion, and wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed by the outer frame and the one or more arms.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. **1** is a perspective view of an outer frame of a replacement heart valve in an expanded configuration according to aspects of the disclosure.

[0014] FIGS. **2A-2C** are perspective views of various inner frames of a replacement heart valve in an expanded configuration according to aspects of the disclosure.

[0015] FIG. **3** is a perspective view of the connection between the inner frame and outer frame of a replacement heart valve according to aspects of the disclosure.

[0016] FIG. **4** is a perspective view of a replacement heart valve according to aspects of the disclosure.

DETAILED DESCRIPTION

[0017] Replacement heart valves may use a combination of outer frames and inner frames, each having different diameters. The outer frame may be configured to anchor the replacement heart valve in the natural annulus and the inner frame maybe configured to include the heart valve and sealing tissue. It would be beneficial for the outer frame to deform independently from the inner frame such that the valve connected to the inner frame remains as close to circular as possible during the deformation of the outer frame.

[0018] The inner and outer frames may be coupled via one or more arms extending from the inner frame and being coupled to the outer frame. The arms may be of various shapes and lengths. For example, the arms may have multiple sections such that a first section extends in a first direction and a second section extends in a second direction with a bend point between the first and second sections. Thus, the arm may have a shape like a check-mark. In some examples, the arms may have three portions, such that the arms have a zig-zag-zig shape.

[0019] The arms may be coupled to the outer frame via rivets, sutures, polymer, etc. For example, there may be a connection point on the outer frame and a connection point on the end of the arm. The connection point on the end of the arm may align with the connection point on the outer frame when the inner frame is within a central opening of the outer frame. According to some examples, the outer and inner frames may include a plurality of cells, such as diamond shaped cells. The arm may extend from an apex of a diamond shaped cell of the inner frame and be coupled to a connection point on the outer frame where two adjacent cells adjoin.

[0020] The one or more arms may allow the inner frame, and therefore the valve mounted therein, to be independent and flexible in movement from the outer frame. This may isolate the inner frame from any outer annular movement from the valve pulsatile loads and motion. For example, a force exerted on the outer frame may be transferred to and/or absorbed (including being partially absorbed) by the arms such that the inner frame does not experience the force (or the entire force). Additionally or alternatively, the arms may allow for lateral and/or axial movements in the heart cycle to be isolated from the inner frame and the valve mounted therein. For example, the mitral valve is a part of the ventricular structure having a D-shape and/or a saddle shape. The replacement valve may have a round, or circular, shape that should remain as close to circular as possible during the cardiac cycle even though the native valve changes shape during the cardiac cycle. By isolating the inner frame from the outer frame via one or more arms, the outer frame may be deformed to the shape of the natural valve during the cardiac cycle while the inner frame, and therefore the replacement valve does not become deformed. According to some examples, the one or more arms may absorb (including partially absorb) the lateral force exerted on the outer frame such that the inner frame may deform less as compared to replacement valves without the one or more arms.

[0021] According to some examples, the one or more arms may allow the inner frame to remain constant regardless of the frame that is chosen. For example, the inner frame may be a predetermined size, such as 27 mm, 29 mm, 33 mm inner frame. The outer frame may be any size. In some examples, the outer frame may have an outer diameter of between about 36 mm to 60 mm at the central waist portion. The one or more arms may be stretched between the inner frame and the outer frame, allowing various combinations of an inner frame and an outer frame. This may allow for a valve and, therefore, an inner frame that is typically used for a first valve replacement to be used in a second valve location as the outer frame may be selected based on the location of the valve replacement, rather than the chosen valve and/or inner frame. For example, an inner frame and valve intended for an aortic valve replacement may be used with no modifications (or only slight modifications) for a triscupid valve replacement as an appropriate outer frame may be selected and coupled to the inner frame via the one or more arms.

[0022] The replacement heart valve, including the outer frame and inner frame, described herein, may be used as a replacement aortic, pulmonary, mitral, or tricuspid valve. When describing certain features, reference is made to orientations of the replacement heart valve based on use as a mitral valve. For example, the disclosure herein may refer to an atrial end and a ventricular end. This is for reference and ease of understanding and is not intended to be limiting to use as a replacement mitral valve.

[0023] FIG. **1** is a perspective view of an outer frame of a replacement heart valve in an expanded configuration. The outer frame **100** may be configured to engage the dilated heart annular area. The outer frame **100** may have an atrial end **102**, ventricular end **104**, and central portion **106** therebetween. The atrial end **102** may be configured and adapted to be disposed on an atrial side of a mitral valve orifice and ventricular end **104** may be configured and adapted to be disposed on a ventricle side of the mitral valve orifice. In some examples, however, the outer frame **100** may be implanted so that atrial end **102** is positioned on the ventricle side and the ventricular end **104** is positioned on the atrial side. The atrial end **102** and ventricular end **104** may extend radially outward from ventral portion **106**. In some examples, the atrial end **102** and ventricular end **104** may flare outward relative to central portion **106**. Additionally or alternatively, atrial end **102** and ventricular end **104** may be flanged or flared relative to central portion **106**.

[0024] The outer frame **100** may be cut (e.g., laser cut) out of a flat sheet of material or a tube. In some examples the material is a nitinol sheet or tube and shape set according to a valve position and/or anatomic design. For example, the outer frame **100** may be shape set for use in an aortic, pulmonary, mitral, or tricuspid valve. According to some examples, the nitinol sheet is 0.1 mm to 1.0 mm thick. In other examples, the nitinol sheet and/or tube may be 0.2 mm to 0.6 mm thick. However, the ranges of the thickness of the nitinol sheet and/or tube are merely examples and are not intended to be limiting.

[0025] Outer frame **100** may comprise a plurality of diamond shaped cells **108**. According to some examples, the plurality of diamond shaped cells **108** may create rows of cells **108**. As shown, there may be five rows of cells. For example, the atrial end **102** may be a first row **110** of cells, between the atrial end **102** and the central portion **106** may be a second row **111** of cells, the central portion **106** may be a third row **112** of cells, between the central portion **106**. The ventricular end **104** may have a fourth row **113** of cells, fifth row **114** of cells, and a sixth row **115** of cells. According to some examples, the third row **112** of cells may have fewer or more cells than the first row **110** or sixth row **115** of diamond shaped cells. While outer frame **100** is shown with six rows of cells **108**, there may be any number of rows based on the size, shape, configuration, etc. of cells. According to some examples, outer frame **100** may not include rows of cells **108** due to the shape and/or configuration of the cells.

[0026] The diamond shaped cells **108** may have configurations other than general diamond shapes, such as hexagonal, triangle, etc. In some examples, the diamond shaped cells **108** may not all have the same configuration. For example, each row **110-115** may have a different shape. In some examples, the first row **110**, third row **112**, and sixth row **115** of cells may be a first shape and the second row **111**, fourth row **113**, and fifth row **114** may be a second shape. However, there may be any combination of shapes and numbers of cells among the first, second, third, fourth, fifth, and sixth rows **110-115** of cells.

[0027] As shown in FIG. **1**, between each diamond shaped cell **108** in the third row **112** of cells, there may be an aperture **116**. The aperture **116** may be formed where adjacent cells **108** in the second row **112** of cells meet or adjoin. The apertures **116** may be aligned axially (i.e., as shown they are in a "row"), but in other examples they may not be aligned axially. For example, if the cells **108** have different configurations, some apertures **116** may not be aligned, or in the same "row" with other apertures. In some examples, the apertures **116** may be located where the cells **108** in the third row **112** of cells meet the cells **108** of the second row **111** or fourth row **113** of cells. Thus, while the apertures **116** are shown as being aligned axially where adjacent cells **108** in the third row **112** of cells meet, the apertures **116** may be located at the apex of the cells **108** in the third row **112** of cells. According to some examples, the apertures may, additionally or alternatively, be located where adjacent cells **108** meet in the second row **111** or fourth row **114** and/or at the apex of the cells **108** in the second row or fourth row **114**. Thus, having the apertures **116** aligned axially in the third row **113** of cells is merely one example of the location of the apertures **116** and is not intended to be limiting.

[0028] Outer frame **100** may include a plurality of arches **118*v*** that extend from the central portion **106** to the ventricular end **104** and a plurality of arches **118*a*** that extend from the central portion **106** to the atrial end **102**. The configuration of arches **118*a***, **118*v*** are generally triangular-shaped, "pointing" towards the atrial end **102** or ventricular end **104**, and include two sections of material and a bend between the two sections of material. As shown, in each arch **118*a***, **118*v***, the material first extends away from central portion **106**, forms a bend at the atrial end **102** or ventricular end **104**, respectively, of outer frame **100**, and then extends back towards central portion **106**. Arches **118*a***, **118*v*** are triangular shaped in this example, and the ventricular ends can be described as tips of the arches. In some examples, the tips of the arches are rounded. The tips at the ventricular end **104** may be rounded, or curved, to avoid damaging the tissue when implanted. However, in some examples, the tips of the arches may be pointed. Additionally or alternatively, the tips of the arches may include an aperture or hook. For example, the tips of arches **118** may include a pin **120*a*** extending from the tip. The pins **120*a*** may face in towards the central opening of outer frame **100**. The pins **120*a*** may be used to connect the replacement valve to a delivery system. In some examples, the replacement valve may be connected to the delivery system via sutures to resist pressure build-up.

[0029] A plurality of spaces **122*a***, **122*v*** may be positioned between between adjacent arches **118*a***, **118*v***. The configurations and sizes of the spaces **122*a***, **122*v*** may be defined by the configuration of adjacent arches **118*a***, **118*v***. In some embodiments, the spaces **122*v*** may be configured to allow the sub-valvular structures, such as chords, to slide between adjacent arches **118*v*** when the outer frame is expanded. However, if sealing member (e.g. an inner and/or outer skirt) is provided on the outer frame **100**, and if that sealing member extends all the way down to the arches **118*v***, that sealing member may occupy the spaces **122*v***, in which case those spaces **122*v*** may not be able to receive any portion of the sub-valvular structure therein. The configuration of the arches **118**_a_, **118**_v_, and thus the plurality of spaces **122**_a_, **122**_v_, may provide easier collapse of the outer frame **100** radially inwards when the anchor is collapsed (e.g., for delivery).

[0030] According to some examples, a plurality of hooks may extend from where adjacent cells **108** meet in the spaces **122**_a_, **122**_v_. The hooks **120**_v_ may help anchor the replacement valve into the tissue. As shown, where adjacent cells **108** of the sixth row **115** of cells meet, hooks **120**_v_ may extend, or flare, outwardly. While the hooks **120**_v_ are shown as being located where adjacent cells **108** of the sixth row **115** of cells meet, hooks **120**_v_ may be positioned at various locations on outer frame **100**. For example, hooks **120**_v_ may be positioned at the proximal end of the fifth row of cells **114**. In some examples, hooks **120**_v_ may be positioned at the proximal end of the cells if any row and/or in combination with hooks **120**_v_ on multiple rows.

[0031] Although not shown in FIG. **1**, it should be understood that the outer frame **100** may include one or more sealing members, such as a skirts, on the inner and/or exterior surface of the outer frame to assist with sealing against the anatomy, mitigating or preventing leakage through or around the outer frame **100**, and/or enhancing eventual tissue in-growth into the prosthetic heart valve.

[0032] FIGS. **2**A-**2**C are perspective views of example inner frames of a replacement heart valve in an expanded configuration. Each inner frame **200**A, **200**B, **200**C may have a similar configuration and, therefore, similar reference numbers may be used. While the disclosure provided herein may refer to inner frame **200**A, the disclosure also applies to inner frames **200**B, **200**C.

[0033] The inner frame **200** may be used for different applications, such as for a mitral valve, tricuspid valve, aortic valve, pulmonary valve, etc. The inner frame **200** may carry the heart valve tissue (e.g. a plurality of tissue or synthetic leaflets that close and open to provide the valve functionality) and one or more sealing members (e.g. tissue or fabric on the inner and/or outer surface of the inner frame **200** and/or tissue or fabric extending between the inner frame **200** and the outer frame **100** to at least partially seal the space between the inner frame **200** and outer frame **100**). The inner frame **200** may have an atrial end **202** and a ventricular end **204**. The atrial end **202** may be configured and adapted to be disposed on an atrial side of a mitral valve orifice and ventricular end **204** may be configured and adapted to be disposed on a ventricle side of the mitral valve orifice. In some examples, however, the inner frame **200** may be implanted so that atrial end **202** is positioned on the ventricle side and the ventricular end **104** is positioned on the atrial side.

[0034] The inner frame **200** may be cut (e.g., laser cut) out of a flat sheet of material or a tube. In some examples the material is a nitinol sheet or tube and shape set according to a valve position and/or anatomic design. According to some examples, the nitinol sheet is 0.1 mm to 1.0 mm thick. In other examples, the nitinol sheet and/or tube may be 0.2 mm to 0.6 mm thick. However, the ranges of the thickness of the nitinol sheet and/or tube are merely examples and are not intended to be limiting.

[0035] Inner frame **200** may comprise a plurality of diamond shaped cells **208**. According to some examples, the plurality of cells may create rows of cells **208**. As shown, there may be two rows of cells. For example, the atrial end **202** may be a first row **210** of cells and the ventricular end **204** may be a second row **211** of cells. While only two rows **210**, **211** of cells are shown, there may be any number of rows of cells in the inner frame.

[0036] The diamond shaped cells **208** may have configurations other than general diamond shapes, such as hexagonal, triangle, etc. In some examples, the diamond shaped cells **108** may not all have the same configuration. For example, each row **210**, **211** may have a different shape.

[0037] Inner frame **200** may include a plurality of arches **218**_a_ that extend from where the first row **210** of cells and the second row of cells **211** meet towards the atrial end **202** and a plurality of arches **218**_v_ that extend from where the first row **210** of cells and the second row of cells **211** meet towards the ventricular end **204**. The arches **218**_a_, **218**_v_ may be similar in shape and/or configuration as arches **118**_a_, **118**_v_. Between adjacent arches **218**_a_, **218**_v_ may be a plurality of spaces **222**_a_, **222**_v_, similar to spaces **122**_a_, **122**_v_.

[0038] A plurality of arms **224** may extend from the tips of arches **218**_a_. According to some examples, the arms may additionally or alternatively be referred to as extension members, tethers, etc. The arms **224** may extend from the tip of arch **218**_a_ towards ventricular end **204**. During manufacturing of the inner frame **200**, the arms **224** may be nested inside of cells **208**.

[0039] As shown in FIG. **2**A, arms **224** may include two sections, or portions, of material and a bend between the two sections. For example, the first section **226** of material may extend from arch **218**_a_ towards the ventricular end **204**, form a bend **228**, and then the second section **230** of material extends back towards the atrial end **202**. The first section **226** may extend from the tip of arch **218**_a_ or a portion of arch **218**_a_ substantially near the tip of arch **218**_a_. The first section **226** of material may extend beyond the height of cell **208**, substantially the height of cell **208**, or less than the height of cell **208** before forming bend **228** and extending back towards the atrial end **202**. The height of the cell may be the distance from the tip of arch **218**_a_ to the opposing apex of the diamond shape cell **208**. The length of the first section **226** of material may be varied based on the desired stiffness of arm **224**. The stiffness of arms **224** may correspond to the amount of force the arms **224** can absorb. Increasing the length of arm **224** may increase the amount of force that may be absorbed by the arms **224**. Increasing the amount of force absorbed by arms **224** may increase the amount of isolation of the inner frame **200** from outer frame **100**. Increasing the amount of isolation of inner frame **200** may prevent inner frame **200** from being deformed (or at least minimize the amount that the inner frame **200** ovalizes) while outer frame **100** is deformed. The length of arm **224** may be increased by increasing the length of the first and/or second section **226**, **230** of material. According to some examples, the first section **226** and/or second section **230** of material for each of the plurality of arms **224** may be the same length or different lengths.

[0040] While arms **224** are shown with two sections **226**, **230** of material separated by a hinge point or bend **228**, arms **224** may have any number of sections of material with any number of bends or hinge points. For example, as shown in FIG. **2**B, arms **224** may only include the first section **226** of material and no bends. In some examples, arms **224** may have a double bend, such that arms **224** form a "Z-like" shape, or have three bend points, such that arms **224** form a "zig-zag-zig" shape. Additionally or alternatively, the sections of material may have any shape. For example, the first section **226** of material is shown as having a curve. However, the first section **226** and/or second section **230** may be linear, zig-zag, wavy, etc. Thus, arms **224**, as shown in FIGS. **2**A and **2**B, are merely exemplary and are not intended to be limiting.

[0041] According to some examples, arms **224** may extend from inner frame **200** rather than outer frame **100** such that all of the available material during manufacturing of outer frame **100** may be used to achieve maximal stiffness while also minimizing the packing diameter.

[0042] FIG. **2**C is an example inner frame **200**C that is connected to outer frame **100** via one or more arms **218***a*. Although the term "arms" is used, in this embodiment, the "arms" may also be thought of as extended portions of the diamond shaped cells **208** in the first row **210**, or simply as arches **218***a*. Arms **218***a* may be flexible such that when arms **218***a* are connected to an outer frame, arms **218***a* may be curved into a "U" shape, or an arch. Additionally or alternatively, when arms **218***a* are connected to the outer frame, arms **218***a* may create any shape or may be bent such that arms **218***a* include one or more bend points. Arms **218***a* may be manufactured to have any length. For example, a smaller inner frame **200**C being coupled to a large outer frame may include longer arms **218***a* as compared to a smaller inner frame **200**C being coupled to a smaller outer frame. According to some examples, arms **218***a* may be coupled to the atrial end, or disk, of outer frame. Additionally or alternatively, arms **218***a* may be coupled to the waist, or central portion, of outer frame.

[0043] In all of the embodiments described herein, the various arms **224** (or arms/arches **218***a* in connection with FIG. **2**C) may be formed integrally with the remainder of inner stent **200**, or otherwise formed separately and later coupled to the inner stent **200**.

[0044] Inner frame **200** and outer frame **100** may be coupled to each other prior to and/or during implantation. Coupling arms **224** of inner frame **200** to outer frame **100** may isolate inner frame **200** from outer frame **100**. For example, forces exerted on outer frame **100** may be absorbed by arms **224** such that inner frame **200** is not compressed (or not meaningfully or significantly compressed) by the forces exerted on outer frame **100**. This may allow inner frame **200** to maintain a round shape while outer frame **100** is deformed by external forces.

[0045] The amount of force that arms **224** (e.g. as shown in FIGS. **2**A-C) may absorb may be based on the number of arms **224** coupling inner frame **200** to outer frame **100**, where the arms **224** are located along the perimeter of atrial end **202**, the length of arms **224**, the number of bend points in arms **224**, etc. For example, elongating the arms **224** may generally increase the amount of force that can be absorbed. The more force absorbed by the arms **224**, the less deformation inner frame **200** may experience when a force is being exerted on outer frame **100**. According to some examples, a smaller number of arms **224** coupling inner frame **200** to outer frame **100** may increase the isolation of inner frame **200** from outer frame **100**. The more isolated inner frame **200** is from outer frame **100**, the less deformation inner frame **200** may experience when a force is being exerted on outer frame **100**. In examples where the arms **224** are longer, the arms **224** may be able to absorb more force as compared to arms **224** that are shorter. In some examples, arms **224** that include more bends **228** may absorb more force than arms **224** with fewer bends **228**. By increasing the amount of force absorbed by arms **224** and/or increasing the isolation of inner frame **200**, the more likely it is that inner frame **200** maintains its shape while a force is being exerted on outer frame **100**. This may allow for the prosthetic valve leaflets to coapt more efficiently.

[0046] FIG. **3** is a perspective view of the connection between inner frame **200** and outer frame **100**. The inner frame **200** may be coupled to outer frame **100** via one or more rivets, sutures, tethers, polymer, an interlocking system, etc. For example, the atrial tip of the second section **230** may include an aperture **216**. Aperture **216** of inner frame **200** may be aligned with aperture **116** of outer frame **100** such that inner frame **200** may be coupled to outer frame **100**. A rivet may be used to connect apertures **116**, **216**. According to some examples, apertures **216**, **116** may be a connection point for coupling inner frame **200** and outer frame **100** using sutures, tethers, polymer, an interlocking system, etc. Thus, while apertures **116**, **216** are shown, they are merely one example of how inner frame **200** and outer frame **100** may be coupled and, therefore, are not intended to be limiting.

[0047] In examples where tethers are used to couple inner frame **200** and outer frame **100**, the tether may allow inner frame **200** be positioned within outer frame **100** without having a stiff or rigid structure therebetween. The tethers may, in some examples, prevent any compression forces being exerted on outer frame **100** from being exerted on, or transferred to, inner frame **200**. For example, the tethers may allow inner frame **200** to float within the central opening of outer frame **100**. As the tethers are not a rigid structure, any force exerted on outer frame **100** will be absorbed by outer frame **100** and would not be transferred by the tethers to inner frame **200**.

[0048] According to some examples, inner frame **200**A-C may be coupled to outer frame **100** at the atrial end of outer frame. The atrium typically does not contract as much as the ventricle during a heart cycle such that the ventricular end of outer frame **100** may experience more deformation than the atrial end of outer frame **100** during a heart cycle. In some examples, the atrial end of outer frame **100** does not substantially deform. By connecting inner frame **200**A-C to the atrial end of outer frame **100**, less force may be exerted on the atrial end of outer frame **100** and, therefore, less force may be exerted on inner frame **200**A-C. In examples where less force is exerted on the atrial end of outer frame **100**, arms **224** may have less force and/or deformation to absorb to prevent deformation of inner frame **200**A-C. According to some examples, inner frame **200**A-C may have fewer number of arms **224** when inner frame **200** is coupled to the atrial end of outer frame **100** compared to when inner frame **200**A-C is coupled to the ventricular end of outer frame **100**. Fewer arms **224** may be needed to absorb the force exerted on outer frame **100** when inner frame **200**A-C is coupled to the atrial end of outer frame **100** as less force is exerted on the atrial end of outer frame **100** as compared to the ventricular end of outer frame **100**.

[0049] According to some examples, the number of cells **208** around the circumference of the inner frame **200** may be a factor, or multiple (i.e. whole number multiple), of the number of cells **108** around the circumference of the outer frame **100**. For example, if the circumference of the inner frame **200** has a total of nine cells **208**, the circumference of the outer frame **200** may have a total of nine, eighteen (18), twenty-seven (27), etc. cells **108**. By having the number of cells **108**, **208** be a factor of each other, there may be symmetry between the connection points of the inner frame **200** and outer frame **100**. According to some examples, a nine cell **208** geometry with three (3) connection points may maintain symmetry between the inner frame **200** and outer frame **100**. In other examples, an eight (8) cell geometry with two (2), four (4), or eight (8) connection points may maintain symmetry between the inner frame **200** and outer frame **100**. Symmetry between the connection points of inner frame **200** and outer frame **100** may balance the load in the sheath of the delivery device when implanting the replacement valve.

[0050] According to some examples, however, the connection points may be asymmetrical. The asymmetrical connection points may compensate for the asymmetrical, or "D-shape," of a valve annulus. For example, there may be more connection points on a short axis as there is likely to be more pressure, or a greater amount of force, being exerted on the outer frame **100** along the short axis. By having more connection points and/or arms **224** along the short axis, the arms **224** may absorb the force thereby preventing the force from being transferred to the inner frame **200**. The short axis may be defined by the catheter once the catheter is inserted into the heart. By defining the short axis via the catheter, that axis can be used to define the orientation of the replacement valve when loading the replacement valve in the catheter during implantation. This may ensure that the axis, or portions, with the greater number of connection points and arms **224** is in the correct orientation.

[0051] FIG. **4** illustrates an example of a replacement heart valve having an inner frame, an outer frame, and arms extending therebetween. According to some examples, the inner frame **200** may have an outer diameter of about 27 mm and the central portion **106** of outer frame **100** may have an outer diameter of about 40 mm. According to some examples, the central portion **106** of outer frame **100** may have an outer diameter between about 32 mm and about 48 mm. However, the central portion **106** of outer frame **100** may have an outer diameter smaller than 32 mm or greater than 48 mm and, therefore, the range of 32-48 mm is merely exemplary and is not intended to be limiting. The diameter of the central portion **106** the outer frame **100** may be determined based on the length of arms **224**. For example, a larger diameter of central portion **106** may cause a physician to choose an inner frame **200** with longer arms **224** as compared to an outer frame **100** with a smaller diameter central portion **106**.

[0052] As shown, inner frame **200** is located within the central opening **450** of outer frame **100**. Arms **224** of inner frame **200** extend a distance outward from inner frame **200** and are coupled to outer frame **100**. The arms **224** define a distance "D1" between outer frame **100** and inner frame **200**. The distance "D1" corresponds to the distance arms **224** may be compressed before an external force exerted on outer frame **100** will be exerted (or meaningfully exerted) on inner frame **200**. The amount of force that may be absorbed by arms **224** may correspond to the amount of potential energy that can be absorbed by arms **224**. For example, the arms **224** may act similar to a spring such that each arm **224** may have a compression constant, or spring constant. The compression constant may be determined based on the type of material the arm **224** is made of, the length of the arm **224**, the number of bends in the arm, the thickness of the material that the arms **224** are made of, the width of the arm **224**, etc. For example, the thickness and/or width of arms **224** may be varied along the length of the arm **224** to as a way to distribute the force along the arm **224**. In some examples, the thickness and/or width of the arms **224** may be varied along the length of the arm **224** to increase the amount of force that can be absorbed by the arm. The amount of energy, and therefore force, that can be absorbed by the arm **224** may be based on the distance "D1" that the arm **224** can be compressed. The greater the compression constant and/or distance the arm **224** can be compressed, the greater the amount of energy, and therefore force, each arm **224** can absorb.

[0053] Using arms **224** to isolate inner frame **200** from forces exerted on outer frame **100** may allow for the outer frame **100** to expand to a larger diameter while maximizing the material of the outer frame and allowing for various sized inner frames. For example, the outer frame **100** may have a closed cell shape such that none of the material for the outer frame **100** is used to connect the outer frame **100** to inner frame **200**. This may allow for the outer frame **100** to maintain the necessary stiffness while still being able to be coupled to an inner frame **200**.

[0054] In some examples, the physician may subsequently be able to insert a second inner frame within the inner frame **200**. This may allow the physician to replace the inner frame **200** independent from the outer frame **100** due to, for example, degraded leaflets.

[0055] Unless otherwise stated, the foregoing alternative examples are not mutually exclusive, but may be implemented in various combinations to achieve unique advantages. As these and other variations and combinations of the features discussed above can be utilized without departing from the subject matter defined by the claims, the foregoing description of the embodiments should be taken by way of illustration rather than by way of limitation of the subject matter defined by the claims. In addition, the provision of the examples described herein, as well as clauses phrased as "such as," "including" and the like, should not be interpreted as limiting the subject matter of the claims to the specific examples; rather, the examples are intended to illustrate only one of many possible embodiments. Further, the same reference numbers in different drawings can identify the same or similar elements.

1. A replacement cardiac valve, comprising:

an outer frame configured to expand from a collapsed configuration to an expanded configuration;

an inner frame configured to expand from a collapsed configuration to an expanded configuration; and

one or more arms extending between the inner frame and the outer frame, wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed by the outer frame and the one or more arms.

2. The replacement cardiac valve of claim **1**, wherein the one or more arms extend from the inner frame and are coupled to the outer frame.

3. The replacement cardiac valve of claim **2**, wherein the outer frames includes a first plurality of diamond shaped cells and the inner frame includes a second plurality of diamond shaped cells such that each of the one or more arms extend from an apex of the second plurality of cells to a connection point between adjacent cells of the first plurality of cells.

4. The replacement cardiac valve of claim **2**, wherein the each of the one or more arms are coupled to the outer frame by a rivet, a suture, a polymer, or an interlocking system.

5. The replacement cardiac valve of claim **1**, wherein the one or more arms has at least one hinge point.

6. The replacement cardiac valve of claim **5**, wherein each of the at least one hinge point corresponds to a change in direction of the arms.

7. The replacement cardiac valve of claim **1**, wherein the one or more arms is a tether.

8. The replacement cardiac valve of claim **1**, wherein a circumference of the outer frame includes a first number of cells and a circumference of the inner frame includes a second number of cells, the first number of cells being a multiple of the second number of cells.

9. A replacement cardiac valve, comprising:

an outer frame having a first plurality of diamond shaped cells, the outer frame configured to expand from a collapsed configuration to an expanded configuration;

an inner frame having a second plurality of diamond shaped cells, the inner frame configured to expand from a collapsed configuration to an expanded configuration; and

one or more arms extending from the inner frame to the outer frame, wherein each of the one or more arms extends from an apex of the second plurality of diamond shapes cells and is coupled to an apex of the first plurality of diamond shaped cells.

10. The replacement cardiac valve of claim **9**, wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed by the outer frame and the one or more arms.

11. The replacement cardiac valve of claim **9**, wherein the each of the one or more arms are coupled to the outer frame by a rivet, a suture, a polymer, or an interlocking system.

12. The replacement cardiac valve of claim **9**, wherein the one or more arms has at least one bend point.

13. The replacement cardiac valve of claim **12**, wherein each of the at least one bend point corresponds to a change in direction of the arms.

14. The replacement cardiac valve of claim **9**, wherein the one or more arms is a tether.

15. A replacement cardiac valve, comprising:

an outer frame configured to expand from a collapsed configuration to an expanded configuration;

an inner frame configured to expand from a collapsed configuration to an expanded configuration; and

one or more arms extending from the inner frame and coupled to the outer frame,

wherein each of the one or more arms has a bend point corresponding to a change in direction of each of the one or more anchoring mechanisms, and

wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed by the outer frame and the one or more arms.

16. The replacement cardiac valve of claim **15**, wherein the each of the one or more arms are coupled to the outer frame by a rivet, a suture, a polymer, or an interlocking system.

17. The replacement cardiac valve of claim **15**, wherein the outer frame has a first plurality of diamond shaped cells and the outer frame has a second plurality of diamond shaped cells.

18. The replacement cardiac valve of claim **17**, wherein the first plurality of diamond shaped cells is a multiple of the second plurality of diamond shaped cells.

19. The replacement cardiac valve of claim **17**, wherein each of the one or more arms extends from an apex of the second plurality of diamond shaped cells.

20. The replacement cardiac valve of claim **17**, wherein each of the one or more arms is coupled to the outer frame at an apex where adjacent cells of the first plurality of diamond shaped cells adjoin.

21. A replacement cardiac valve, comprising:

an outer frame having a first plurality of diamond shaped cells, the outer frame configured to expand from a collapsed configuration to an expanded configuration;

an inner frame having a second plurality of diamond shaped cells, the inner frame configured to expand from a collapsed configuration to an expanded configuration; and

one or more arms extending an apex of the second plurality of cells to a connection point between adjacent cells of the first plurality of cells,

wherein each of the one or more arms includes one or more portions, a first portion of each of the one or more arms extending in a first direction and a second portion of each of the one or more arms extending in a second direction opposite the first direction,

wherein each of the one or more arms has a bend point between the first portion and the second portion, and

wherein the one or more arms are configured to isolate the inner frame such that a force exerted on the outer frame is absorbed by the outer frame and the one or more arms.

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