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Prosthetic Heart Valve, Systems, And Methods

Abstract

Prosthetic valve support structures of this specification include a body portion, an atrial flange portion, and a leaflet engaging portion. As the support structure (and the valve as a whole) is pushed out of or otherwise unrestrained from a delivery device, the free end(s) of the leaflet engaging portion will begin to bend radially outward or away from the body portion and will continue bending as more is exposed until its free end(s) are angled in an inflow direction, thereby positioning themselves between the radial outside of the native valve leaflets and the outflow track beyond the native valve annulus. As the support structure fully expands, the native valve leaflets remain trapped or engaged between the leaflet engaging portion and the body portion.

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Background/Summary

RELATED APPLICATIONS [0001] This application is a continuation of and claims priority to U.S. patent application Ser. No. 18/812,932 filed Aug. 22, 2024, entitled Prosthetic Heart Valve, Systems, And Methods, which is a continuation of and claims priority to International Application PCT/US2023/066708 filed May 5, 2023, entitled Prosthetic Heart Valve, Systems, And Methods, which claims benefit of and priority to U.S. Provisional Application Ser. No. 63/364,248 filed May 5, 2022 entitled Valve and Valve Docking System, U.S. Provisional Application Ser. No. 63/366,001 filed Jun. 7, 2022 entitled Heart Valve and Valve Docking System, and U.S. Provisional Application Ser. No. 63/383,335 filed Nov. 11, 2022 entitled Valve and Valve Docking System, all of which are hereby incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION
[0002] Heart valve disease is a common condition affecting millions of people worldwide. The heart has four valves, which regulate blood flow by opening and closing during each heartbeat. When these valves become damaged or diseased, they may not function properly, leading to a variety of symptoms such as shortness of breath, fatigue, and chest pain. In severe cases, heart valve disease can lead to heart failure or even death.
[0003] Traditional treatment for heart valve disease involves surgical replacement of the affected valve with a prosthetic valve. While this procedure is effective, it is invasive and requires a significant recovery period. Additionally, some patients may not be eligible for surgery due to other health conditions.
[0004] In recent years, there has been growing interest in minimally invasive techniques for heart valve replacement, such as Transcatheter Aortic Valve Replacement (TAVR). This technique involves inserting a collapsible valve into the heart through a catheter, typically inserted into the femoral artery. The valve is then deployed within the damaged valve, replacing it and restoring normal blood flow.
[0005] More recently, there has been a growing interest in using this technique for the replacement of the mitral and tricuspid valves, known as Transcatheter Mitral Valve Replacement (TMVR) and Transcatheter Tricuspid Valve Replacement (TTVR), respectively. These valves are more complex than the aortic valve, and their replacement using traditional surgical techniques can be challenging. TMVR and TTVR offer a less invasive option for patients with mitral or tricuspid valve disease, who may not be eligible for traditional surgical valve replacement.
[0006] TMVR and TTVR require specialized devices, which are designed to fit within the unique shape of the mitral or tricuspid valve. These devices are typically made of biocompatible materials and are designed to be deployed through a catheter, similar to the TAVR procedure.
[0007] Overall, TMVR and TTVR offer a promising new option for patients with mitral or tricuspid valve disease, who may not be eligible for traditional surgical valve replacement. As with any new medical technology, there are still many challenges to be addressed, including device design, patient selection, and long-term outcomes. However, the potential benefits of these techniques make them an exciting area of research and development in the field of cardiology.

SUMMARY OF THE INVENTION

[0008] Prosthetic valve support structures of this specification include a body portion, an atrial flange portion, and a leaflet engaging portion. As the support structure (and the valve as a whole) is pushed out of or otherwise unrestrained from a delivery device, the free end(s) of the leaflet engaging portion will begin to bend radially outward or away from the body portion and will continue bending as more is exposed until its free end(s) are angled in an inflow direction, thereby positioning themselves between the radial outside of the native valve leaflets and the outflow track beyond the native valve annulus. As the support structure fully expands, the native valve leaflets remain trapped or engaged between the leaflet engaging portion and the body portion.

[0009] In some aspects, the techniques described herein relate to a prosthetic heart valve, including: a body portion having a generally cylindrical shape; an atrial flange portion extending radially outward from an inflow end of the body portion and forming a plurality of petal shapes annularly around the body portion; and, a leaflet engaging portion including a plurality of engagement struts connected at an outflow end of the body portion and extending in an inflow direction along an outside of the body portion.

[0010] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the body portion includes a plurality of elongated vertical body struts that alternate in axial positions relative to each other.

[0011] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the body portion includes a plurality of horizontal body struts forming a “V” shape or angle and that are each connected to two of the plurality of vertical body struts.

[0012] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the body portion has a length within an inclusive range of about 14 mm to about 18 mm, and has a radius within an inclusive range of about 27 mm to about 30 mm.

[0013] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the atrial flange portion includes a plurality of upper radial flange struts and a plurality of lower radial flange struts that each extend from the body portion; wherein the upper radial flange struts are positioned further toward an inflow end of the prosthetic heart valve than the lower radial flange struts.

[0014] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the atrial flange portion includes a plurality of radial flange struts; wherein the upper portion of the radial flange struts are connected to the atrial flange portion and the lower portion of the radial flange struts are not connected to the atrial flange portion and angled toward an outflow end of the prosthetic heart valve.

[0015] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the plurality of upper radial flange struts and the plurality of lower radial flange struts each have: a first angle within an inclusive range of about 90 degrees and 130 degrees, a relative straight portion with a length within an inclusive range of about 3 mm and about 10 mm, a second angle within an inclusive range of about 20 degrees and about 150 degrees, and a terminal portion with a length within an inclusive range of about 1 mm and 7 mm.

[0016] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein outer ends of the plurality of upper radial flange struts and the plurality of lower radial flange struts are connected to each other via one of a plurality of circumferential radial struts that form petal shapes that accommodate a position difference between the plurality of upper radial flange struts and the plurality of lower radial flange struts.

[0017] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the plurality of engagement struts form a first curve which curves around to about 180 degrees, a first straight portion with a length within an inclusive range of about 3 mm and about 10 mm, a second curve curving in an opposite direction of curve within an inclusive range of about 90 degrees to about 150 degrees, a rounded portion with a length within an inclusive range of about 2

mm to about 10 mm.
[0018] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein an end region of the plurality of engagement struts are positioned axially between the plurality of lower radial flange struts and the plurality of lower radial flange struts.
[0019] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the end region of the plurality of engagement struts are positioned to axially overlap the plurality of lower radial flange struts at radially adjacent position within an inclusive range of about 0.1 mm and about 10 mm.
[0020] In some aspects, the techniques described herein relate to a prosthetic heart valve, further including a material covering disposed over a framework, wherein the material covering forms one or more triangular gaps along an inflow edge of the body portion.
[0021] In some aspects, the techniques described herein relate to a prosthetic heart valve, including: a valve framework having an expanded configuration including: a cylindrical body portion, a plurality of radial struts extending radially from a first end of the cylindrical body portion; and, a plurality of engagement struts connected near a second end of the cylindrical body portion and positioned along an outer side of the cylindrical body portion extending toward the first end; wherein end regions of the plurality of engagement struts extend beyond at least some of the plurality of radial struts.
[0022] In some aspects, the techniques described herein relate to a prosthetic heart valve, including: a valve framework having a cylindrical body portion and a leaflet engaging portion connected at a distal region of the body portion; wherein the leaflet engaging portion includes a plurality of engagement struts that extend distally from the body portion when the framework is in a compressed configuration within a delivery device and wherein the plurality of engagement struts bend proximally backward along an outside of the body portion when the framework is in an expanded configuration.
[0023] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the valve framework further includes a plurality of radial struts extending radially out from a proximal region of the body portion.
[0024] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein end regions of the plurality of engagement struts are positioned proximally beyond some of the plurality of radial struts.
[0025] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the plurality of radial struts include a first set of radial struts and a second set of radial struts, wherein the first set of radial struts are positioned proximally of the second set of radial struts.
[0026] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the end regions of the plurality of engagement struts are position proximally beyond the first set of radial struts and distally of the second set of radial struts.
[0027] In some aspects, the techniques described herein relate to a prosthetic heart valve, wherein the plurality of engagement struts form a first curve which curves around to about 180 degrees, a first straight portion with a length within an inclusive range of about 3 mm and about 10 mm, a second curve curving in an opposite direction of curve within an inclusive range of about 90 degrees to about 150 degrees, a rounded portion with a length within an inclusive range of about 2 mm to about 10 mm.
[0028] In some aspects, the techniques described herein relate to a method of delivering a prosthetic heart valve, including: advancing a delivery device in proximity of a native valve, the delivery device including a prosthetic valve having a framework; exposing distal end of the framework including a distal end of a cylindrical body portion and a plurality of leaflet engagement struts connected near the distal end of the cylindrical body portion; allowing the leaflet engagement struts to bend towards a proximal end of the cylindrical body portion and position native leaflets of the native valve between the leaflet engagement struts and the cylindrical body portion; and,

completely releasing a remaining portion of the framework within the delivery device.
[0029] In some aspects, the techniques described herein relate to a prosthetic heart valve, including: a body portion having a generally cylindrical shape; an atrial flange portion extending radially and annularly outward from an inflow end of the body portion; and, a leaflet engaging portion; wherein the atrial flange portion and the leaflet engaging portion are configured to axially overlap each other at radially adjacent position within an inclusive range of about 0.1 mm and about 10 mm.
[0030] In some aspects, the techniques described herein relate to a prosthetic heart valve, including: a body portion having a generally cylindrical shape; an intra-annulus sealing portion including a plurality of struts positioned radially outside of the body portion and configured to engage an interior of a native valve annulus; and, a leaflet engaging portion including a plurality of engagement struts connected at an outflow end of the body portion and extending in an inflow direction along an outside of the body portion.
[0031] In some aspects, the techniques described herein relate to a prosthetic heart valve, further including an atrial flange portion extending radially outward from an inflow end of the body portion; and wherein the intra-annulus sealing portion extends distally from the atrial flange portion.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0032] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which
[0033] FIG. **1** is a perspective view of a prosthetic heart valve support structure.
[0034] FIG. **2** is a cross-sectional view of the prosthetic heart valve support structure of FIG. **1**.
[0035] FIG. **3** is a top view of a framework of the prosthetic heart valve support structure of FIG. **1**.
[0036] FIG. **4** is a side view of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0037] FIG. **5** is a side view of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0038] FIG. **6** is a perspective view of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0039] FIG. **7** is a perspective view of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0040] FIG. **8** is a strut of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0041] FIG. **9** is a strut of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0042] FIG. **10** is a compressed view of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0043] FIG. **11** is a partially compressed view of the framework of the prosthetic heart valve support structure of FIG. **1**.
[0044] FIG. **12** is a view of the framework of the prosthetic heart valve support structure of FIG. **1** after deployment.
[0045] FIG. **13** is a view of the framework of the prosthetic heart valve support structure of FIG. **1** within a native valve.
[0046] FIG. **14** is a view of the framework of the prosthetic heart valve support structure of FIG. **1** within a native valve.
[0047] FIG. **15** is a view of framework of the prosthetic heart valve support structure of FIG. **1** within a native valve.
[0048] FIG. **16** is a perspective view of a prosthetic heart valve.

[0049] FIG. **17** is a side view of the prosthetic heart valve of FIG. **16**.
[0050] FIG. **18** is a side view of the prosthetic heart valve of FIG. **16**.
[0051] FIG. **19** is enlarged cross-sectional view of the prosthetic heart valve of FIG. **16**.
[0052] FIG. **20** is enlarged cross-sectional view of the prosthetic heart valve of FIG. **16**.
[0053] FIG. **21** is enlarged cross-sectional view of the prosthetic heart valve of FIG. **16**.
[0054] FIG. **22** is enlarged cross-sectional view of the prosthetic heart valve of FIG. **16**.
[0055] FIG. **23** is a perspective view of a prosthetic heart valve.
[0056] FIG. **24** is a view of the prosthetic heart valve of FIG. **23**.
[0057] FIG. **25** is a side view of the prosthetic heart valve of FIG. **23**.
[0058] FIG. **26** is a bottom view of the prosthetic heart valve of FIG. **3**.
[0059] FIG. **27** is a top view of the prosthetic heart valve of FIG. **23**.
[0060] FIG. **28** is a cross-sectional view of the prosthetic heart valve of FIG. **23**.
[0061] FIG. **29** is a cross-sectional view of the prosthetic heart valve of FIG. **23**.
[0062] FIG. **30** is an enlarged view of the prosthetic heart valve of FIG. **23**.
[0063] FIG. **31** is an enlarged view of the prosthetic heart valve of FIG. **23**.
[0064] FIG. **32** is an enlarged view of the prosthetic heart valve of FIG. **23**.
[0065] FIG. **33** is an enlarged view of the prosthetic heart valve of FIG. **23**.
[0066] FIG. **34** is a perspective view of a framework of the prosthetic heart valve of FIG. **23**.
[0067] FIG. **35** is a side view of a framework of the prosthetic heart valve of FIG. **23**.
[0068] FIG. **36** is a side view of a framework of the prosthetic heart valve of FIG. **23**.
[0069] FIG. **37** is a top view of a framework of the prosthetic heart valve of FIG. **3**.
[0070] FIG. **38** is a bottom view of a framework of the prosthetic heart valve of FIG. **23**.
[0071] FIG. **39** is an enlarged view of a framework of the prosthetic heart valve of FIG. **23**.
[0072] FIG. **40** is an enlarged view of a framework of the prosthetic heart valve of FIG. **23**.
[0073] FIG. **41** is an enlarged view of a framework of the prosthetic heart valve of FIG. **23**.
[0074] FIG. **42** is an enlarged view of a framework of the prosthetic heart valve of FIG. **23**.
[0075] FIG. **43** is an enlarged view of a framework of the prosthetic heart valve of FIG. **23**.
[0076] FIG. **44** is a cross-sectional view of a framework of the prosthetic heart valve of FIG. **23**.
[0077] FIG. **45** is a simplified line view of several components of the prosthetic heart valve of FIG. **23**.
[0078] FIG. **46** is a view of the prosthetic heart valve of FIG. **23** with valve leaflets.
[0079] FIG. **47** is a side view of the prosthetic heart valve of FIG. **23** in a native heart valve.
[0080] FIG. **48** is a side view of the prosthetic heart valve of **3**. **23** in a native heart valve.
[0081] FIG. **49** is a side view of the prosthetic heart valve of FIG. **23** in a native heart valve.

DETAILED DESCRIPTION

[0082] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0083] While different embodiments may be described in this specification, it is specifically contemplated that any of the features from different embodiments can be combined together in any combination. In other words, the features of different embodiments can be mixed and matched with each other. Hence, while every permutation of features from different embodiments may not be explicitly shown, it is the intention of this specification to cover any such combinations.

[0084] The present specification is generally directed to prosthetic or artificial heart valves. These heart valves may be used to replace any of the native heart valves (e.g., aortic valve, mitral valve, pulmonary valve, or tricuspid valve), however, the artificial heart valves of this specification may

be particularly useful for replacing a mitral or tricuspid valve.
[0085] Generally, the present artificial heart valves include a support structure that supports artificial valve leaflets or similar mechanisms that allow blood to generally flow in only one direction through the artificial heart valve. This specification focuses mostly on aspects of the support structure and therefore the figures may not all disclose artificial leaflets or similar structures therein. However, it should be understood that the use of leaflets and similar structures with the support structures are specifically contemplated. In other words, while much of this disclosure may focus on aspects of artificial valve support structures, the artificial valve as a whole is specifically included as part of the present invention.
[0086] When referring to the artificial valves and support structures in this specification, the terms "top end," "inflow end," and similar variants may be used interchangeably to mean an end of the device through which blood normally first enters the valve/device. For example, referring to a tricuspid valve, the end of the device in or closes to the right atrium. The terms "bottom end," "outflow end," and similar variants may be used interchangeably to mean an end of the device through which blood normally exits the valve/device. For example, referring to a tricuspid valve, the end of the device in or closes to the right ventricle. In addition, the artificial valves and support structures in this specification may be referred to as having proximal ends/portions and distal ends/portions in the context of a delivery device/catheter. Typically, the term proximal indicates a portion or direction along the delivery device closer to the physician and distal indicates a portion or direction along or away from the delivery device in the opposite direction of the physician. In some of the examples described in this specification, the top or inflow end of the support structure may also be the proximal end, and the bottom or outflow end of the support structure may also be the distal end.
[0087] Generally, some of the artificial valve support structures of this specification include a body portion, an atrial flange portion, and a leaflet engaging portion. These features may take on different shapes, depending on whether the support structures are in a radially compressed configuration for deployment or a radially expanded configuration after deployment.
[0088] When the support structure is in its expanded configuration, the body portion may have a generally cylindrical shape with a passage extending between an inflow end and an outflow end. Alternatively, the body portion may have a generally concave, convex, or funnel shape, or may have a middle region with an increased or decreased diameter relative to the ends (e.g., hourglass shape or "bulging middle"). Typically, artificial leaflets or similar valve structures are fixed, mounted, or connected within the passage, such as at the middle or at either end of the passage. These artificial leaflets or similar valve structures can be tied to the body portion, connected with adhesive, or connected by similar means.
[0089] In the expanded configuration of the support structure, the atrial flange portion is a flange, lip, projection, or overhang that forms a generally annular region that extends radially outward from an inflow end of the body portion. The atrial flange portion may help seal around an inflow end of the device with the annulus of the native valve being replaced, thereby preventing blood from circumventing the passage of the body portion. In that respect, it may be desirable for the atrial flange portion to conform to the shape of the annulus of the valve. The atrial flange may extend completely and continuously around the entire circumference of the body portion or may only extend partially around the circumference of the body portion (e.g., two or more segments or a plurality of struts).
[0090] In the expanded configuration of the support structure, the atrial flange portion may be relatively flat or may have one or more curved surfaces. Additionally or alternatively, the flange may be generally perpendicular to an axis of the body portion or may radially extend at any angle 0 and 180 degrees relative to said axis. In one example, the atrial flange has an initial angle of about 110 degrees (plus or minus 10 degrees) bending slightly towards the direction of the annulus and then further bends upward (e.g., away from the annulus) to conform to the walls of the atrium. In

some instances, it may be helpful for the atrial flange to generally conform to a top or inflow surface of a valve annulus (e.g., mitral or tricuspid valve annulus), as well as sidewalls of the surrounding atrium. Hence, depending on the length of the atrial flange, it may be helpful for the end region of the atrial flange to bend or be angled such that its edges are direction generally in an inflow direction similar to the walls of the right/left atrium (e.g., a similar angle to the longitudinal axis of the body portion).

[0091] In the expanded configuration of the support structure, the leaflet engaging portion may be positioned radially around the outside of the body portion in a manner to capture the native valve leaflets of the patient between the leaflet engaging portion and the body portion of the support structure. In one example, the leaflet engaging portion may be a plurality of struts and/or may be a continuous radial member. The leaflet engaging portion may further be connected to the body portion at or near an outflow end of the body portion and extend towards the inflow end of the body when the support structure is in its fully expanded configuration. The leaflet engaging portion may include one or more curved regions, such as a curved region near the free end(s) of the leaflet engaging portion that curves radially outward so as to engage an outflow surface of a native annulus of a native heart valve. Additionally or alternatively, the leaflet engaging portion may include one or more curves that position at least a portion of the leaflet engaging structure closer to or in contact with the body portion to help pinch or engage the native valve leaflets. Alternatively, the leaflet engaging portion may be spaced with a gap (e.g., uniform or non-uniform) with the body portion.

[0092] In the compressed configuration of the support structure, the body portion may be radially or diametrically compressed. The atrial flange may also be radially compressed and may further be **1**) folded proximally or in an inflow direction such that its free end(s) are positioned further away from the body portion, or 2) may be folded distally or in an outflow direction such that the atrial flange is pressed against the body portion. The leaflet engaging portion may be 1) folded distally or in an outflow direction such that its free end(s) are positioned further away from the body portion, or 2) may be folded proximally or in an inflow direction such that the leaflet engaging portion is pressed against the body portion.

[0093] In some examples, it can be helpful to have the leaflet engaging portion folded distally in a delivery device in its compressed configuration such that its free end(s) are positioned away from the body portion. As the support structure (and the valve as a whole) is pushed out of or otherwise unrestrained from a delivery device, the free end(s) of the leaflet engaging portion will exit and be exposed first. As the free end(s) are further exposed, they will begin to bend radially outward or away from the body portion. If positioned beyond the native leaflets of the valve, the leaflet engaging portion will continue bending as more is exposed until its free end(s) are angled in an inflow direction, thereby positioning themselves between the radial outside of the native valve leaflets and the outflow track beyond the native valve annulus. As the support structure fully expands, the native valve leaflets remain trapped or engaged between the leaflet engaging portion and the body portion. This functionality should be understood to also be a method of deployment of the support structure.

[0094] In some examples, it can be helpful to construct the support structure such that in its expanded configuration, the end(s) of the leaflet engaging portion and the atrial flange portion each contact and therefore pinch or engage each side of the native valve annulus (or nearby tissue). This may help provide a better seal to the atrial flange portion to prevent blood from bypassing the artificial valve or creating a paravalvular leak. This may also help maintain the artificial valve in its intended position within a patient's heart.

[0095] In some examples, it can be helpful to construct the support structure such that in its expanded configuration, the end(s) of the leaflet engaging portion are positioned at a more proximal location or further in an inflow direction than at least some radially-adjacent portions (e.g., struts) of the atrial flange portion. When these portions are viewed from a side perspective,

they overlap each other with regard to the axial position of their ends. This may be particularly helpful in two respects. First, this arrangement forces the leaflets and the annulus to be positioned over the leaflet engaging portion and then below the lower portion flange (e.g., lower radial strut), forcing the leaflets/annulus into an alternating or wave-like shape. Hence, the leaflet engaging portion and the atrial flange portion tend to pinch the leaflets/annulus and create a paperclip effect. Second, this arrangement may hold the material covering on the underside of the atrial flange portion taut around the top of the leaflet engaging portion so that there is good contact between the material covering and the leaflets/annulus to promote sealing, healing, and possibly tissue in-growth.

[0096] The support structure may have different approaches to its construction. In one example, the support structure comprises an underlying framework and a material covering placed onto or over part or all of the framework.

[0097] The framework may be composed of a shape memory material which has a specific shape imparted to it and which it returns to after being constrained. Example shape memory materials include Nitinol and similar alloys.

[0098] The framework may be composed of an entire single unitary framework. For example, the framework may be created from a shape memory tube (e.g., Nitinol) that is laser cut and then heat set to its desired expanded shape. Alternatively, a plurality of shape memory struts/shapes may be welded or otherwise connected together and then the desired expanded shape imparted to the connected struts/shapes.

[0099] The framework may also be composed of separate components that are connected to each other, either by welding, tying, adhesive, or via each component being separately connected to the material covering (i.e., the material covering interconnects the components). For example, the body portion, the atrial flange portion, and the leaflet engaging portion may all be separate components (e.g., welded together or connected via the material covering).

[0100] Some components of the framework may be composed of different types and structures material. For example, the body portion may be composed of a plurality of braided shape memory wires while the atrial flange portion and the leaflet engaging portion may be composed of non-braided shape memory struts/shapes (e.g., laser cut Nitinol components). In another example, the body portion and the leaflet engaging portion may be composed of non-braided shape memory struts/shapes (e.g., laser cut Nitinol components) and the atrial flange portion may be composed of a flexible polymer or similar material (e.g., silicone, PET, EPTFE etc.).

[0101] The framework may have different thicknesses in different areas (i.e., not only different lengths and widths, but thickness of the framework material itself). For example, the atrial flange portion may have a larger thickness than the body portion. In another example, the leaflet engaging portion may have a larger thickness than the body portion.

[0102] Certain components of the framework may be composed of elongated arms or struts without the material covering located on them. For example, the leaflet engaging portion may be composed of a plurality of struts positioned and connected at circumferential locations around the body portion. These locations can be either uniformly spaced or non-uniformly spaced only in certain areas. However, these arms or struts may have a coating and/or caps on their distal end. For example, the arms or struts may have a flexible coating that helps frictionally engage the leaflets and an end cap on the free ends of the arms/struts that is also composed of a flexible material to help minimize tissue damage during deployment and chronic implantation. Such a coating/cap may be composed of pericardial tissue, EPTFE, textile material, PET, polyurethane, silicone, and similar materials. The elongated arms or struts may all have the same length or may have different lengths, such as alternating between longer and shorter lengths.

[0103] The material covering may be connected to or otherwise positioned on part or all of the framework. Additionally or alternatively, the material covering may be disposed on only the inside of the framework, only the outside of the framework, or on both the inside and outside of the

framework. In one example, the material covering is positioned on the body portion and the atrial flange portion, but not on the leaflet engaging portion. In another example, the material covering is positioned only on the atrial flange portion. In another example, the material covering is positioned only on the body portion. Additionally or alternatively, the material may create openings or other shapes (e.g., triangular edges) against the framework.

[0104] The material covering may be composed of a biocompatible, flexible material. The material covering may be a solid, non-porous sheet (e.g., a polymer sheet) or a woven fabric. Example materials include textile material, EPTFE sheets, PET sheets, Silicone, polyurethane, similar materials, or derivatives thereof. This material covering may also be configured, at least in certain areas, to encourage ingrowth of tissue.

[0105] The valve leaflets may be connected to the body portion, such as near the middle or near either end of the body portion. Generally, the valve leaflets are configured to open to allow blood flow from the inflow end (e.g., from the left/right atrium) and remain closed against blood pressure from the outflow end (e.g., from the left/right ventricle). The valve component may include one, two or three leaflets. The valve leaflets may be individually attached to the support structure or may all be attached to each other into a valve assembly that is then attached to the support structure. The valve leaflets may be attached to the body portion in a normally open or a normally closed position. The shape of the valve leaflets is such that the leaflets take a natural cusp like shape similar to a native aortic valve. or similar valve. This shape along with the covering material of the body structure can create a sinus like shape similar to a valve sinus to allow for favorable flow conditions and beneficial blood flow washout to prevent stasis locations and thrombus formation. The valve leaflets may be attached to the valve body in a configuration to allow for an amount of overlap or coaptation at the free edge with a range of 0 to 20 mm. There may be an intentional gap in the valve leaflet coaptation to allow for a small amount of blood to leak through the valve so as to not over pressure the heart after the new valve is in place. The valve leaflets may be composed of an artificial material or from natural biological material. The valve leaflets may be processed using anti-calcification and tissue fixation processes to prevent the human body from rejecting the implanted device and to also prevent leaflet calcification. The tissue may be processed in a condition that allows for the valve prosthesis to be stored and sterilized in glutaraldehyde or in dry storage after other means of sterilization such as ETO. The tissue can also be processed with or coated with antithrombotic chemicals or coatings.

[0106] The support structure may also include features that allow engagement with a delivery device to assist in deployment of the support structure. Additionally or alternatively, features may be included that allow the support structure to be recaptured after at least partial deployment from the delivery device. For example, the support structure may include one or more apertures or enlargements, such as on its framework, that are releasably engaged with portions of the delivery device. The apertures or enlargements may be included at or near the proximal or inflow end of the support structure when in its compressed configuration. For example, the apertures or enlargements may be located at locations at the edge of the atrial flange portion and/or at locations near the end of the body portion. The delivery device may include a breakable thread that passes through/around the apertures/enlargements, depressions in an inner pusher that capture the apertures/enlargements, hooks, posts, loops, stent-like mesh, or similar mechanisms such that a physician may advance, retract, and/or release the support structure from the delivery device.

[0107] Any of the support structures in this specification may be delivered from one of several known heart valve delivery devices. For example, the devices in U.S. Pub. No. 2017/0165064, 2019/0008640, and 2022/0287836, the content of which is hereby incorporated by reference.

[0108] FIGS. **1**-**13** illustrate various aspects of one example of a support structure **100** of an artificial valve in its expanded configuration. As seen best in FIGS. **1** and **2**, the support structure **100** generally includes a body portion **110**, an atrial flange portion **106**, and a leaflet engaging portion **108**.

[0109] In the present example, the body portion **110** has a generally cylindrical shape, though other shapes are possible, such as an hourglass shape, a conical shape, a concave shape, or a convex shape.
[0110] In the present example, the atrial flange portion **106** extends radially outward from a top end or an inflow end of the body portion **110**. The atrial flange portion **106** may form a complete circular or annular shape beyond that of the body portion **110**, though it may alternatively have other shapes such as an oval shape and may only extend around a portion of the circumference of the body portion **110** (e.g., flange regions on only opposite sides of each other).
[0111] In the present example, the atrial flange **106** may have at least two regions having different angles relative to each other, as best seen in the cross-sectional view of FIG. **2**. A first region initially extends radially away from the inflow end of the body portion **110**. Relative to an axis extending through the inner passage of the support structure, the first region may have an angle within an inclusive range of about 70 degrees and 140 degrees (e.g., about 110 degrees). A second region radially extends from the first region and has an angle within an inclusive range of **120** degrees and 170 degrees (e.g., about 160 degrees). Generally, these two regions of the atrial flange portion **106** may help it conform to the top/inflow surface of the native valve annulus, as well walls or other areas of the atrium.
[0112] In the present example, the leaflet engagement portion **108** may comprise a plurality of engagement struts **114** that are connected at an outflow end of the body portion **110** and extend in an inflow or upward direction. As will be described in further detail later, the engagement struts **114** curve towards the body portion **110** and then away from the body portion **110**, terminating with a cap member **120**. The initial curve towards the body portion **110** may help pinch or engage the native leaflets with the body portion **110**. The cap **120** may comprise a flexible or relatively softer material (e.g., pericardial tissue, EPTFE, PET, textile materials, silicone, polyurethane, or similar materials) to help prevent damage to the patient's heart tissue. The cap may be adhered to or otherwise connected to the very distal end of the engagement strut **114**.
[0113] In the present example, the engagement struts **114** are positioned at equal distances from each other around the circumference of the body portion **110**. Again, non-uniform positioning of these struts **114** is also possible, such as only on opposite sides of the body portion **110** or in locations that may help avoid chordae within the ventricle.
[0114] The support structure **100** in the present example includes a rigid framework **102** and a material covering **104** that is disposed over portions of the framework **102**. The material covering **104** is positioned over all or most of an outside of the body portion **110** of the framework **102**, over an outside of the atrial flange portion **106** of the framework **102**, and around on an inner side of the atrial flange portion **106** of the framework **102**. The engagement struts **114** are generally left uncovered by the material covering **104**. As previously described, other variations are also possible, such as locating the material covering on only the inside, only the outside, and/or on any combination of the portions **106**, **108**, **110**.
[0115] In the present example, the material covering **104** may be attached by adhesive, stitches, combinations thereof, and similar mechanisms. The material covering **104** may be composed of textile material, EPTFE sheets, PET sheets, and similar materials discussed elsewhere in this specification. In addition to the material covering **104**, additional materials may be included on an underside of the atrial flange **106** to help create a better seal with the native valve annulus, such as hydrogel.
[0116] FIGS. **3-9** illustrate various aspects of the framework **102** in the present example. The body portion **110** of the framework **102** is composed of a plurality of elongated vertical body struts **116**B and a plurality of horizontal body struts **116**A. The vertical body struts **116**B are generally parallel to an axis through the support structure's passage (i.e., an axis from the inflow end to the outflow end), while the horizontal body struts **116**A are positioned around this axis in a circular shape.
[0117] The horizontal body struts **116**A may form a “V” shape or a relatively sharp angle pointing

towards the outflow direction, though the opposite direction is also possible. Each end of a horizontal body strut **116**A connects to a vertical body strut **116**B. The "V" shape of the horizontal body strut **116**A provides a bend point at the apex of its "V" to increase and decrease its angle depending on whether the support structure **100** is in its compressed configuration or expanded configuration. In other words, the "V" shape facilitates this radial compression and expansion. Alternatively, other shapes with angles in them may also be possible for the horizontal body structure **116**A, such as a "W" shape with two or more angles. In the present example, there are two rows of horizontal body struts **116**A, though more rows are possible.

[0118] In one example, the body portion **110** of the framework **102** has a length within an inclusive range of about 14 mm to about 18 mm, and has a diameter within an inclusive range of about 27 mm to about 30 mm.

[0119] The atrial flange portion **106** of the framework **102** includes a plurality of flange struts **112**. The shape of these flange struts **112** can be best seen in FIG. **8**. Each flange strut **112** extends from one of the vertical body struts **116**B and forms a first angle **112**A within an inclusive range of about 90 degrees and 130 degrees, a relative straight portion **112**B with a length within an inclusive range of about 3 mm and about 10 mm, a second angle **112**C within an inclusive range of about 20 degrees and about 150 degrees, and a terminal portion **112**D with a length within an inclusive range of about 1 mm and 7 mm (again, angles relative to an inflow/outflow oriented axis of the support structure **100**). Generally, the specific angles and sizes may vary somewhat depending on the heart and valve size of the patient.

[0120] The leaflet engaging portion **108** of the framework **102** includes a plurality of engagement struts **114**, the shape of which can be best seen best in FIG. **9**. The leaflet engaging struts **114** are connected to the outflow end of the vertical body struts **116**B. From the vertical body strut **116**B, the engagement strut forms a first curve **114**E which curves around beyond **180** degrees (e.g., an inclusive range of about 150 degrees to about 230 degrees), a first straight portion **114**D with a length within an inclusive range of about 3 mm and about 10 mm, a second curve **114**C curving in an opposite direction of curve **114**D within an inclusive range of about 90 degrees to about 150 degrees, a second straight portion **114**B with a length within an inclusive range of about 2 mm to about 10 mm, and finally a third curve **114**A in the same direction as the second curve **114**C and within an inclusive range of about 60 degrees and about 150 degrees. While these curves all generally occur in the same plane, it is possible to include additional curves that may take some of the engagement struts **114** out of a single plane (i.e., curving in multiple dimensions).

[0121] As previously discussed, the engagement struts **114** are not covered by the material covering **104** in the present example, but may be. Additionally, the engagement struts **114** may be coated or wrapped in a relatively softer material (e.g., a textile or EPTFE layer). Further, the ends of the engagement struts may include cap members **120** composed of similar materials or other materials described in this specification.

[0122] The framework **102** of the present example may be composed of a single unitary body, such as laser cut from a shape memory tube (e.g., Nitinol tube). Alternatively, one or more of the struts of the framework may be welded or otherwise attached to each other. Alternatively, some of the components may be separate from each other, only connected by other materials, such as the material covering **104** or other attachment mechanisms. For example, the body portion **110**, the leaflet engagement portion **108**, and/or the atrial flange portion **106** may not be directly attached to each other in any combination. If shape memory material is used for the framework **102**, the framework may be cut to a desired pattern and then heat set to impart a desired shape in its expanded configuration.

[0123] FIGS. **10-12** illustrate how the support structure **100** may deploy from a delivery catheter **50**. In FIG. **10**, the support structure **100** is illustrated mostly within with delivery catheter **50** (note, for clarity only the framework **102** is illustrated in this figure). As the support structure **100** begins to be pushed out, the free ends of the engagement struts **114** begin to radially expand outward.

[0124] In FIG. **11**, the support structure **100** has moved further distally out of the delivery catheter **50**. The distal or outflow end of the body portion **110** has radially expanded and the engagement struts **114** of the leaflet engagement portion **108** have completely escaped the delivery catheter **50** and have inverted themselves such that their free ends are now located towards a proximal or inflow end of the body portion **110**.
[0125] In FIG. **12**, the support structure is fully deployed to its expanded configuration. FIG. **13** illustrates the expanded configuration within a tricuspid valve **14**. As can be seen, the engagement struts **114** have been positioned around the leaflets **14**B so as to capture the leaflets **14**B against the body portion **110**. Additionally, it can be seen that the bottom of the atrial flange portion **106** contacts and engages a top portion of the valve annulus **14**A, while the angled free ends of the engagement struts engage a bottom portion of the valve annulus **14**A. Hence, the support structure **100** may better engage the annulus **14**A and keep the valve leaflets **14**B out of the way.
[0126] FIG. **14** illustrates one approach to delivering a support structure **100** within a tricuspid valve **14** of a heart **10** by advancing a delivery catheter through the inferior vena cava **16** and into the right atrium **18**, such that the support structure is delivered from an inflow or atrial end relative to the tricuspid valve **14**.
[0127] FIG. **15** illustrates another approach to delivering a support structure **100** with a mitral valve **12** by performing a transeptal procedure to allow the delivery catheter to pass through the septum between the right atrium **18** and the left atrium **20**. This allows the support structure to be delivered from an inflow or atrial end relative to the mitral valve **12**.
[0128] Additional approaches to delivering the support structure **100** are also possible. For example, either valve **14**, **20** may be approached from its respective ventricle (**22**, **24**). In such cases, the support structure may be arranged in an opposite orientation as shown in FIGS. **10-12**.
[0129] FIGS. **16-22** illustrate an embodiment of a framework **130** that is otherwise similar to the previously described framework **102**. However, the framework **130** further includes a strut **132** that connects to two adjacent flange struts **112** and forms a “V” shape downward towards an outflow end of the framework **130**. While this strut **132** may be considered part of the atrial flange portion **106**, it may be positioned within the annulus of the valve while portions of the flange struts **112** remain on a top or atrial surface of the annulus of the native valve. Hence, the atrial flange portion **106** of this embodiment may be further considered to have a top sealing portion (i.e., flange struts **112**) and an intra-annulus engaging/sealing portion (struts **132**). In that manner, the framework **130** may better seal the framework/valve to prevent blood leakage around the framework/valve.
[0130] As best seen in FIG. **20**, the strut **132** initially extends relatively horizontal from the flange strut **112** and then forms a first angle **132**A that may be within an inclusive range of about 135 degrees to about 180 degrees towards an outflow end of the framework **130**. The strut **132** may further have a straight region **132**B with a length in an inclusive range of about 3 mm to about 10 mm. Finally, the strut **132** forms a middle angle **132**C, opposite of the first angle **132**A within an inclusive range of about 90 degrees and about 120 degrees. The straight region **132**B and angle **132**A symmetrically repeat on the opposite side of the middle angle **132**C, thereby creating a generally “V” shape between two of each of the flange struts **112**.
[0131] As seen best in FIG. **21**, the “V” shaped strut **132** may be further angled generally straight/parallel to an axis of the framework **130** or may be angled such that the tip of the “V” shape, or angle **132**C, is positioned somewhat close to the body portion **110**. In other words, the strut **132** may angle radially inwards toward the outflow end of the framework. This may help the “V” shape of the strut **132** to fit into and engage the annulus of the native valve. In one example, the strut **132** is angled radially inward within a range of about 0 degrees to about 30 degrees.
[0132] FIGS. **23-33** illustrate various aspects of another example of a support structure **150** that is generally similar to the previously described support structure **100**, but includes several notable differences discussed further below. As seen best in FIG. **18**, the support structure **150** generally includes a body portion **110**, an atrial flange portion **106**, and a leaflet engaging portion **108**.

[0133] In the present example, the body portion **160** has a generally cylindrical shape, though other shapes are possible, such as an hourglass shape, a conical shape, a concave shape, or a convex shape.
[0134] In the present example, the atrial flange portion **156** extends radially outward from a top end or an inflow end of the body portion **160**. The atrial flange portion **156** may form a complete circular or annular shape beyond that of the body portion **160**, though it may alternatively have other shapes such as an oval shape and may only extend around a portion of the circumference of the body portion **160** (e.g., flange regions on only opposite sides of each other). As seen best in FIG. **23**, the atrial flange portion **156** also generally forms a plurality of petal shapes, pointed shapes, or outwardly narrowing shapes, such that the width of each of these areas decreases as the distance from the body portion **160** increases.
[0135] In the present example, the atrial flange **156** may have at least two regions having different angles relative to each other, as best seen in the cross-sectional view of FIG. **22**. A first region initially extends radially away from the inflow end of the body portion **160**. Relative to an axis extending through the inner passage of the support structure, the first region may have an angle within an inclusive range of about 70 degrees and 140 degrees (e.g., about 120 degrees). A second region radially extends from the first region and has an angle within an inclusive range of 150 degrees and 220 degrees (e.g., about 200 degrees). Generally, these two regions of the atrial flange portion **156** may help it conform to the top/inflow surface of the native valve annulus, as well walls or other areas of the atrium or leaflet/annulus.
[0136] In the present example, the leaflet engagement portion **158** may comprise a plurality of engagement struts **164** that are connected at an outflow end of the body portion **160** and extend in an inflow or upward direction. As will be described in further detail later, the engagement struts **164** curve generally parallel to the body portion **160** and then away from the body portion **160**, terminating with an enlargement **164**A (FIG. **23**). The initial curve towards the body portion **160** may help engage or capture the native leaflets with the body portion **160**. The enlargement **164**A may be generally rounded to prevent damage to a patient's valve tissue and may further include one or more apertures that may be optionally used to releasably engage the support structure **150** by a delivery catheter **50**.
[0137] In the present example, the engagement struts **164** are positioned at equal distances from each other around the circumference of the body portion **160**. Again, non-uniform positioning of these struts **164** is also possible, such as only on opposite sides of the body portion **160** or in locations that may help avoid chordae within the ventricle.
[0138] The support structure **150** in the present example includes a rigid framework **152** and a material covering **154** that is disposed over portions of the framework **152**. The material covering **154** is positioned over all or most of an inside and outside of the body portion **160** of the framework **152** (seen best in FIGS. **28** and **29**), and over an outside of the atrial flange portion **156** of the framework **152**. The engagement struts **164** are generally left uncovered by the material covering **154**. As previously described, other variations are also possible, such as locating the material covering **154** on only the inside, only the outside, and/or on any combination of the portions **156**, **158**, **160**.
[0139] As best seen in FIGS. **28** and **29**, the material covering **154** at the outflow end of the body portion **160** may form petals, pointed areas, or triangular areas **154**A that generally match the underlying shapes of the framework **152** of the body portion **160**. Alternatively, the outflow end of the body portion **160** may have a uniform circular-shaped edge.
[0140] Similarly, the edge of the material covering **154** at the inflow end of the body portion **160** may include one or more inset pointed or triangular gaps, spaces, or recesses **154**B. While the triangular areas **154**A are shown immediately adjacent to each other, the recesses **154**B may be less frequent between relatively uniform edge regions. However, the inflow edge or outflow edge may take on either of the disclosed patterns in any combination, as well as have a completely uniform

and perpendicular edge. As also seen in FIG. **23**, the material covering **154**C may also conform to the shape of the triangles or pointed petal shape of the atrial flange portion **156**.

[0141] In the present example, the material covering **154** may be attached by adhesive, stitches, combinations thereof, and similar mechanisms. The material covering **154** may be composed of textile material, EPTFE sheets, PET sheets, and similar materials discussed elsewhere in this specification. In addition to the material covering **154**, additional materials may be included on an underside of the atrial flange portion **156** to help create a better seal with the native valve annulus, such as hydrogel.

[0142] FIGS. **34-44** illustrate various aspects of the framework **152** in the present example. The body portion **160** of the framework **152** is composed of a plurality of elongated vertical body struts **166**B and a plurality of horizontal body struts **166**A (best seen in the cross-sectional view of FIG. **37**). The vertical body struts **166**B are generally parallel to an axis through the support structure's passage (i.e., an axis from the inflow end to the outflow end), while the horizontal body struts **166**A are positioned around this axis in a circular shape.

[0143] The vertical body struts **166**B may alternate between different heights or axial positions, such that a first vertical body strut **166**B has a first axial position and the two vertical body struts **166**B adjacent to the first is positioned further in an inflow direction relative to the adjacent two. Hence, the vertical body struts **166**B may form an alternating pattern.

[0144] The horizontal body struts **166**A may form a “V” shape or a relatively sharp angle pointing towards the outflow direction, though the opposite direction is also possible. Each end of a horizontal body strut **166**A connects to a vertical body strut **166**B, as well as a vertical body strut **166**B passes directly through the middle of the “V” shape. The “V” shape of the horizontal body strut **166**A provides a bend point at the apex of its “V” to increase and decrease its angle depending on whether the support structure **150** is in its compressed configuration or expanded configuration. In other words, the “V” shape facilitates this radial compression and expansion. Alternatively, other shapes with angles in them may also be possible for the horizontal body structure **166**A, such as a “W” shape with two or more angles. In the present example, there are two rows of horizontal body struts **166**A, though more rows are possible.

[0145] In one example, the body portion **160** of the framework **152** has a length within an inclusive range of about 14 mm to about 18 mm, and has a radius within an inclusive range of about 27 mm to about 30 mm.

[0146] The atrial flange portion **156** of the framework **152** includes a plurality of flange struts **162**. The shape of these flange struts **162** can be best seen in FIGS. **38-46**. The atrial flange portion **156** alternates with an upper radial strut **162**C and a lower radial strut **162**D. Both struts **162**C, **162**D each extend from a vertical body strut **166**B. While both struts **162**C, **162**D may have similar shapes/size/curvature, the upper radial struts **162**C are generally higher (i.e., further in an inflow direction) than lower radial struts **162**D, due to the higher and lower positions of the vertical body struts **166**B (e.g., due to the “V” shape/position of the horizontal body struts **166**A). In the present example, an aperture portion **166**C is located adjacent to the vertical body strut **166**A and the upper radial strut **162**. This aperture portion **166**C may be optionally included for use with a delivery catheter **50**.

[0147] As seen in FIG. **33**, each upper radial flange strut **162**C forms a first angle **162**E within an inclusive range of about 90 degrees and 130 degrees, a relative straight portion **162**F with a length within an inclusive range of about 3 mm and about 10 mm, a second angle **162**G within an inclusive range of about 20 degrees and about 150 degrees, and a terminal portion **162**A with a length within an inclusive range of about 1 mm and 7 mm (again, angles relative to an inflow/outflow oriented axis of the support structure **150**). Generally, the specific angles and sizes may vary somewhat depending on the heart and valve size of the patient. The terminal portion **162**A may optionally include an aperture that can be used by a delivery catheter **50** to help releasably retain the support structure **150** during deployment.

[0148] As seen in FIG. **40**, each lower radial flange strut **162**D forms a first angle **162**H within an inclusive range of about 90 degrees and 150 degrees, a relative straight portion **1621** with a length within an inclusive range of about 0 mm and about 5 mm, a second angle **162**J within an inclusive range of about 0 degrees and about 60 degrees, and a terminal portion **162**K with a length within an inclusive range of about 1 mm and 7 mm (again, angles relative to an inflow/outflow oriented axis of the support structure **150**). Generally, the specific angles and sizes may vary somewhat depending on the heart and valve size of the patient. The terminal portion **162**K may optionally include an aperture that can be used by a delivery catheter **50** to help releasably retain the support structure **150** during deployment.
[0149] The radially outer ends of each upper radial strut **162**C and lower radial strut **162**D are connected to each other via one of a plurality of circumferential radial struts **162**B. Since the upper radial strut **162**C and lower radial strut **162**D are located at different heights and distances from each other, the circumferential radial struts **162**B tend to form relatively triangular or petal shapes that terminate with terminal portion **162**A. Hence, the circumferential radial struts **162**B may curve in several dimensions to accommodate the upper radial strut **162**C and lower radial strut **162**D position difference.
[0150] The leaflet engaging portion **158** of the framework **152** includes a plurality of engagement struts **164**, the shape of which can be best seen best in FIG. **39**. Generally the engagement struts **164** have a straight portion **164**B that is parallel to an axis through the support structure's passage (i.e., an axis from the inflow end to the outflow end). In other words, the engagement strut **164** does not angle towards the body portion **160** like the prior support structure **100**, though such a configuration is possible. The engaging struts **164** are connected to the outflow end of the vertical body struts **166**B. From the vertical body strut **166**B, the engagement strut **164** forms a first curve **164**C which curves around to about 180 degrees (e.g., an inclusive range of about 150 degrees to about 230 degrees), a first straight portion **164**B with a length within an inclusive range of about 3 mm and about 10 mm, a second curve **164**D curving in an opposite direction of curve **164**C within an inclusive range of about 90 degrees to about 150 degrees, and a rounded portion **164**A with a length within an inclusive range of about 2 mm to about 10 mm. While these curves all generally occur in the same plane, it is possible to include additional curves that may take some of the engagement struts **114** out of a single plane (i.e., curving in multiple dimensions). The rounded portion **164**A may optionally include an aperture that may be used by the delivery catheter **50** to releasably retain the support structure **150** during deployment.
[0151] As previously discussed, the engagement struts **164** are not covered by the material covering **154** in the present example, but may be. Additionally, the engagement struts **164** may be coated or wrapped in a relatively softer material (e.g., a textile or EPTFE layer). Further, the rounded portion **164**A of the engagement struts **164** may include a coating composed of similar materials or other materials described in this specification.
[0152] One aspect of the support structure **150** and framework **152** of note is the positions of the atrial flange **156** relative to the engagement struts **164**, as seen best in the simplified line view of FIG. **45**, as well as FIG. **39**. In its expanded configuration, the end portions of the engagement struts **164** (i.e., portions of the leaflet engaging portion) are positioned at a more proximal location or further in an inflow direction than portions the radially-adjacent lower radial struts **162**D of the atrial flange portion **156**. In other words, lower radial struts **162**D on each side of each of the engagement struts **164** curve axially in a distal/outflow direction beyond the end portion of the engagement struts **164**. In one example, the axially-adjacent overlap is within an inclusive range of about 0.1 mm to about 10 mm.
[0153] This arrangement may be particularly helpful in several respects. First, this arrangement forces the leaflets and the annulus of the native valve to be positioned over the engagement struts **164** and then below the lower radial struts **162**D, forcing the leaflets/annulus into an alternating or wave-like shape. Hence, the leaflet engaging portion **158** (i.e., engagement struts **164**) and the atrial

flange portion **156** (i.e., lower radial struts **162**D) tend to pinch the leaflets/annulus and create a paperclip effect. This design may allow for positive remodeling (e.g., size reduction of any enlargement) of the ventricle as the body adapts to the reduced regurgitation vs the prior faulty native valve. Some other prosthetic replacement valves may be relatively large plug-like designs and may rely on radial force to anchor and seal, but the present top-down approach to sealing at the annulus may allow the ventricle to better recover over time and reduce in diameter without interference from the present replacement valve.

[0154] Second, this arrangement may hold the material covering on the underside of the atrial flange portion taut around the top of the leaflet engaging portion so that there is good contact between the material covering and the leaflets/annulus to promote sealing, healing, and possibly tissue in-growth.

[0155] Third, portions of the lower radial struts **162**D (e.g., those closes to the outflow end of the framework **152**, such as **162**H) may be positioned within the annulus of the native valve. Since portions of the lower radial struts **162**D may curve radially outward, this shape may help further seal the framework **152** with the native annulus, further limiting the passage of blood around the framework/valve.

[0156] The framework **152** of the present example may be composed of a single unitary body, such as laser cut from a shape memory tube (e.g., Nitinol tube). Alternatively, one or more of the struts of the framework may be welded or otherwise attached to each other. Alternatively, some of the components may be separate from each other, only connected by other materials, such as the material covering **154** or other attachment mechanisms. For example, the body portion **160**, the leaflet engagement portion **158**, and/or the atrial flange portion **156** may not be directly attached to each other in any combination. If shape memory material is used for the framework **152**, the framework may be cut to a desired pattern and then heat set to impart a desired shape in its expanded configuration.

[0157] The support structure **150** may deploy from a delivery catheter **50** in the same manner as described for the support structure **100** in FIGS. **10**-**12**. In that respect, the engagement struts **164** may begin in a compressed configuration with their ends (rounded enlargement **164**A) positioned distally away from the body portion **160** within the delivery catheter **50**. As the support structure **150** is pushed out or an outer sheath is retracted from over the support structure **150**, the engagement struts **164** extend radially outward from the delivery catheter **50**, and then, as the support structure **150** continues to advance or be exposed, the engagement struts **164** bend backward such that the rounded enlarged end **164**A is positioned in an inflow direction relative to the outflow end of the body portion **160**. In other words, as deployment occurs, the engagement struts **164** bend radially backward or invert which allows them to capture the native valve leaflets **14**B with the body portion **160** and press against the valve annulus, as seen in FIG. **47**.

[0158] In a compressed configuration within the delivery catheter **50**, it should be noted that the terminal portion **162**A with an aperture may be located at a proximal end of the compressed support structure **150** while engagement struts **164** are constrained distally such that the rounded portion **164**A is at a distal most location within the delivery device **50**. In that respect, apertures are located at both the proximal and distal ends of the support structure **150** in its compressed configuration. Additionally, aperture portion **166**C also includes an aperture midway along the length of the compressed configuration. These apertures may be engaged with features of the delivery device **50**, such as posts, hooks, tethers, or similar structures that help retain portions of the support structure until **150** until fully deployed.

[0159] As previously discussed, although the support structure **100** and **150** are mostly described in this specification, it is specifically contemplated that a valve mechanism **170**, such as prosthetic or biological valve leaflets, be attached within the valve support mechanism, as seen in FIG. **46**.

[0160] FIG. **48** illustrates one approach to delivering a support structure **150** within a tricuspid valve **14** by advancing a delivery catheter through the inferior vena cava **16** and into the right

atrium **18**, such that the support structure **150** is delivered from an inflow or atrial end relative to the tricuspid valve **14**.
[0161] FIG. **49** illustrates another approach to delivering a support structure **150** with a mitral valve **12** by performing a transeptal procedure to allow the delivery catheter to pass through the septum between the right atrium **18** and the left atrium **20**. This allows the support structure **150** to be delivered from an inflow or atrial end relative to the mitral valve **12**.
[0162] Additional approaches to delivering the support structure **150** are also possible. For example, either valve **14**, **20** may be approached from its respective ventricle. In such cases, the support structure may be arranged in an opposite orientation as shown in FIGS. **10**-**12**.
[0163] Any of the support structures in this specification, including support structures **100** and **150**, may be delivered from one of several known heart valve delivery devices. For example, the devices in U.S. Pub. No. 2017/0165064, 2019/0008640, and 2022/0287836, the content of which is hereby incorporated by reference.
[0164] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

Claims

1. A method of placing a prosthetic heart valve framework in a heart: delivering the prosthetic heart valve framework in a compressed state towards a target valve annulus in a heart; progressively expanding the prosthetic heart valve framework such that: a. a leaflet of the target valve annulus is contacted by a first end of the prosthetic heart valve framework and urged towards a second end of the prosthetic heart valve framework; b. a leaflet of the target valve annulus is contacted by the second end of the prosthetic heart valve framework and urged towards the first end of the prosthetic heart valve framework; c. the first end contacting a leaflet and the second end contacting a leaflet moving to overlap with each other so that a leaflet is pinched between the first and second ends in a paper clip effect that urges the leaflets and annulus of the target valve into a circumferential wave-like shape; and, securing the prosthetic heart valve framework in place in the target valve annulus.
2. The method of claim 1 wherein the overlap between the first end contacting a leaflet and the second end contacting a leaflet is within the inclusive range of 0.1 mm to about 10 mm.
3. The method of claim 1 wherein the first end contacting a leaflet and the second end contacting a leaflet are radially offset from each other.
4. The method of claim 1 wherein the first end comprises a plurality of engagement struts and the second end comprises a plurality of radial struts and wherein the overlap is comprised of an engagement strut overlapping with and between two radial struts.
5. The method of claim 4 wherein the overlap is achieved by the engagement strut moving towards, past and between two radial struts.
6. The method of claim 5 wherein the overlap is achieved by the two radial struts moving towards, past and between the engagement strut.
7. The method of claim 1 wherein the first end comprises a plurality of engagement struts and the second end comprises a plurality of radial struts and wherein the overlap is comprised of a radial strut overlapping with and between two engagement struts.
8. The method of claim 7 wherein the overlap is achieved by the two engagement struts moving towards, past and on either side the radial strut.
9. The method of claim 8 wherein the overlap is achieved by the radial strut moving towards, past and between the two engagement struts.

10. The method of claim 1 wherein the overlap is comprised of axial overlap
11. The method of claim 1 wherein the overlap is comprised of radial overlap.
12. The method of claim 1 wherein the overlap is comprised of both axial and radial overlap.
13. A method of replacing a native heart valve comprising: delivering a valve framework percutaneously in an unexpanded state towards a valve annulus of a native heart valve in a heart; deploying the valve framework through progressive expansion such that: a. a leaflet of the valve annulus is contacted by a distal end of the valve framework and urged towards a proximal end of the valve framework; b. a leaflet of the valve annulus is contacted by the proximal end of the valve framework and urged towards the distal end of the valve framework; c. the distal end contacting a leaflet and the proximal end contacting a leaflet moving to overlap with each other so that a leaflet is pinched between the distal and proximal ends in a paper clip effect that urges the leaflets and annulus of the valve into a circumferential wave-like shape; and, securing the valve framework in place at the valve annulus; securing a replacement valve in the valve framework.
14. The method of claim 13 wherein the overlap between the distal end contacting a leaflet and the proximal end contacting a leaflet is within the inclusive range of 0.1 mm to about 10 mm.
15. The method of claim 13 wherein the distal end contacting a leaflet and the proximal end contacting a leaflet are radially offset from each other.
16. The method of claim 13 wherein the distal end comprises a plurality of engagement struts and the proximal end comprises a plurality of radial struts and wherein the overlap is comprised of an engagement strut overlapping with and between two radial struts.
17. The method of claim 16 wherein the overlap is achieved by the engagement strut moving towards, past and between two radial struts.
18. The method of claim 17 wherein the overlap is achieved by the two radial struts moving towards, past and between the engagement strut.
19. The method of claim 13 wherein the distal end comprises a plurality of engagement struts and the proximal end comprises a plurality of radial struts and wherein the overlap is comprised of a radial strut overlapping with and between two engagement struts.
20. The method of claim 19 wherein the overlap is achieved by the two engagement struts moving towards, past and on either side the radial strut.
21. The method of claim 20 wherein the overlap is achieved by the radial strut moving towards, past and between the two engagement struts.
22. The method of claim 13 wherein the overlap is comprised of axial overlap
23. The method of claim 13 wherein the overlap is comprised of radial overlap.
24. The method of claim 13 wherein the overlap is comprised of both axial and radial overlap.