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United States Patent Application Publication 20250255718
Kind Code A1
Publication Date August 14, 2025
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TRANSCATHETER DELIVERABLE PROSTHETIC HEART VALVES AND METHODS OF DELIVERY

Abstract

A prosthetic valve includes a frame and a flow control component. The frame has an aperture extending through the frame about a central axis. The flow control component is mounted within the aperture and is configured to permit blood flow in a first direction approximately parallel to the vertical axis from an inflow end to an outflow end of the flow control component and to block blood flow in a second direction, opposite the first direction. The frame has an expanded configuration with a first height along the central axis, a first lateral width along a lateral axis perpendicular to the central axis, and a first longitudinal length along a longitudinal axis perpendicular to the central axis and the lateral axis. The frame has a compressed configuration with a second height less than the first height and a second lateral width less than the first lateral width.

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Appl. No.: **19/191923**

Filed: **April 28, 2025**

Related U.S. Application Data

parent US continuation 17682875 20220228 parent-grant-document US 12310850 child US 19191923
parent US continuation 16155890 20181010 parent-grant-document US 10321995 child US 16443862
parent US continuation 17167983 20210204 parent-grant-document US 11344413 child US

17682875
parent US continuation PCT/US2019/051957 20190919 PENDING child US 17167983
parent US continuation-in-part 16443862 20190617 parent-grant-document US 11273033 child US 17682875
parent US continuation-in-part 16449420 20190623 parent-grant-document US 11278437 child US 17682875
parent US continuation-in-part 16163577 20181018 parent-grant-document US 11071627 child US PCT/US2019/051957
us-provisional-application US 62766611 20180920
us-provisional-application US 62777070 20181208
us-provisional-application US 62766611 20180920
us-provisional-application US 62737343 20180927
us-provisional-application US 62749121 20181022
us-provisional-application US 62777070 20181208

Publication Classification

Int. Cl.: **A61F2/24** (20060101); **A61F2/95** (20130101)

U.S. Cl.:

CPC **A61F2/2427** (20130101); **A61F2/2409** (20130101); **A61F2/2412** (20130101); **A61F2/2418** (20130101); **A61F2/2433** (20130101); A61F2/95 (20130101); A61F2210/0014 (20130101); A61F2220/0008 (20130101); A61F2220/0016 (20130101); A61F2220/0075 (20130101); A61F2230/0006 (20130101); A61F2230/001 (20130101); A61F2230/0069 (20130101); A61F2250/0039 (20130101)

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 17/682,875, entitled “Side-Delivered Transcatheter Heart Valve Replacement,” filed Feb. 28, 2022, which is a continuation-in-part of U.S. patent application Ser. No. 16/443,862, entitled “Side-Delivered Transcatheter Heart Valve Replacement,” filed Jun. 17, 2019 (now U.S. Pat. No. 11,273,033), which is a continuation of U.S. patent application Ser. No. 16/155,890, entitled “Side-Delivered Transcatheter Heart Valve Replacement,” filed Oct. 10, 2018 (now U.S. Pat. No. 10,321,995), which claims priority to and the benefit of U.S. Provisional Patent Application No. 62/766,611, entitled “Side-Loading Transcatheter Heart Valve Replacement,” filed Sep. 20, 2018, the disclosure of each of which is incorporated herein by reference in its entirety. [0002] U.S. patent application Ser. No. 17/682,875 is also a continuation-in-part of U.S. patent application Ser. No. 16/449,420, entitled “Compression Capable Annular Frames for Side Delivery of Transcatheter Heart Valve Replacement,” filed Jun. 23, 2019 (now U.S. Pat. No. 11,278,437), which claims priority to and the benefit of U.S. Provisional Patent Application No. 62/777,070, entitled “Compression Capable Annular Frames for Orthogonal Delivery of Transcatheter Heart Valve Replacement,” filed Dec. 8, 2018, the disclosure of each of which is incorporated herein by reference in its entirety. [0003] U.S. patent application Ser. No. 17/682,875 is also a continuation of U.S. patent application Ser. No. 17/167,983, entitled “Transcatheter Deliverable Prosthetic Heart Valves and Methods of Delivery,” filed Feb. 4, 2021 (now U.S. Pat. No. 11,344,413), which is a continuation of International Patent Application No. PCT/US2019/051957, entitled “Transcatheter Deliverable Prosthetic Heart Valves and Methods of Delivery,” filed Sep. 19, 2019, the disclosure

of each of which is incorporated herein by reference in its entirety. [0004] International Patent Application No. PCT/US2019/051957 is a continuation-in-part of U.S. patent application Ser. No. 16/163,577, entitled “Orthogonally Delivered Transcatheter Heart Valve Frame for Valve in Valve Prostheses,” filed Oct. 18, 2018 (now U.S. Pat. No. 11,071,627), the disclosure of which is incorporated herein by reference in its entirety. [0005] International Patent Application No. PCT/US2019/051957 also claims priority to and the benefit of U.S. Provisional Patent Application No. 62/766,611, entitled “Side-Loading Transcatheter Heart Valve Replacement,” filed Sep. 20, 2018; U.S. Provisional Patent Application No. 62/737,343, entitled “Side-Loading Transcatheter Heart Valve Replacement,” filed Sep. 27, 2018; U.S. Provisional Patent Application No. 62/749,121, entitled “Guidewire Delivery of Tricuspid Valve,” filed Oct. 22, 2018; and U.S. Provisional Patent Application No. 62/777,070, entitled “Compression Capable Annular Frames for Orthogonal Delivery of Transcatheter Heart Valve Replacement,” filed Dec. 8, 2018, the disclosure of each of which is incorporated herein by reference in its entirety.

BACKGROUND

[0006] Embodiments are described herein that relate to prosthetic heart valves, and devices and methods for use in the delivery and deployment of such valves.

[0007] Prosthetic heart valves can pose challenges for delivery and deployment within a heart, particularly for delivery by catheters through the patient's vasculature rather than through a surgical approach. Traditional valves have a central cylinder axis that is parallel to the lengthwise axis of the delivery catheter and are deployed from the end of the delivery catheter and expanded radially outward from the central annular axis, in a manner akin to pushing a closed spring-loaded umbrella out of a sleeve to make it spring open. Traditional valves can only be expanded as large as what the internal diameter of the delivery catheter will allow. Efforts to increase the expanded diameter of traditional valves have run into the problems of trying to compress too much material and structure into too little space.

[0008] A need exists for valves that can be delivered through small diameter delivery catheters, particularly to native valves such as tricuspid valves.

SUMMARY

[0009] The embodiments described herein relate generally to transcatheter prosthetic valves and methods for delivering transcatheter prosthetic valves. In some embodiments, a prosthetic valve includes a frame and a flow control component. The frame has an aperture extending through the frame about a central axis. The flow control component is mounted within the aperture and is configured to permit blood flow in a first direction approximately parallel to the central axis from an inflow end to an outflow end of the flow control component and to block blood flow in a second direction, opposite the first direction. The frame has an expanded configuration with a first height along the central axis, a first lateral width along a lateral axis perpendicular to the central axis, and a first longitudinal length along a longitudinal axis perpendicular to the central axis and the lateral axis. The frame has a compressed configuration with a second height, less than the first height, along the central axis and a second lateral width, less than the first lateral width, along the lateral axis.

Description

BRIEF DESCRIPTION OF THE FIGURES

[0010] FIGS. **1**A-IF are schematic illustrations of a transcatheter prosthetic valve according to an embodiment.

[0011] FIGS. **2**-**4**A illustrate a transcatheter prosthetic valve according to an embodiment and being delivered within a delivery catheter to a target tissue, being inserted into a native annulus of the target tissue and being deployed in the native annulus of the target tissue, respectively.

[0012] FIG. **4**B is a partial cut-away view of a transcatheter prosthetic valve showing an inner valve sleeve thereof according to an embodiment.
[0013] FIG. **5** is a side view of a transcatheter prosthetic valve according to an embodiment.
[0014] FIGS. **6**-**9** illustrate a process of delivering the transcatheter prosthetic valve of FIG. **5** to a native annulus of a target tissue.
[0015] FIGS. **10**-**12** are various views of a transcatheter prosthetic valve in a compressed configuration within a delivery catheter according to an embodiment.
[0016] FIG. **13** is a partial cross-sectional view of the transcatheter prosthetic valve of FIG. **10**.
[0017] FIGS. **14**A-**14**C illustrate a transcatheter prosthetic valve being transitioned from an expanded configuration (FIG. **14**A) to a compressed configuration (FIG. **14**C) according to an embodiment.
[0018] FIG. **15** is a perspective view of the transcatheter prosthetic valve of FIG. **14**A in the compressed configuration within a delivery catheter.
[0019] FIGS. **16**A-**16**D illustrate a transcatheter prosthetic valve being transitioned from an expanded configuration (FIG. **16**A) to a compressed configuration (FIG. **16**D) according to an embodiment.
[0020] FIGS. **17**A-**17**E illustrate a transcatheter prosthetic valve being transitioned from an expanded configuration (FIG. **17**A) to a compressed configuration (FIG. **17**E) according to an embodiment.
[0021] FIGS. **18**A-**18**D illustrate a transcatheter prosthetic valve being transitioned from an expanded configuration (FIG. **18**A) to a compressed configuration (FIG. **18**D) according to an embodiment.
[0022] FIGS. **19**A-**19**D illustrate a transcatheter prosthetic valve being transitioned from a compressed configuration (FIG. **19**A) to an expanded configuration (FIG. **19**D) according to an embodiment.
[0023] FIG. **20** is a side perspective view of a transcatheter prosthetic valve according to an embodiment.
[0024] FIG. **21** is partial cross-sectional view of the transcatheter prosthetic valve of FIG. **20**.
[0025] FIG. **22** is an exploded view of a two-panel transcatheter prosthetic valve according to an embodiment.
[0026] FIG. **23** is a side view of the two-panel transcatheter prosthetic valve of FIG. **22**.
[0027] FIG. **24** is a side view of the two-panel transcatheter prosthetic valve of FIG. **22** in a compressed configuration.
[0028] FIG. **25** is an exploded view of a two-panel transcatheter prosthetic valve according to an embodiment.
[0029] FIG. **26** is a side view of the two-panel transcatheter prosthetic valve of FIG. **25**.
[0030] FIG. **27** is a side view of the two-panel transcatheter prosthetic valve of FIG. **25** in a compressed configuration.
[0031] FIGS. **28** and **29** are a side perspective view and a top view, respectively, of a transcatheter prosthetic valve according to an embodiment.
[0032] FIGS. **30** and **31** are a side perspective view and a top view, respectively, of a transcatheter prosthetic valve according to an embodiment.
[0033] FIGS. **32**A and **32**B are side perspective views of a transcatheter prosthetic valve according to an embodiment in an expanded configuration and a collapsed configuration, respectively.
[0034] FIGS. **33**A-**33**E illustrate a transcatheter prosthetic valve being transitioned from an expanded configuration (FIG. **33**A) to a compressed configuration (FIG. **33**E) according to an embodiment.
[0035] FIGS. **34**A and **34**B illustrate a transcatheter prosthetic valve according to an embodiment in a collapsed configuration and an expanded configuration, respectively.
[0036] FIGS. **35**A and **35**B illustrate a transcatheter prosthetic valve according to an embodiment.

[0037] FIGS. **36**A and **36**B illustrate a transcatheter prosthetic valve according to an embodiment.
[0038] FIGS. **37**A and **37**B are a side perspective view and a top perspective view, respectively, of a transcatheter prosthetic valve according to an embodiment.
[0039] FIGS. **37**C and **37**D are perspective views of the transcatheter prosthetic valve of FIG. **37**A being transitioned to a collapsed configuration.
[0040] FIGS. **38**A-**38**C are various views of a transcatheter prosthetic valve according to an embodiment.
[0041] FIGS. **39** and **40** are side perspective views of a transcatheter prosthetic valve each according to a different embodiment.
[0042] FIGS. **41**A-**41**G are various views of one or more portions of a transcatheter prosthetic valve according to embodiments.
[0043] FIGS. **42-46** are various views of one or more portions of a wire frame of a transcatheter prosthetic valve according to embodiments.
[0044] FIGS. **47**A and **47**B are side perspective views of an etched metal alloy sheet used to form a frame of a transcatheter prosthetic valve each according to a different embodiment.
[0045] FIGS. **48** and **49** are side views of a transcatheter prosthetic valve deployed in a native annulus of a target tissue each according to a different embodiment.
[0046] FIG. **50** is side view of a transcatheter prosthetic valve deployed in and anchored to a native annulus of a heart.
[0047] FIGS. **51**A-**51**C are various views of a transcatheter prosthetic valve according to an embodiment.
[0048] FIGS. **51**D and **51**E illustrate the transcatheter prosthetic valve of FIG. **51**A at least partially disposed within a delivery catheter.
[0049] FIGS. **52**A and **52**B illustrate a transcatheter prosthetic valve partially deployed and fully deployed, respectively, in a native annulus of a target tissue.
[0050] FIGS. **53**A-**53**F are various views of a transcatheter prosthetic valve according to an embodiment.
[0051] FIGS. **54**A-**54**E are various views of a transcatheter prosthetic valve according to an embodiment.
[0052] FIG. **55**A is a side perspective view of a transcatheter prosthetic valve according to an embodiment.
[0053] FIG. **55**B is a cross-sectional view of the transcatheter prosthetic valve of FIG. **55**A.
[0054] FIGS. **56**A and **56**B are side views of a transcatheter prosthetic valve according to an embodiment in an expanded configuration and a collapsed configuration, respectively.
[0055] FIGS. **57**A and **57**B are side views of a transcatheter prosthetic valve according to an embodiment in an expanded configuration and a collapsed configuration, respectively.
[0056] FIGS. **58**A and **58**B are a side perspective view and a top view, respectively, of a transcatheter prosthetic valve according to an embodiment.
[0057] FIGS. **59** and **60** are side perspective views of a transcatheter prosthetic valve each according to a different embodiment.
[0058] FIGS. **61-64** are various views of one or more portions of a wire frame of a transcatheter prosthetic valve according to embodiments.
[0059] FIG. **65**A is a top view of a transcatheter prosthetic valve shown within a cross-sectional view of an atrial floor and deployed within a native annulus.
[0060] FIG. **65**B is a bottom view of a transcatheter prosthetic valve shown within a cross-section view of a ventricular ceiling and deployed within a native annulus.
[0061] FIG. **66** is a side perspective view of a wire frame of a transcatheter prosthetic valve according to an embodiment.
[0062] FIG. **67** is a side perspective view of a valve sleeve of a transcatheter prosthetic valve according to an embodiment.

[0063] FIG. **68**A is a side perspective view of a valve sleeve of a transcatheter prosthetic valve according to an embodiment.
[0064] FIG. **68**B is a cross-sectional view of the valve sleeve of FIG. **68**A disposed within a frame of the transcatheter prosthetic valve.
[0065] FIG. **69** is a side perspective view of a valve sleeve of a transcatheter prosthetic valve according to an embodiment.
[0066] FIG. **70**A is a side perspective view of a valve sleeve of a transcatheter prosthetic valve according to an embodiment.
[0067] FIG. **70**B is a cross-sectional view of the valve sleeve of FIG. **70**A disposed within a frame of the transcatheter prosthetic valve.
[0068] FIGS. **71**A-**71**C are various views of a transcatheter prosthetic valve according to an embodiment.
[0069] FIGS. **72**A-**72**C are schematic illustrations of a delivery system for delivering a transcatheter prosthetic valve according to an embodiment.
[0070] FIG. **72**D is a flowchart describing a method for delivering a transcatheter prosthetic valve according to an embodiment.
[0071] FIG. **73**A is an illustration of the human heart anatomy and FIG. **73**B is an enlarged illustration of a portion of the human heart anatomy of FIG. **73**A.
[0072] FIG. **74** is an illustration of a transcatheter prosthetic valve deployed within a native annulus of the human heart of FIGS. **73**A and **73**B according to an embodiment.
[0073] FIGS. **75**A-**75**D, **76**A-**76**C, **77**A-**77**D, and **78**A-**78**D illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart each according to a different embodiment.
[0074] FIGS. **79**A-**79**E illustrate a transcatheter prosthetic valve being transitioned from a compressed configuration (FIG. **79**A) to an expanded configuration (FIGS. **79**D and **79**E) according to an embodiment.
[0075] FIGS. **80**A-**80**D illustrate a transcatheter prosthetic valve being transitioned from a compressed configuration (FIG. **80**A) to an expanded configuration (FIG. **80**D) according to an embodiment.
[0076] FIG. **80**E is an illustration of a side view of a transcatheter prosthetic valve in a compressed configuration within a delivery catheter, and showing a secondary catheter configured to move the valve through the delivery catheter according to an embodiment.
[0077] FIGS. **81**A-**81**D are side views of a portion of a secondary catheter including a guidewire collar each according to a different embodiment.
[0078] FIGS. **82**A-**82**C are schematic illustrations of a delivery system for delivering a transcatheter prosthetic valve according to an embodiment.
[0079] FIG. **82**D is a flowchart describing a method for delivering a transcatheter prosthetic valve according to an embodiment.
[0080] FIGS. **83**A-**83**F illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.
[0081] FIGS. **84**A-**84**H illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.
[0082] FIGS. **85**A-**85**F illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.
[0083] FIGS. **86**A-**86**F illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.
[0084] FIGS. **87**A-**87**E illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.
[0085] FIGS. **88**A and **88**B illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.

[0086] FIGS. **89**A-**89**C illustrate a process of deploying a transcatheter prosthetic valve in a native annulus of the human heart according to an embodiment.
[0087] FIGS. **90**A-**90**C illustrate a process of anchoring a transcatheter prosthetic valve to a target tissue via a tissue anchor according to an embodiment.
[0088] FIGS. **91**A-**91**D are side views of a tissue anchor each according to a different embodiment.
[0089] FIG. **92**A-**92**D illustrate a process of deploying and anchoring a transcatheter prosthetic valve in a native annulus of a target tissue.
[0090] FIG. **93**A-**93**E illustrate a process of deploying and anchoring a transcatheter prosthetic valve in a native annulus of a target tissue.
[0091] FIG. **94** is a flowchart describing a method for delivering a transcatheter prosthetic valve according to an embodiment.
[0092] FIG. **95** is a flowchart describing a method for loading a transcatheter prosthetic valve into a delivery catheter according to an embodiment.
[0093] FIG. **96**A is a cross-sectional view of a transcatheter prosthetic valve illustrating a valve sleeve disposed within a frame, according to an embodiment.
[0094] FIG. **96**B is a side view of the transcatheter prosthetic valve of FIG. **96**A in an expanded configuration.
[0095] FIGS. **96**C-**96**F illustrate a process of deploying the transcatheter prosthetic valve of FIG. **96**A into a native annulus of a target tissue.
[0096] FIGS. **97**A-**97**C illustrate a process of deploying a transcatheter prosthetic valve to a target tissue via a tissue anchor according to an embodiment.
[0097] FIGS. **98**A-**98**C illustrate a process of deploying a transcatheter prosthetic valve to a target tissue via a tissue anchor according to an embodiment.
[0098] FIGS. **99**A-**99**D illustrate at least a portion of a transcatheter prosthetic valve according to an embodiment.
[0099] FIG. **100** is an illustration of the human heart, showing an approximate location of the valves, the atriums, the ventricles, and the pertinent blood vessels that enter and exit the chambers of the heart.
[0100] FIGS. **101**A-**101**G illustrate a process of deploying a transcatheter prosthetic valve into a native annulus of a target tissue according to an embodiment.
[0101] FIGS. **102**A-**102**D illustrate a process of deploying a transcatheter prosthetic valve into a native annulus of a target tissue according to an embodiment.
[0102] FIGS. **103**A-**103**G illustrate a process of deploying a transcatheter prosthetic valve into a native annulus of a human heart according to an embodiment.
[0103] FIGS. **104**A-**104**F illustrate a process of deploying a transcatheter prosthetic valve into a native annulus of a human heart according to an embodiment.

DETAILED DESCRIPTION

[0104] Disclosed embodiments are directed to an orthogonally delivered transcatheter prosthetic valves and/or components thereof, and methods of manufacturing, loading, delivering, and deploying the transcatheter prosthetic valves and/or components thereof. The transcatheter prosthetic valves have a tubular frame and a flow control component mounted within a central lumen of the tubular frame. The flow control component is configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve. The valve is compressible and expandable along a long-axis substantially parallel to a lengthwise cylindrical axis of a delivery catheter. The valve is configured to transition between a compressed configuration for introduction into the body using the delivery catheter, and an expanded configuration for implanting at a desired location in the body. The valve is configured to permit blood flow in a first direction through an inflow end of the valve and to block blood flow in a second direction, opposite the first direction, through an outflow end of the valve.

[0105] In some embodiments, the transcatheter prosthetic valve has the compressible configuration in a lengthwise or orthogonal direction relative to the central axis of the flow control component can allow a large diameter valve (e.g., having a height of about 5-60 mm and a diameter of about 20-80 mm) to be delivered and deployed from the inferior vena cava directly into the mitral or tricuspid valve using, for example, a 24-36 Fr delivery catheter and without delivery and deployment from the delivery catheter at an acute angle of approach.
[0106] In some embodiments, the transcatheter prosthetic valve has a central axis when in the compressed configuration that is co-axial or at least substantially parallel with the first direction (e.g., the blood flow direction). In some embodiments, the compressed configuration of the valve is orthogonal to the first direction. In some embodiments, the long-axis is oriented at an intersecting angle of between 45-135 degrees to the first direction when in the compressed configuration and/or the expanded configuration.
[0107] In some embodiments, the transcatheter prosthetic valve includes a tension arm extending from a distal side of the tubular frame, which can be used, for example, as a Right Ventricular Outflow Tract ("RVOT") tab. The tension arm can include a wire loop or wire frame, integrated frame section, or stent, extending from about 10-40 mm away from the tubular frame.
[0108] In some embodiments, the transcatheter prosthetic valve includes (i) an upper tension arm attached to a distal upper edge of the tubular frame, the upper tension arm comprised of wire loop or wire frame extending from about 2-20 mm away from the tubular frame, and (ii) a lower tension arm (e.g., used as a RVOT tab) extending from a distal side of the tubular frame, the lower tension arm comprised of wire loop or wire frame extending from about 10-40 mm away from the tubular frame.
[0109] In some embodiments, the transcatheter prosthetic valve includes at least one tissue anchor connected to the tubular frame for engaging annular tissue.
[0110] In some embodiments, the transcatheter prosthetic valve is one of a balloon-inflated valve or a self-expanding valve.
[0111] In some embodiments, the tubular frame forms a two-part framework. A first part includes a flared atrial cuff joined to a second part that comprises cylindrical member/segment. The cuff is joined to the cylindrical member/segment around the circumference of a top edge of the cylindrical member/segment.
[0112] In some embodiments, the tubular frame has a side profile of a flat cone shape having a diameter R of 40-80 mm, a diameter r of 20-60 mm, and a height of 5-60 mm. In some embodiments, the tubular frame has a side profile of an hourglass flat conical shape having a top diameter R1 of 40-80 mm, a bottom diameter R2 of 50-70 mm, an internal diameter r of 20-30 mm, and a height of 5-60 mm. In some embodiments, the tubular frame has an outer diameter of 20-80 mm and an inner diameter of 21-79 mm.
[0113] In some embodiments, the tubular frame is formed of a braided wire, laser-cut wire, photolithography produced wire cells, 3D printed wire cells, wire cells formed from intermittently connected single strand wires in a wave shape, a zigzag shape, or spiral shape, and/or combinations thereof, and is covered with a biocompatible material. In some embodiments, the tubular frame is formed of a plurality of compressible wire cells having an orientation and cell geometry substantially orthogonal to a central vertical axis of the valve to minimize wire cell strain when the tubular frame is configured in a vertical compressed configuration, a rolled compressed configuration, or a folded compressed configuration.
[0114] In some embodiments, the tubular frame has a central channel and an outer perimeter wall circumscribing a central vertical axis in an expanded configuration. The perimeter wall has a front wall portion and a back wall portion connected along a proximal side to a proximal fold area and connected along a distal side to a distal fold area. The front wall portion has a front upper collar portion and a front lower body portion. The back wall portion has a back upper collar portion and a back lower body portion. In some embodiments, the front lower body portion and the back lower

body portion in an expanded configuration form a shape selected from a funnel, cylinder, flat cone, or circular hyperboloid. In some embodiments, the proximal fold area and the distal fold area each comprise a sewn seam, a fabric panel, or a rigid hinge. In some embodiments, the proximal fold area and the distal fold area each comprise a flexible fabric span without any wire cells.

[0115] In some embodiments, the tubular frame has an inner surface covered with a biocompatible material comprising pericardial tissue, and an outer surface covered with a biocompatible material comprising a woven synthetic polyester material.

[0116] In some embodiments, the flow control component has an internal diameter of 20-35 mm and a height of 5-40 mm, and a plurality of leaflets of pericardial material joined to form a rounded cylinder at an inflow end and having a flat closable aperture at an outflow end. For example, a flow control component can include 2-4 leaflets of pericardial material.

[0117] In some embodiments, the flow control component is supported with one or more longitudinal supports integrated into or mounted upon the flow control component. The one or more longitudinal supports selected from rigid or semi-rigid posts, rigid or semi-rigid ribs, rigid or semi-rigid battens, rigid or semi-rigid panels, and combination thereof.

[0118] In some embodiments, a delivery system for deployment of the transcatheter prosthetic valve includes (i) a delivery catheter comprising an elongated tube with a central lumen; (ii) a hypotube sheathed guidewire assembly having an outer sheath and an inner guidewire shaft configured to push against a guidewire collar on a tension arm of a compressed transcatheter prosthetic valve to deliver the valve; (ii) the transcatheter prosthetic valve having a tension arm extending from a distal side of the tubular frame. The tension arm is comprised of wire loop or wire frame, integrated frame section, or stent, extending about 10-40 mm away from the tubular frame. The tension arm having a guidewire collar element attached the tension arm, wherein the guidewire collar element is sized and configured with a guidewire aperture to allow the inner guidewire shaft of the hypotube sheathed guidewire assembly to pass through the guide aperture, and to block passage of the outer sheath of the guidewire assembly through the guidewire aperture.

[0119] In some embodiments, a method for manufacturing the transcatheter prosthetic valve includes (i) using additive or subtractive metal or metal-alloy manufacturing to produce the tubular frame, wherein the additive metal or metal-alloy manufacturing is 3D printing or direct metal laser sintering (powder melt), and wherein the subtractive metal or metal-alloy manufacturing is photolithography, laser sintering/cutting, CNC machining, or electrical discharge machining; (ii) mounting a flow control component within the tubular frame; (iii) covering an outer surface of the tubular frame with a pericardium material or similar biocompatible material.

[0120] In some embodiments, a method for orthogonal delivery of the transcatheter prosthetic valve to a desired location in the body includes (i) advancing a delivery catheter to the desired location in the body and (ii) delivering the transcatheter prosthetic valve to the desired location in the body by releasing the valve from the delivery catheter. The valve being in the compressed configuration when in the delivery catheter. The valve transitioning to the expanded configuration when released from the delivery catheter.

[0121] In some embodiments, the method further includes attaching a pulling wire (e.g., a rigid elongated pulling/pushing rod or draw wire) to a sidewall of the transcatheter prosthetic valve and pulling the valve into a tapering fixture or funnel (e.g., attached to a proximal end of the delivery catheter) such that the tapering fixture or funnel compresses or spirals the valve to the compressed configuration for loading into the delivery catheter.

[0122] In some embodiments, the method includes releasing the valve from the delivery catheter by (i) pulling the valve out of the delivery catheter using the pulling wire that is releasably connected to the distal side of the valve, wherein advancing the pushing rod away from the delivery catheter pulls the compressed valve out of the delivery catheter, or (ii) pushing the valve out of the delivery catheter using the pulling wire that is releasably connected to the proximal side of the valve, wherein advancing the pushing rod out of from the delivery catheter pushes the compressed valve

out of the delivery catheter.
[0123] In some embodiments, the method includes releasing the valve from the delivery catheter while increasing blood flow during deployment of the valve by (i) partially releasing the valve from the delivery catheter to establish blood flow around the partially released valve and blood flow through the flow control component; (ii) completely releasing the valve from the delivery catheter while maintaining attachment to the valve with a positioning catheter or the pulling wire to transition to a state with increased blood flow through the flow control component and decreased blood flow around the valve; (iii) deploying the valve into a final mounted position to transition to a state with complete blood flow through the flow control component and minimal or no blood flow around the valve; and (iv) disconnecting and withdrawing the positioning catheter or pulling wire from the valve.
[0124] In some embodiments, the method further includes inserting a tension arm (e.g., a RVOT tab) in the RVOT during the transition from partial release of the valve to complete release of the valve.
[0125] In some embodiments, the method further includes rotating the transcatheter prosthetic valve using a steerable catheter along an axis parallel to the plane of the valve annulus such that (i) the upper tension arm is conformationally pressure locked against supra-annular tissue and (ii) the lower tension arm is conformationally pressure locked against sub-annular tissue.
[0126] In some embodiments, the method further includes anchoring one or more tissue anchors attached to the valve into annular tissue.
[0127] In some embodiments, a method for orthogonal delivery of the transcatheter prosthetic valve to the desired location in the body includes (i) advancing a first delivery catheter to the desired location in the body, (ii) delivering the tubular frame to the desired location in the body by releasing the tubular frame from the delivery catheter, (iii) advancing a second delivery catheter to the desired location in the body, and (iv) delivering the flow control component into the central lumen of the tubular frame. The tubular frame being in the compressed configuration when in the first delivery catheter and the flow control component being in the compressed configuration when in the second delivery catheter. The tubular frame transitioning to the expanded configuration when released from the first delivery catheter and the flow control component transitioning to the expanded configuration when released from the second delivery catheter to mount into the tubular frame.
[0128] In some embodiments, a method for compressing the transcatheter prosthetic valve for lengthwise orthogonal release from a delivery catheter includes (i) flattening, rolling, or folding the valve into a compressed configuration wherein the long-axis of the valve is substantially parallel to a lengthwise cylindrical axis of the delivery catheter. In some embodiments, the method includes one of (i) unilaterally rolling the valve into the compressed configuration from one side of the tubular frame; (ii) bilaterally rolling the valve into the compressed configuration from two opposing sides of the tubular frame; (iii) flattening the tubular frame into two parallel panels that are substantially parallel to the long-axis, and then rolling the flattened tubular frame into the compressed configuration; or (iv) flattening the tubular frame along a vertical axis to reduce a vertical dimension of the valve from top to bottom.
[0129] In some embodiments, a method for orthogonal delivery of the transcatheter prosthetic valve to a desired location in the body includes (i) advancing a guidewire to a desired location within a body, said guidewire having an outer sheath and an inner shaft; (ii) advancing a delivery catheter over the guidewire to the desired location; (iii) mounting a valve capsule onto a proximal end of the guidewire, said valve capsule containing a compressed valve having a threaded guidewire collar having an aperture sized to permit the inner shaft of the guidewire to extend through the aperture and to block the outer sheath of the guidewire from extending through the aperture; (iv) loading the valve capsule into a proximal end of the delivery catheter; (v) advancing the compressed valve from the valve capsule into and through a lumen of the delivery catheter to

the desired location in the body by advancing the outer sheath over the inner shaft to deploy the valve at the desired location.

[0130] In some embodiments, a method for orthogonal delivery of the transcatheter prosthetic valve to a native annulus of a human heart can include at least one of (i) advancing the delivery catheter to the tricuspid valve or pulmonary artery of the heart through the inferior vena cava (IVC) via the femoral vein, (ii) advancing to the tricuspid valve or pulmonary artery of the heart through the superior vena cava (SVC) via the jugular vein, or (iii) advancing to the mitral valve of the heart through a trans-atrial approach, e.g., fossa ovalis or lower, via the IVC-femoral or the SVC-jugular approach; and (iv) delivering transcatheter prosthetic valve to the native annulus by releasing the valve from the delivery catheter.

[0131] In some embodiments, the method further includes positioning a tension arm of the transcatheter prosthetic valve into a RVOT of a right ventricle of a human heart. For example, the method can further include (i) positioning a lower tension arm of the valve into the RVOT of the right ventricle and (ii) positioning an upper tension arm-connected to the lower tension arm-into a supra-annular position such that the upper tension arm provides a supra-annular downward force in the direction of the right ventricle and the lower tension arm provides a sub-annular upward force in the direction of the right atrium.

[0132] In some embodiments, a prosthetic valve includes a tubular frame, a distal subannular anchoring tension arm, and a flow control component. The tubular frame has a sidewall and an atrial collar attached around a top edge of the sidewall. The distal subannular anchoring tension arm is attached to and extends away from a lower distal sidewall of the tubular frame. The flow control component is mounted within the tubular frame and configured to permit blood flow in a first direction through an inflow end of the prosthetic valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the prosthetic valve. The prosthetic valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body. The prosthetic valve, in the compressed configuration, has a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction and substantially parallel to a lengthwise cylindrical axis of the lumen of the delivery catheter. The prosthetic valve is expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction.

[0133] In some embodiments, a prosthetic valve includes a valve frame and a flow control component. The valve frame has an aperture extending through the valve frame along a central axis. The flow control component is mounted within the aperture and is configured to permit blood flow in a first direction approximately parallel to the central axis from an inflow end to an outflow end of the flow control component and to block blood flow in a second direction, opposite the first direction. The valve frame has an expanded configuration with a first height along the central axis, a first lateral width along a lateral axis perpendicular to the central axis, and a first longitudinal length along a longitudinal axis perpendicular to the central axis and the lateral axis. The valve frame has a compressed configuration with a second height, less than the first height, along the central axis and a second lateral width, less than the first lateral width, along the lateral axis.

[0134] In some embodiments, a frame for a prosthetic valve includes a tubular frame having a central lumen defined by an inner circumferential surface of the tubular frame and defining a vertical axis of the tubular frame. The tubular frame has an outer circumferential surface engageable with native annular tissue. The tubular frame is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body. The valve, in compressed configuration, has a horizontal long-axis oriented at an intersecting angle between 45-135 degrees relative to the vertical axis of the of the tubular frame and substantially parallel to a lengthwise cylindrical axis of a lumen of the delivery catheter when disposed therein. The valve is expandable to an expanded configuration having a horizontal long-axis oriented at an intersecting angle between 45-135 degrees relative to the vertical axis of the

tubular frame.
[0135] In some embodiments, a method for delivering a prosthetic valve to a native valve between a ventricle and an atrium of a heart includes advancing to the atrium of the heart a delivery catheter containing a prosthetic valve. The prosthetic valve includes a tubular frame having a side wall and an atrial collar attached around a top edge of the side wall, a distal subannular anchoring tension arm attached and extending distally away from a lower distal side wall of the tubular frame, and a flow control component mounted within the tubular frame. The flow control component configured to permit blood flow in a first direction through an inflow end of the prosthetic valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the prosthetic valve. The prosthetic valve is disposed in the delivery catheter in a compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction and substantially parallel to a length-wise cylindrical axis of the delivery catheter, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction. The method includes releasing the distal subannular anchoring tension arm of the prosthetic valve from the delivery catheter by pulling the tension arm out of the delivery catheter by pushing away from the delivery catheter a rigid elongated pushing rod that is releasably connected to the tension arm. The distal subannular anchoring tension arm is delivered to the ventricle side of the annulus of the native valve. The remainder of the prosthetic valve is then released from the delivery catheter to an expanded configuration so that the tubular frame is disposed within the annulus of the native valve.
[0136] In some embodiments, a method of delivering a prosthetic valve to an annulus of a native valve between a ventricle and an atrium of a heart includes disposing in the atrium of the heart a distal portion of a delivery catheter having a lumen and a longitudinal axis, with a distal end of the delivery catheter directed towards the annulus of the native valve. The prosthetic valve being disposed within the distal portion of the delivery catheter in a compressed configuration. The prosthetic valve having a tubular frame with a tension arm coupled thereto and a flow control component mounted within the tubular frame and having an expanded configuration in which the prosthetic valve is configured to permit blood flow in a first direction through an inflow end of the prosthetic valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the prosthetic valve. The tension arm extends laterally from the tubular frame and is disposed on the ventricle side of the annulus of the native valve when the tubular frame is disposed within the annulus. The prosthetic valve, when in the expanded configuration, has an extent in any direction lateral to the first direction that is larger than a diameter of the lumen of the distal portion of the delivery catheter. The prosthetic valve, when in the compressed configuration, is disposed within the distal portion of the delivery catheter and is elongated in a longitudinal direction and compressed in a lateral direction relative to the dimensions of the prosthetic valve in the expanded configuration. The prosthetic valve has a long axis in the longitudinal direction that is parallel to the longitudinal axis of the delivery catheter and oriented at an intersecting angle of between 45 and 135 degrees to the first direction, with the tension arm disposed distally in the longitudinal direction, towards the distal end of the delivery catheter. The method further includes releasing the tension arm from the lumen of the catheter. At least a distal portion of the tension arm is disposed on the ventricle side of the annulus of the native valve while the distal end of the delivery catheter remains on the atrium side of the annulus. The remainder of the prosthetic valve is released from the lumen of the delivery catheter so that the tubular frame is disposed within the annulus of the native valve.
[0137] In some embodiments, a method of delivering a prosthetic valve to an annulus of a native valve between a ventricle and an atrium of a heart includes disposing in the atrium of the heart a distal portion of a delivery catheter having a lumen and a longitudinal axis, with a distal end of the delivery catheter directed towards the annulus of the native valve. The prosthetic valve being disposed within the distal portion of the delivery catheter in a compressed configuration. The

prosthetic valve having a tubular frame with a tension arm coupled thereto and a flow control component mounted within the tubular frame and having an expanded configuration in which the prosthetic valve is configured to permit blood flow in a first direction through an inflow end of the prosthetic valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the prosthetic valve. The tension arm extends laterally from the tubular frame and is disposed on the ventricle side of the annulus of the native valve when the tubular frame is disposed within the annulus. The tubular frame is disposed within the lumen of the delivery catheter with the tension arm disposed towards the distal end of the delivery catheter. The method further includes releasing the tension arm from the lumen of the delivery catheter. At least a distal portion of the tension arm is disposed on the ventricle side of the annulus of the native valve while the distal end of the delivery catheter remains on the atrium side of the annulus. The remainder of the prosthetic valve is released from the lumen of the delivery catheter. The prosthetic valve is held at an oblique angle relative to the annulus of the native valve and blood is allowed to flow from the atrium to the ventricle both through the native valve and through the prosthetic valve to allow assessment of the function of the native valve and the prosthetic valve.

[0138] In some embodiments, a method for delivering a prosthetic valve includes advancing, over a guidewire having a diameter, a delivery catheter to dispose a distal end of the delivery catheter at a desired location within a body. A proximal end of the guidewire is mounted onto a valve capsule containing a prosthetic valve in a compressed configuration. The prosthetic valve has a guidewire collar with an aperture therethrough having an internal diameter larger than the diameter of the guidewire. The guidewire is disposed through the aperture of the guidewire collar. The valve capsule is loaded into a proximal end of the delivery catheter. A pusher is disposed over the guidewire proximal to the prosthetic valve. The pusher has an outside diameter larger than the internal diameter of the aperture in the guidewire collar. The prosthetic valve is advanced from the valve capsule into and through a lumen of the delivery catheter to the distal end thereof by advancing the pusher over the guidewire and the prosthetic valve is deployed from the distal end of the delivery catheter to the desired location.

[0139] In some embodiments, a method of delivering a prosthetic valve to an annulus of a native valve between a ventricle and an atrium of a heart includes disposing in the atrium of the heart a distal portion of a delivery catheter having a lumen and a longitudinal axis, with a distal end of the delivery catheter directed towards the annulus of the native valve. A tubular frame for the prosthetic valve being disposed within the lumen of the delivery catheter in a compressed configuration. The tubular frame defines a central lumen having a central axis and a tension arm coupled thereto. The tubular frame has an expanded configuration in which the tubular frame. The tubular frame, when in the expanded configuration, has an extent in any direction lateral to the central axis that is larger than a diameter of the lumen of the distal portion of the delivery catheter. The tubular frame, when in the compressed configuration, is disposed within the distal portion of the delivery catheter and is elongated in a longitudinal direction and compressed in a lateral direction relative to the dimensions of the tubular frame in the expanded configuration. The tubular frame has a long-axis in the longitudinal direction that is parallel to the longitudinal axis of the delivery catheter and oriented at an intersecting angle between 45 and 135 degrees relative to the central axis with the tension arm disposed distally in the longitudinal direction, towards the distal end of the delivery catheter. The method further includes releasing the tension arm from the lumen of the catheter. At least a distal portion of the tension arm is disposed on the ventricle side of the annulus of the native valve while the distal end of the delivery catheter remains on the atrium side of the annulus and the remainder of the tubular frame is released from the lumen of the delivery catheter so that the tubular frame is disposed within the annulus of the native valve.

[0140] In some embodiments, a prosthetic valve has an annular valve frame defining a central axis and has an expanded configuration with a vertical height along the central axis, a lateral width along a lateral axis perpendicular to the central axis, and a longitudinal length along a longitudinal

axis perpendicular to the central axis and the lateral axis. A method for preparing the prosthetic valve for delivery to a patient by a delivery catheter having a lumen with a lumen diameter includes compressing the annular support frame vertically by reducing the dimension of the annular support frame along the central axis from the expanded configuration to a dimension less than the lumen diameter. The annular support frame is compressed laterally by reducing the dimension of the annular support frame along the lateral axis from the expanded configuration to a dimension less than the lumen diameter. The compressing of the annular support frame vertically and the compressing of the annular support frame laterally collectively disposing the annular support frame in a compressed configuration. The annular support frame, when in the compressed configuration, is inserted into the lumen of the delivery catheter.

[0141] In some embodiments, a method of delivering a prosthetic valve to an annulus of a native valve between a ventricle and an atrium of a heart includes disposing in the atrium of the heart a distal portion of a delivery catheter having a lumen and a longitudinal axis, with a distal end of the delivery catheter directed towards the annulus of the native valve. The prosthetic valve is disposed within the distal portion of the delivery catheter in a compressed configuration. The prosthetic valve has a tubular frame with a distal lower tension arm and a distal upper tension arm coupled to a distal sidewall thereof and a flow control component mounted within the tubular frame. The prosthetic valve has an expanded configuration in which the flow control component permits blood flow through the prosthetic valve in a first direction and blocks blood flow through the prosthetic valve in a second direction, opposite the first direction. The prosthetic valve is disposed within the lumen of the delivery catheter with the distal lower tension arm and the distal upper tension arm disposed towards the distal end of the delivery catheter. The method further includes releasing the distal lower tension arm from the lumen of the delivery catheter and releasing the distal upper tension arm from the lumen of the delivery catheter. A portion of the distal lower tension arm is placed on the ventricle side of the annulus of the native valve while the distal upper tension arm remains on the atrium side of the annulus. After releasing the distal lower tension arm and releasing the distal upper tension arm, the remainder of the prosthetic valve is released from the lumen of the delivery catheter and the prosthetic valve is deployed into and secured to the annulus of the native valve while the distal upper tension arm is in contact with supra-annular tissue on the atrium side of the annulus and the distal lower tension arm is in contact with subannular tissue on the ventricle side of the annulus during the deploying.

[0142] The embodiments herein and the various features and advantageous details thereof are explained more fully with reference to the non-limiting embodiments that are illustrated in the accompanying drawings and detailed in the following description. Descriptions of well-known components and processing techniques are omitted so as to not unnecessarily obscure the embodiments herein. The examples used herein are intended merely to facilitate an understanding of ways in which the embodiments herein may be practiced and to further enable those of skill in the art to practice the embodiments herein. Accordingly, the examples should not be construed as limiting the scope of the embodiments herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the inventive concepts to those skilled in the art. Like numbers refer to like elements throughout.

[0143] The terminology used herein is for the purpose of describing particular embodiments only and is not intended to limit the full scope of the claims. As used herein, the singular forms “a,” “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

[0144] It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims (e.g., bodies of the appended claims) are generally intended as

"open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.).

[0145] It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof. As used in this document, the term "comprising" means "including, but not limited to."

[0146] As used herein the term "and/or" includes any and all combinations of one or more of the associated listed items.

[0147] It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

[0148] As will be understood by one skilled in the art, for any and all purposes, such as in terms of providing a written description, all ranges disclosed herein also encompass any and all possible subranges and combinations of subranges thereof. Any listed range can be easily recognized as sufficiently describing and enabling the same range being broken down into at least equal subparts. As will be understood by one skilled in the art, a range includes each individual member.

[0149] Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. Nothing in this disclosure is to be construed as an admission that the embodiments described in this disclosure are not entitled to antedate such disclosure by virtue of prior invention.

[0150] The term "valve prosthesis" or "prosthetic valve" can refer to a combination of a frame and a leaflet or flow control structure or component, and can encompass both complete replacement of an anatomical part (e.g., a new mechanical valve replaces a native valve), as well as medical devices that take the place of and/or assist, repair, or improve existing anatomical parts (e.g., the native valve is left in place).

[0151] The disclosed valves include a member (e.g., a frame) that can be seated within a native valve annulus and can be used as a mounting element for a leaflet structure, a flow control component, or a flexible reciprocating sleeve or sleeve-valve. It may or may not include such a leaflet structure or flow control component, depending on the embodiment. Such members can be referred to herein as an "annular support frame," "tubular frame," "wire frame," "flange," "collar," and/or any other similar terms.

[0152] The term "flow control component" can refer in a non-limiting sense to a leaflet structure having 2-, 3-, 4-leaflets of flexible biocompatible material such a treated or untreated pericardium that is sewn or joined to a annular support frame, to function as a prosthetic heart valve. Such a valve can be a heart valve, such as a tricuspid, mitral, aortic, or pulmonary, that is open to blood flowing during diastole from atrium to ventricle, and that closes from systolic ventricular pressure applied to the outer surface. Repeated opening and closing in sequence can be described as "reciprocating." The flow control component is contemplated to include a wide variety of (bio) prosthetic artificial heart valves, including ball valves (e.g., Starr-Edwards), bileaflet valves (St. Jude), tilting disc valves (e.g., Bjork-Shiley), stented pericardium heart-valve prosthesis' (bovine, porcine, ovine) (Edwards line of bioprostheses, St. Jude prosthetic valves), as well as homograft and autograft valves. Bioprosthetic pericardial valves can include bioprosthetic aortic valves, bioprosthetic mitral valves, bioprosthetic tricuspid valves, and bioprosthetic pulmonary valves.

[0153] In some embodiments, the frame and the flow control component can be separate structures and delivered together or separately. The term "valve frame" or "prosthetic valve frame" or "valve-in-valve" can refer to a three-dimensional structural component, usually tubular, cylindrical, or oval

or ring-shaped, and that can be seated within a native valve annulus and used as a mounting element for a commercially available valve such as a Sapien, Sapien 3, or Sapien XT from Edwards Lifesciences, the Inspiris Resilia aortic valve from Edwards Lifesciences, the Masters HP 15 mm valve from Abbott, Lotus Edge valve from Boston Scientific, the Crown PRT leaflet structure from Livanova/Sorin, the Carbomedics family of valves from Sorin, or other flow control component, or a flexible reciprocating sleeve or sleeve-valve.

[0154] The term “expandable” as used herein may refer to a component of the heart valve capable of expanding from a first, delivery diameter to a second, implantation diameter. An expandable structure, therefore, does not mean one that might undergo slight expansion from a rise in temperature, or other such incidental cause. Conversely, “non-expandable” should not be interpreted to mean completely rigid or a dimensionally stable, as some slight expansion of conventional “non-expandable” heart valves, for example, may be observed.

[0155] The terms “side-delivered,” “side-delivery,” “orthogonal,” “orthogonally delivered” and so forth are used to describe that the valves are compressed and delivered at a roughly 90 degree angle compared to traditional transcatheter heart valves. Orthogonal delivery is a transverse delivery where a perimeter distal sidewall exits the delivery catheter first, followed by the central aperture, followed by the proximal sidewall.

[0156] Mathematically, the term “orthogonal” refers to an intersecting angle of 90 degrees between two lines or planes. As used herein, the term “substantially orthogonal” refers to an intersecting angle or 90 degrees plus or minus a suitable tolerance. For example, “substantially orthogonal” can refer to an intersecting angle ranging from 75 to 105 degrees.

[0157] The disclosed valve embodiments may be delivered by a transcatheter approach. The term “transcatheter” is used to define the process of accessing, controlling, and delivering a medical device or instrument within the lumen of a catheter that is deployed into a heart chamber (or other desired location in the body), as well as an item that has been delivered or controlled by such as process. Transcatheter access is known to include via femoral artery and femoral vein, via brachial artery and vein, via carotid and jugular, via intercostal (rib) space, and via sub-xiphoid. Transcatheter can be synonymous with transluminal and is functionally related to the term “percutaneous” as it relates to delivery of heart valves.

[0158] In some of the disclosed embodiments, the prosthetic valve is secured in part to native tissue by a tissue anchor. The term “tissue anchor” or “plication tissue anchor” or “secondary tissue anchor,” or “dart” or “pin” refers to a fastening device that connects the upper atrial frame to the native annular tissue, usually at or near the periphery of the collar. The anchor may be positioned to avoid piercing tissue and just rely on the compressive force of the two plate-like collars on the captured tissue, or the anchor, itself or with an integrated securement wire, may pierce through native tissue to provide anchoring, or a combination of both. The anchor may have a specialized securement mechanism, such as a pointed tip with a groove and flanged shoulder that is inserted or popped into a mated aperture or an array of mated apertures that allow the anchor to attach, but prevent detachment when the aperture periphery locks into the groove near the flanged shoulder. The securement wire may be attached or anchored to the collar opposite the pin by any attachment or anchoring mechanisms, including a knot, a suture, a wire crimp, a wire lock having a cam mechanism, or combinations.

[0159] Some disclosed embodiments include a support post. The term “support post” refers to a rigid or semi-rigid length of material such as Nickel-Titanium alloy (Nitinol™) or polyetheretherketone (PEEK), that may be mounted on a spoked frame and that runs axially, or down the center of, or within a sewn seam of, the flexible sleeve. The sleeve may be unattached to the support post, or the sleeve may be directly or indirectly attached to the support post.

[0160] The term “body channel” may be used to define a blood conduit or vessel within the body, the particular application of the disclosed embodiments of prosthetic valves determines the body channel at issue. An aortic valve replacement, for example, would be implanted in, or adjacent to,

the aortic annulus. Likewise, a tricuspid or mitral valve replacement would be implanted at the tricuspid or mitral annulus. Certain features are particularly advantageous for one implantation site or the other. However, unless the combination is structurally impossible, or excluded by claim language, any of the valve embodiments described herein could be implanted in any body channel.
[0161] As used herein, the term “lumen” can refer to the inside of a cylinder or tube. The term “bore” can refer to the inner diameter of the lumen.
[0162] In some embodiments, components may be fabricated from a synthetic material such a polyurethane or polytetrafluoroethylene. Where a thin, durable synthetic material is contemplated, e.g., for a covering, synthetic polymer materials such expanded polytetrafluoroethylene (PTFE) or polyester may optionally be used. Other suitable materials may optionally include thermoplastic polycarbonate urethane, polyether urethane, segmented polyether urethane, silicone polyether urethane, polyetheretherketone (PEEK), silicone-polycarbonate urethane, polypropylene, polyethylene, low-density polyethylene, high-density polyethylene, and ultra-high molecular weight polyethylene. Additional biocompatible polymers may optionally include elastomers, polyolefins, polyethylene-glycols, polyethersulphones, polysulphones, polyvinylpyrrolidones, polyvinylchlorides, other fluoropolymers, polyesters, polyethylene-terephthalate (PET) (e.g., Dacron), Poly-L-lactic acids (PLLA), polyglycolic acid (PGA), poly (D, L-lactide/glycolide) copolymer (PDLA), silicone polyesters, polyamides (Nylon), PTFE, elongated PTFE, expanded PTFE, polyurethanes, siloxane polymers and/or oligomers, and/or polylactones, and block co-polymers using the same.
[0163] The annular support frame is optionally internally or externally covered, partially or completely, with a biocompatible material such as pericardium. The annular or tubular frame may also be optionally externally covered, partially or completely, with a second biocompatible material such as polyester or Dacron®. Disclosed embodiments may use tissue, such as a biological tissue that is a chemically stabilized pericardial tissue of an animal, such as a cow (bovine pericardium), sheep (ovine pericardium), pig (porcine pericardium), or horse (equine pericardium). Preferably, the tissue is bovine pericardial tissue. Examples of suitable tissue include that used in the products Duraguard®, Peri-Guard®, and Vascu-Guard®, all products currently used in surgical procedures, and which are marketed as being harvested generally from cattle less than 30 months old. Other patents and publications disclose the surgical use of harvested, biocompatible animal thin tissues suitable herein as biocompatible “jackets” or sleeves for implantable stents, including for example, U.S. Pat. No. 5,554,185 to Block, U.S. Pat. No. 7,108,717 to Design & Performance-Cyprus Limited disclosing a covered stent assembly, U.S. Pat. No. 6,440,164 to Scimed Life Systems, Inc. disclosing a bioprosthetic valve for implantation, and U.S. Pat. No. 5,336,616 to LifeCell Corporation discloses acellular collagen-based tissue matrix for transplantation.
[0164] In some embodiments, frame components may include drug-eluting wire frames. Drug-eluting wire frames may consist of three parts: wire frame platform, coating, and drug. Some of the examples for polymer-free coated frames are Amazon Pax (MINVASYS) using Amazonia CroCo (L605) cobalt chromium (Co—Cr) wire frame with Paclitaxel as an antiproliferative agent and abluminal coating have been utilized as the carrier of the drug. BioFreedom (Biosensors Inc.) using stainless steel as base with modified abluminal coating as carrier surface for the antiproliferative drug Biolimus A9. Optima (CID S.r.I.) using 316 L stainless steel wire frame as base for the drug Tacrolimus and utilizing integrated turbostratic carbofilm as the drug carrier. VESTA sync (MIV Therapeutics) using GenX stainless steel (316 L) as base utilizing microporous hydroxyapatite coating as carrier for the drug Sirolimus. YUKON choice (Translumina) used 316 L stainless steel as base for the drugs Sirolimus in combination with Probucol.
[0165] Biosorbable polymers may also be used herein as a carrier matrix for drugs. Cypher, Taxus, and Endeavour are the three basic type of bioabsorbable DES. Cypher (J&J, Cordis) uses a 316 L stainless steel coated with polyethylene vinyl acetate (PEVA) and poly-butyl methacrylate (PBMA) for carrying the drug Sirolimus. Taxus (Boston Scientific) utilizes 316 L stainless steel wire frames

coated with translute Styrene Isoprene Butadiene (SIBS) copolymer for carrying Paclitaxel, which elutes over a period of about 90 days. Endeavour (Medtronic) uses a cobalt chrome driver wire frame for carrying Zotarolimus with phosphorylcholine as drug carrier. BioMatrix employing S-Wire frame (316 L) stainless steel as base with polylactic acid surface for carrying the antiproliferative drug Biolimus. ELIXIR-DES program (Elixir Medical Corp) consisting both polyester and polylactide coated wire frames for carrying the drug Novolimus with cobalt-chromium (Co—Cr) as base. JACTAX (Boston Scientific Corp.) utilized D-lactic polylactic acid (DLPLA) coated (316 L) stainless steel wire frames for carrying Paclitaxel. NEVO (Cordis Corporation, Johnson & Johnson) used cobalt chromium (Co—Cr) wire frame coated with polylactic-co-glycolic acid (PLGA) for carrying the drug Sirolimus.

[0166] FIGS. **1**A-**1**F are various schematic illustrations of a transcatheter prosthetic valve **102** according to an embodiment. The transcatheter prosthetic valve **102** is configured to deployed in a desired location within a body (e.g., of a human patient) and to permit blood flow in a first direction through an inflow end of the transcatheter prosthetic valve **102** and to block blood flow in a second direction, opposite the first direction, through an outflow end of the transcatheter prosthetic valve **102**. For example, the transcatheter prosthetic valve **102** can be a transcatheter prosthetic heart valve configured to be deployed within the annulus of a native tricuspid valve or native mitral valve of a human heart to supplement and/or replace the functioning of the native valve.

[0167] The transcatheter prosthetic valve **102** (also referred to herein as "valve") is compressible and expandable in at least one direction perpendicular to a long-axis **111** of the valve **102** (also referred to herein as "horizontal axis," "longitudinal axis," or "lengthwise axis"). The valve **102** is configured to compressible and expandable between an expanded configuration (FIGS. **1**A, **1**B, **1**C, and **1**E) for implanting at a desired location in a body (e.g., a human heart) and a compressed configuration (FIGS. **1**D and **1**F) for introduction into the body using a delivery catheter (not shown).

[0168] In some embodiments, the valve **102** can be centric, or radially symmetrical. In other embodiments, the valve **102** can be eccentric, or radially (y-axis) asymmetrical. In some eccentric embodiments, the valve **102** (or an outer frame thereof) may have a D-shape (viewed from the top) so the flat portion can be matched to the anatomy in which the valve **102** will be deployed. For example, in some instances, the valve **102** may be deployed in the tricuspid annulus and may have a complex shape determined by the anatomical structures where the valve **102** is being mounted. In the tricuspid annulus, the circumference of the tricuspid valve may be a rounded ellipse, the septal wall is known to be substantially vertical, and the tricuspid is known to enlarge in disease states along the anterior-posterior line. In other instances, the valve **102** may be deployed in the mitral annulus (e.g., near the anterior leaflet) and may have a complex shape determined by the anatomical structures where the valve **102** is being mounted. For example, in the mitral annulus, the circumference of the mitral valve may be a rounded ellipse, the septal wall is known to be substantially vertical, and the mitral is known to enlarge in disease states.

[0169] As shown, the valve **102** generally includes an annular support frame **110** and a flow control component **150**. In addition, the valve **102** and/or at least the annular support frame **110** of the valve **102** optionally can include one or more of a distal upper tension arm **131**, a distal lower tension arm **132**, a proximal upper tension arm **133**, a proximal lower tension arm **134**, a guidewire collar **140**, and/or an anchor delivery conduit **145**.

[0170] The annular support frame **110** (also referred to herein as "tubular frame," "valve frame," "wire frame," or "fame") can have or can define an aperture **114** that extends along a central axis **113**. The aperture **114** (e.g., a central axial lumen) can be sized and configured to receive the flow control component **150** across a diameter of the aperture **114**. The frame **110** may have an outer circumferential surface for engaging native annular tissue that may be tensioned against an inner aspect of the native annulus to provide structural patency to a weakened native annular ring.

[0171] The frame **110** includes a cuff or collar **120** and a tubular section **112**. The cuff or collar **120** (referred to herein as "cuff") can be attached to and/or can form an upper edge of the frame **110**. When the valve **102** is deployed within a human heart, the cuff **120** can be an atrial cuff or collar. The atrial collar **120** can be shaped to conform to the native deployment location. In a mitral replacement, for example, the atrial collar **120** will be configured with varying portions to conform to the native valve. In one embodiment, the collar **120** will have a distal and proximal upper collar portion. The distal collar portion can be larger than the proximal upper collar portion to account for annular or subannular geometries.
[0172] The frame **110** may optionally have a separate atrial collar attached to the upper (atrial) edge of the frame **110**, for deploying on the atrial floor that is used to direct blood from the atrium into the flow control component **150** and to seal against blood leakage (perivalvular leakage) around the frame **110**. The frame **110** may also optionally have a separate ventricular collar attached to the lower (ventricular) edge of the frame **110**, for deploying in the ventricle immediately below the native annulus that is used to prevent regurgitant leakage during systole, to prevent dislodging of the valve **102** during systole, to sandwich or compress the native annulus or adjacent tissue against the atrial collar or cuff **120**, and/or optionally to attach to and support the flow control component **150**. Some embodiments may have both an atrial collar and a ventricular collar, whereas other embodiments either include a single atrial collar, a single ventricular collar, or have no additional collar structure.
[0173] In some embodiments, the frame **110** can have an outer perimeter wall circumscribing the aperture **114** and the central axis **113** in the expanded configuration. The perimeter wall can encompass both the collar **120** and the tubular section **112**. In some embodiments, the perimeter wall can be further defined as having a front wall portion and a back wall portion, which are connected along a near side (e.g., relative to the inferior vena cava ("IVC")) or proximal side to a proximal fold area, and connected along a far or distal side to a distal fold area. The front wall portion can be further defined as having a front upper collar portion and a front lower body portion, and the back wall portion can be further defined as having a back upper collar portion and a back lower body portion. The front upper collar portion and the back upper collar portion can collectively form the collar or cuff **120**. The front lower body portion and the back lower body portion can collectively form the tubular section **112**.
[0174] The frame **110** can be a ring, or cylindrical or conical tube, but may also have a side profile of a flat-cone shape, an inverted flat-cone shape (narrower at top, wider at bottom), a concave cylinder (walls bent in), a convex cylinder (walls bulging out), an angular hourglass, a curved, graduated hourglass, a ring or cylinder having a flared top, flared bottom, or both.
[0175] The frame **110** may have a height in the range of about 5-60 mm, may have an outer diameter dimension, R, in the range of about 20-80 mm, and may have an inner diameter dimension in the range of about 21-79 mm, accounting for the thickness of the frame **110** (e.g., a wire material forming the frame **110**).
[0176] The frame **110** design is preferably compressible and when released has the stated property that it returns to its original (uncompressed) shape. The frame **110** may be compressed for transcatheter delivery and may be expandable using a transcatheter expansion balloon or as a self-expandable shape-memory element. In some instances, suitable shape-memory materials can include metals and plastics that are durable and biocompatible. For example, the frame **110** can be made from super elastic metal wire, such as a Nitinol wire or other similarly functioning material. Nitinol can be desirable useful since it can be processed to be austenitic, martensitic, or super elastic. Martensitic and super elastic alloys can be processed to demonstrate the desired compression. The material may be used for the frame **110** or any portion thereof. It is contemplated to use other shape memory alloys such as Cu—Zn—Al—Ni alloys, Cu—Al—Ni alloys, as well as polymer composites including composites containing carbon nanotubes, carbon fibers, metal fibers, glass fibers, and polymer fibers.

[0177] The frame **110** may be constructed as a braid, wire, or laser cut wire frame. Such materials are available from any number of commercial manufacturers, such as Pulse Systems. One possible construction of the wire frame **110** envisions the laser cutting of a thin, isodiametric Nitinol tube. The laser cuts form regular cutouts in the thin Nitinol tube. In one embodiment, the Nitinol tube is expanded to form a three-dimensional structure formed from diamond-shaped cells. The structure may also have additional functional elements, e.g., loops, anchors, etc. for attaching accessory components such as biocompatible covers, tissue anchors, releasable deployment and retrieval control guides, knobs, attachments, rigging, and so forth. Secondarily the frame **110** can be placed on a mold of the desired shape, heated to a corresponding martensitic temperature, and quenched. The treatment of the wire frame in this manner will form a frame **110** that has shape memory properties and will readily revert to the memory shape at the calibrated temperature. Laser cut wire frames are preferably made from Nitinol, but also without limitation made from stainless steel, cobalt chromium, titanium, and other functionally equivalent metals and alloys.
[0178] Alternatively, the frame **110** can be constructed utilizing simple braiding techniques. Using a Nitinol wire—for example, a 0.012″ wire—and a simple braiding fixture, the wire can be wound on the braiding fixture in a simple over/under braiding pattern until an isodiametric tube is formed from a single wire (e.g., the frame **110**). The two loose ends of the wire are coupled using a stainless steel or Nitinol coupling tube into which the loose ends are placed and crimped. In some embodiments, angular braids of approximately 60 degrees can be desirable. Secondarily, the braided wire frame **110** is placed on a shaping fixture and placed in a muffle furnace at a specified temperature to set the wire frame **110** to the desired shape and to develop the martensitic or super elastic properties desired.
[0179] Since the frame **110** is made of super elastic metal or alloy such as Nitinol, the frame **110** is compressible. Preferably, the frame **110** is constructed of a plurality of compressible wire cells having an orientation and cell geometry substantially orthogonal to the central axis **113** to minimize wire cell strain in the frame **110** when configured in a vertical compressed configuration, a rolled compressed configuration, or a folded compressed configuration.
[0180] In a particular embodiment, the frame **110** (e.g., of a prosthetic heart valve) may start in a roughly tubular configuration, and be heat-shaped to provide an upper atrial cuff or flange (e.g., the cuff **120**) for atrial sealing and a lower trans-annular tubular or cylindrical section having an hourglass cross-section for about 60-80% of the circumference to conform to the native annulus along the posterior and anterior annular segments while remaining substantially vertically flat along 20-40% of the annular circumference to conform to the septal annular segment.
[0181] The flow control component **150** can refer in a non-limiting sense to a device for controlling fluid flow therethrough. In some embodiments, the flow control component **150** can be a leaflet structure having 2-, 3-, 4-leaflets, or more, made of flexible biocompatible material such a treated or untreated pericardium. The leaflets can be sewn or joined to a support structure and/or can be sewn or joined to the frame **110**. The flow control component **150** can be mounted within the frame **110** and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve. For example, the flow control component **150** can be configured such that the valve **102** functions, for example, as a heart valve, such as a tricuspid valve, mitral valve, aortic valve, or pulmonary valve, that can open to blood flowing during diastole from atrium to ventricle, and that can close from systolic ventricular pressure applied to the outer surface. Repeated opening and closing in sequence can be described as “reciprocating.” The flow control component **150** is contemplated to include a wide variety of (bio) prosthetic artificial valves, including ball valves (e.g., Starr-Edwards), bileaflet valves (St. Jude), tilting disc valves (e.g., Bjork-Shiley), stented pericardium heart-valve prosthesis' (bovine, porcine, ovine) (Edwards line of bioprostheses, St. Jude prosthetic valves), as well as homograft and autograft valves. Bioprosthetic pericardial valves can include bioprosthetic aortic valves, bioprosthetic mitral valves, bioprosthetic tricuspid valves,

and bioprosthetic pulmonary valves.
[0182] The arrangement of the valve **102** can be such that a commercially available valve (flow control component **150**) can be received or accepted by and/or otherwise mounted in the frame **110**. Commercially available valves (flow control components **150**) may include, for example, a Sapien, Sapien 3, or Sapien XT from Edwards Lifesciences, an Inspiris Resilia aortic valve from Edwards Lifesciences, a Masters HP 15 mm valve from Abbott, a Lotus Edge valve from Boston Scientific, a Crown PRT leaflet structure from Livanova/Sorin, a valve from the Carbomedics family of valves from Sorin, or other flow control component(s), or a flexible reciprocating sleeve or sleeve-valve.
[0183] As described above, the valve **102** and/or at least the frame **110** of the valve **102** can optionally include one or more of the distal upper tension arm **131**, the distal lower tension arm **132**, the proximal upper tension arm **133**, the proximal lower tension arm **134**, the guidewire collar **140**, and/or the anchor delivery conduit **145**. The tension arms **131**, **132**, **133**, and **134** can be configured to engage a portion of the annular tissue to mount the frame **110** to the annulus of the native valve in which the valve **102** is deployed. The tension arms **131**, **132**, **133**, and/or **134** can be any suitable configuration such as those described below with respect to specific embodiments. The anchor delivery conduit **145** can be attached to the frame **110** and configured to receive a tissue anchor **190** (FIG. **1**B) therethrough. The tissue anchor **190**, in turn, can anchor the valve **102** and/or at least the frame **110** to the annular tissue.
[0184] The valve **102** can be delivered to the desired location in the body via a procedure generally including advancing a delivery catheter over a guide wire (not shown in FIGS. **1**A-**1**F) to place a distal end of the delivery catheter at or near the desired location. The guidewire, therefore, may be disposed within the lumen of the delivery catheter. The valve **102** can be disposed within the lumen of the delivery catheter (e.g., in the compressed configuration) and advanced over the guidewire through the delivery catheter. More particularly, in embodiments including the guidewire collar **140**, the guidewire can extend through an aperture of the guidewire collar **140**, thereby allowing the valve **102** to be advanced over or along the guidewire. The guidewire collar **140** can be attached to the frame **110** and/or to at least one of the tension arms **131**, **132**, **133**, and/or **134**. The guidewire collar **140** can be configured to selectively engage a portion of the guidewire or a portion of a guidewire assembly and/or can have any suitable configuration as described below with respect to specific embodiments.
[0185] The valve **102** is compressible and expandable between the expanded configuration and the compressed configuration. The valve **102** is in the expanded configuration when deployed or implanted (or ready to be deployed or implanted) at the desired location in the body (e.g., the annulus of a native valve). The valve **102**, when in the expanded configuration shown in FIG. **1**C, has an extent in any direction along or lateral to the central axis **113** that is larger than a diameter of a lumen of the delivery catheter used to deliver the valve **102** to the desired location in the body. Said another way, the valve **102** has an extent in any direction perpendicular to the longitudinal axis **111** of the valve **102** that is larger than the diameter of the lumen of the delivery catheter.
[0186] The valve **102** is in the compressed configuration when being delivered to the desired location in the body via the delivery catheter. When in the compressed configuration shown in FIG. **1**D, the valve **102** can be disposed within the delivery catheter and can be compressed in a lateral direction relative to the dimensions of the valve **102** in the expanded configuration and can be elongated in a longitudinal direction along the longitudinal axis **111**. The longitudinal axis **111** can be parallel to a longitudinal axis of the delivery catheter and can be oriented at an intersecting angle between 45 and 135 degrees relative to the central axis **113** (e.g., perpendicular or at about 90 degrees). In some embodiments, the horizontal x-axis (e.g., the longitudinal axis **111**) of the valve **102** is orthogonal to (90 degrees), or substantially orthogonal to (75-105 degrees), or substantially oblique to (45-135 degrees) to the central vertical y-axis (e.g., the central axis **113**) when in an expanded configuration. In some embodiments, the horizontal x-axis (e.g., the longitudinal axis **111**) of the valve **102** in the compressed configuration is substantially parallel to a lengthwise

cylindrical axis of the delivery catheter.
[0187] As used herein, the terms “intersecting angle” and/or “orthogonal angle” can refer to both (i) the relationship between the lengthwise cylindrical axis of the delivery catheter and the long-axis **111** of the compressed valve **102**, where the long-axis **111** is perpendicular to the central axis **113** of traditional valves, and (ii) the relationship between the long-axis **111** of the compressed or expanded valve **102** and the axis defined by the blood flow through the prosthetic valve **102** where the blood is flowing, e.g., from one part of the body or chamber of the heart to another downstream part of the body or chamber of the heart, such as from an atrium to a ventricle through a native annulus.
[0188] As shown in FIGS. **1**C and **1**D, the valve **102** can have a first height or size along the central axis **113** when in the expanded configuration and can have a second height or size, less than the first height or size, along the central axis **113** when in the compressed configuration. The second height or size of the valve **102** when in the compressed configuration is smaller than the diameter of the lumen of the delivery catheter, allowing the valve **102** to be delivered therethrough.
[0189] The valve **102** can also be compressed in additional directions. For example, FIGS. **1**E and **1**F are top views of the valve **102** in the expanded configuration and the compressed configuration, respectively. The valve **102** has a lateral axis **115** that is perpendicular to the longitudinal axis **111** and the central axis **113**. The valve **102**, when in the expanded configuration, has an extent in any direction along or lateral to the lateral axis **115** that is larger than a diameter of the lumen of the delivery catheter used to deliver the valve **102**. In other words, the valve **102** can have a first width or size along the lateral axis **115** when in the expanded configuration shown in FIG. **1**E and can have a second width or size, less than the first width or size, along the lateral axis **115** when in the compressed configuration shown in FIG. **1**F.
[0190] The valve **102** may be compressed (as described above) and delivered in a sideways or orthogonal manner such that the longitudinal axis **111** is substantially parallel to a delivery axis (e.g., a lengthwise axis of a delivery catheter). The shape of the expanded valve **102** can be that of a large diameter shortened cylinder with an extended collar or cuff (e.g., the cuff **120**). The valve **102** can be compressed, in some embodiments, where the central axis **113** of the valve **102** is roughly perpendicular to (orthogonal to) the lengthwise axis of the delivery catheter. In some embodiments, the valve **102** can be compressed vertically (e.g., along the central axis **113**), similar to collapsing the height of a cylinder accordion-style from taller to shorter. In addition, or as an alternative, the valve **102** can be compressed laterally (e.g., along the lateral axis **115**) similar to folding or compressing a front panel against a back panel. In other embodiments, the valve **102** can be compressed by rolling. In other embodiments, the valve **102** can be compressed using a combination of compressing, folding, and/or rolling. The compression along the central axis **113** (e.g., compression in a vertical direction) and compression along the lateral axis **115** (e.g., compression in a lateral or width-wise direction) is in contrast to the compression of traditional co-axially delivered prosthetic valves, which are generally compressed along the lateral axis (e.g., the lateral axis **115**) and the longitudinal axis (e.g., the longitudinal axis **111**) and elongated along the central axis (e.g., the central axis **113**).
[0191] In some embodiments, the valve **102** can have an expanded height (y-axis) of 5-60 mm. In some embodiments, the valve **102** can have an expanded diameter length and width of 20-80 mm, preferably 40-80 mm, and in certain embodiments length and/or width may vary and include lengths of 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm, 55 mm, 60 mm, 65 mm, 70 mm, 75 mm, and 80 mm, in combination with widths that are the same or different as the length.
[0192] In some embodiments, the valve **102** can have a compressed height (y-axis) and/or width (z-axis) of 6-15 mm, preferably 8-12 mm, and more preferably 9-10 mm, and an expanded deployed height of about 5-60 mm, preferably about 5-30 mm, and more preferably about 5-20 mm or even 8-12 mm or 8-10 mm. In some embodiments, the length of the valve **102** (x-axis) does not require compression since it can extend along the length of the central cylindrical axis of the delivery

catheter when disposed therein.
[0193] In some embodiments, the valve **102** can be arranged such that an inner frame or structure of the flow control component **150** that holds, for example, leaflet tissue is 25-29 mm in diameter, the frame **110** or a portion thereof is 50-70 mm in diameter, and the collar structure (cuff **120**) of the frame **110** extends beyond the top edge of the frame **110** by 10-30 mm to provide a seal on the atrial floor against perivalvular leaks (PVLs).
[0194] Referring back to FIG. **1**B, the valve **102** can be disposed within an annulus of a native valve in the human heart such as, for example, the pulmonary valve (PV) or the mitral valve (MV) —or the aortic valve or tricuspid valve, not shown in FIG. **1**B). As described above, the valve **102** can be in the compressed configuration and delivered to the annulus via the delivery catheter. The valve **102** can be released from the delivery catheter and allowed to expand to the expanded configuration shown in FIG. **1**B. The deployment of the valve **102** can include placing the distal lower tension arm **132** in the ventricle below the annulus while the remaining portions of the valve **102** is in the atrium. The valve **102** can be placed in the annulus of the native valve (PV or MV) and at least a portion of the distal lower tension arm **132** can be positioned in an outflow tract of the ventricle (e.g., the RVOT, as shown in FIG. **1**B). In embodiments in which the valve **102** includes additional tension arms, the distal upper tension arm **131** and the proximal upper tension arm **133** can be disposed in the atrium above the native valve and the proximal lower tension arm **134** can be disposed in the ventricle below the native valve. As such, the one or more optional tension arms **131**, **132**, **133**, **134** included in the valve **102** can exert a force on the native valve structure or tissue to mount the valve **102** within the annulus of the native valve. For example, the upper tension arms **131** and/or **133** can exert a supra-annular downward force in the direction of the right ventricle and the lower tension arms **132** and/or **134** can exert a sub-annular upward force in the direction of the right atrium.
[0195] The mounting of the valve **102** in the annulus optionally can include anchoring the valve **102** to the native valve via the tissue anchor **190**. The tissue anchor **190** can be, for example, tines or barbs that are located to provide attachment to tissue adjacent the annulus. The tissue anchor **190** can be forced into the annular tissue by mechanical means such as using a balloon catheter. In one non-limiting embodiment, the tissue anchor **190** may optionally be semi-circular hooks that upon expansion of the frame **110** (or valve **102**), pierce, rotate into, and hold annular tissue securely. The tissue anchors **190** can be deployed by over-wire delivery through a delivery catheter (e.g., via the anchor delivery conduit **145**). The delivery catheter may have multiple axial lumens for delivery of a variety of anchoring tools, including anchor setting tools, force application tools, hooks, snaring tools, cutting tools, radio frequency and radiological visualization tools and markers, and suture/thread manipulation tools. Once the tissue anchor(s) **190** are attached to the valve, tensioning tools may be used to adjust the length of one or more tethers or the like that connect to the implanted valve **102** to adjust and secure the implanted valve **102** as necessary for proper functioning. It is also contemplated that the tissue anchor(s) **190** may be spring-loaded and may have tether-attachment or tether-capture mechanisms built into the tethering face of the anchor(s) **190**. The anchors **190** or tether may pass through the anchor delivery conduit **145** of the valve **102** or frame **110**. The anchors **190** may also have in-growth material, such as polyester fibers, to promote in-growth of the anchors into the heart tissue. In one embodiment, where the valve **102** may or may not include a ventricular collar, the anchor **190** (e.g., a dart, tine, or barb) is not attached to a lower ventricular collar but is attached directly into annular tissue or other tissue useful for anchoring.
[0196] In some embodiments, the frame **110** and the flow control component **150** can be separate structures and delivered to a desired location in the body either together or separately. For example, the flow control component **150** can be positioned within the aperture **114** of the frame **110** to form the complete valve **102**, and the valve **102** can be compressed and delivered to the desired location in the body via the delivery catheter as described in detail above. In other embodiments, the frame

110 and the flow control component **150** can be delivered to the desired location in the body separately. For example, the frame **110** can be compressed and delivered to the desired location in the body via the delivery catheter. The frame **110** can be released from the delivery catheter and deployed, for example, in the annulus of the native valve. The frame **110** is in the expanded configuration once released from the delivery catheter, and thus, is deployed in the annulus of the native valve in the expanded configuration. The flow control component **150** can then be delivered separately (e.g., via the delivery catheter) and mounted into the deployed frame **110**.

[0197] Provided below is a discussion of certain aspects or embodiments of transcatheter prosthetic valves. The transcatheter prosthetic valves (or aspects or portions thereof) described below with respect to specific embodiments can be substantially similar in at least form and/or function to the valve **102** and/or corresponding aspects of the valve **102** described above with reference to FIGS. **1**A-**1**F. Thus, certain aspects of the specific embodiments are not described in further detail herein.

[0198] FIG. **2** is an illustration of a low profile, e.g., 8-20 mm, side-loaded prosthetic valve **1102** according to an embodiment. The valve **1102** can be substantially similar to the valve **102** shown in FIGS. **1**A-**1**F. FIG. **2** shows the valve **1102** in an expanded configuration and deployed into the native annulus.

[0199] FIG. **3** is an illustration of the valve **1102** having a frame **1110** and a flow control component **1150** shown compressed or housed within a delivery catheter **1172**.

[0200] FIG. **4**A is an illustration of the valve **1102** shown ejected from the delivery catheter **1172** and positioned against the anterior side of the native annulus. While the valve **1102** is held at this oblique angle by a secondary catheter **1180**, valve function and patient condition are assessed, (as described in more detail below) and if appropriate, the valve is completely deployed within the native annulus, and anchored using traditional anchoring elements (e.g., such as the tissue anchor **190**).

[0201] FIG. **4**B is an illustration of an open cross-section view of a low profile, side-loaded prosthetic valve **1202** according to an embodiment. The valve **1202** includes an inner valve sleeve or flow control component **1250** and a frame **1210**. The valve **1202** can be similar to the valve **1102**.

[0202] FIG. **5** is an illustration of a low profile, side-loaded heart prosthetic valve **1302** according to an embodiment. The valve **1302** has a braid or laser-cut construction for a tubular frame **1310**, with a valve sleeve or flow control component **1350** that extends beyond the bottom of the tubular frame **1310**. FIG. **5** shows a longer lower tension arm **1332** for extending sub-annularly towards the RVOT, and a shorter upper tension arm **1331** for extending over the atrial floor.

[0203] FIG. **6** is an illustration of the valve **1302** being in a compressed configuration within a delivery catheter **1372**. FIG. **6** shows the valve **1302** attached to a secondary steerable catheter **1380** for ejecting, positioning, and anchoring the valve **1302**. The secondary catheter **1380** can also be used to retrieve a failed deployment of the valve **1302**.

[0204] FIG. **7** is an illustration of the valve **1302** shown in a partially compressed configuration, partially within the delivery catheter **1372** and partially ejected from the delivery catheter **1372**. FIG. **7** shows that while the valve **1302** is still compressed the lower tension arm **1332** can be manipulated through the leaflets and chordae tendineae of the native valve to find a stable anterior-side lodgment for the distal side of the valve **1302**.

[0205] FIG. **8** is an illustration of the valve **1302** engaging the tissue on the anterior side of the annulus of a native valve with the curved distal sidewall of the tubular frame **1310** sealing around the native annulus. FIG. **8** shows the valve **1302** held by the steerable secondary catheter **1380** at an oblique angle in which valve function can be assessed.

[0206] FIG. **9** is an illustration of valve **1302** fully deployed into the annulus of the native valve. The distal side of the valve **1302** is shown engaging the tissue on the anterior side of the native annulus with the curved distal sidewall of the tubular frame **1310** sealing around the native annulus, and with the proximal sidewall tension-mounted into the posterior side of the native annulus.

[0207] FIG. **10** is an illustration of a plan view of an embodiment of a prosthetic valve **1402** shown in a compressed configuration within a delivery catheter **1472**. FIG. **10** shows a tubular frame **1410** rolled-over, outwardly, resulting in a 50% reduction in height of the catheter-housed valve **1402**. The low profile, side-loaded valve **1402** does not require the aggressive, strut-breaking, tissue-tearing, stitch-pulling forces that traditional transcatheter valves are engineered to mitigate.
[0208] FIG. **11** is an illustration of a cross-sectional view of the compressed valve **1402** within the delivery catheter **1472**. This cross-sectional end view shows one embodiment of a single-fold compression configuration where the tubular frame **1410** and attached two-panel sleeve or flow control component **1450** are rolled-over, outwardly, five times, resulting in a 50% reduction in height, and providing the ability to fit within the inner diameter of the 1 cm (10 mm) delivery catheter **1472**.
[0209] FIG. **12** is an illustration of a cross-sectional view of another embodiment of the compressed valve **1402** folded within the delivery catheter **1472**. This cross-sectional end view shows another embodiment of a single-fold compression configuration where the tubular frame **1410** and attached two-panel sleeve or flow control component **1450** are folded-over, outwardly, four times, resulting in a 50% reduction in height, and providing the ability to fit within the inner diameter of the 1 cm (10 mm) delivery catheter **1472**.
[0210] FIG. **13** is an illustration of a cross-sectional view of the valve **1402** to further illustrate how the folding and rolling configurations can be effectuated due to the minimal material requirement of the low profile, side-loaded valve **1402**.
[0211] FIG. **14**A-**14**C illustrate a sequence of a low profile valve **1502** being rolled into a compressed configuration for placement within a delivery catheter **1572**. The valve **1502** includes a tubular frame **1510** having an aperture **1514** and supporting a sleeve or flow control component **1550**.
[0212] FIG. **15** is an illustration of an end view that shows the valve **1502** having been longitudinally rolled and loaded within the delivery catheter **1572** and shows the frame **1510** and sleeve flow control component **1550**.
[0213] FIGS. **16**A to **16**D illustrate one embodiment showing a four step process for compressing a prosthetic valve **1602** to provide a long-axis (e.g., similar to the long-axis **111** shown in FIGS. **1**A-**1**F) that is co-planar or parallel with the lengthwise axis of a delivery catheter (not shown). These figures show that the valve **1602**, having a tubular frame **1610** made of a cuff and a trans-annular tubular section, having a flow control component **1650** mounted within the tubular frame **1610** and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve **1602**, is compressible about a long-axis that is parallel to a lengthwise axis of a delivery catheter. These figures show that the valve **1602** is compressible to a compressed configuration for introduction into the body using a delivery catheter where the compressed configuration has a long-axis that is perpendicular to the blood flow direction axis (e.g., oriented at an intersecting (orthogonal) angle of between 45-135 degrees (e.g., 90 degrees) to the first (blood flow) direction), and where the long-axis of the compressed configuration of the valve **1602** is substantially parallel to a lengthwise axis of the delivery catheter, wherein the valve **1602** has a height of about 5-60 mm and a diameter of about 25-80 mm.
[0214] FIG. **16**A shows an illustration of the valve **1602** in an uncompressed configuration. FIG. **16**B shows an illustration of an initial rolling or folding of the cuff of the tubular frame **1610**. The folding or rolling can be inwards as shown here, or may be outwardly rolled, or may also be flattened together for rolling the entire valve **1602** up from bottom to top. FIG. **16**C shows an illustration of the valve **1602** that has been rolled or folded, using multiple folds or rolls, along a long-axis into a tube-shape. FIG. **16**D shows an illustration of the completely compressed valve **1602**, that has been folded or rolled, e.g., using a compression accessory, into a compressed configuration, and which can be then loaded into a delivery catheter (not shown). The compressed

valve **1602** may be self-expanding when released from the delivery catheter using shape-memory alloys, or the valve **1602** may be balloon expanded in a secondary process once the valve **1602** is released from the delivery catheter.

[0215] FIG. **17**A is an illustration of a side perspective view of a side deliverable transcatheter prosthetic valve **1702** with at least one fold area according to an embodiment, in an expanded configuration. FIG. **17**A shows a distal fold area **1723**A in a collar portion **1720** of an annular frame **1710** that permits compression of the valve **1702** without subjecting the annular frame **1710** or an inner flow control component **1750** to damaging compression forces.

[0216] FIG. **17**B is an illustration of a side perspective view of the valve **1702** showing an anterior side **1721** of the collar portion **1720** of the valve **1702** commence a unilateral rolling process, indicated by the arrow **1763**. FIG. **17**B shows two fold areas, a proximal (near) fold area **1723**A and distal (far) area **1723**B. The fold areas **1723**A and **1723**B may be devoid of wire cells (wire frame portions) or may consist of cells that are large or oriented to minimize the folding or rolling damage from the compression process. Leaflets **1753** of the flow control component **1750** are visible from this angle.

[0217] FIG. **17**C is an illustration of a side perspective view of the valve **1702** showing a second rolling step of the unilateral rolling process **1763**. The anterior collar **1721** is rolled over to the central distal fold area **1723**B and the proximal fold area **1723**A with a posterior-septal collar **1722** in an unrolled expanded configuration.

[0218] FIG. **17**D is an illustration of a side perspective view of the valve **1702** showing a third rolling step of the unilateral rolling process **1763**. The valve **1702** continues to be roll compressed towards the posterior-septal collar **1722**.

[0219] FIG. **17**E is an illustration of a side perspective view of the valve **1702** showing a completion of the unilateral rolling process **1763** to achieve a compressed configuration.

[0220] FIG. **18**A is an illustration of a side perspective view of a valve **1802** in an expanded configuration, showing two sides of the valve **1802** commence a bilateral rolling process **1864**, with two of four (shown) fold areas, distal fold area **1823**B and second distal fold are **1824**B. An anterior collar **1821** of a frame **1810** of the valve **1802** and a posterior-septal collar **1822** of the frame **1810** are shown with outer frame wall **1816** and leaflets **1853** in dashed line for reference.

[0221] FIG. **18**B is an illustration of a side perspective view of the valve **1802** showing a second rolling step of the bilateral rolling process **1864**. A rim of the annular support frame **1810** is shown rolling inward towards a central axis **1811**. The distal fold area **1823**B and the second distal fold area **1824**B are shown opposite from a proximal fold area **1823**A and second proximal fold area **1824**A, respectively. Flow control leaflets **1853** of a flow control component **1850** of the valve **1802** are shown for reference.

[0222] FIG. **18**C is an illustration of a side perspective view of the valve **1802** showing a third rolling step of the bilateral rolling process **1864**. Here, the rolled rim is further rolled inward towards the central axis **1811**.

[0223] FIG. **18**D is an illustration of a side perspective view of the valve **1802** showing a completion of the bilateral rolling process **1864** shown rolled inward towards the central axis **1811**. FIG. **18**D shows the valve **1802** as it would appear in a compressed configuration within a delivery catheter (not shown).

[0224] FIG. **19**A is an illustration of a side perspective view of a valve **1902** in a compressed configuration, that has been compressed using a rolling and folding process **1965**. A lower portion of the valve **1902** is rolled, and an upper collar portion of the valve **1902** is folded lengthwise around a central long-axis **1911**.

[0225] FIG. **19**B is an illustration of a side perspective view of the valve **1902**, partially uncompressed, showing unrolling of the lower body portion and unfolding of the flattened upper collar portion. FIG. **19**B shows fold areas **1923**A and **1923**B in the collar portion.

[0226] FIG. **19**C is an illustration of a side perspective view of the valve **1902**, further

uncompressed, showing the unrolled lower body portion and the unfolded upper collar portion. The fold areas in the collar are wider as the valve **1902** assumes its expanded configuration.
[0227] FIG. **19**D is an illustration of a side perspective view of the valve **1902** in an expanded configuration, showing a different side/orientation, which is 90 degrees from the prior views.
[0228] FIG. **20** is an illustration of a side perspective view of a valve **2002** having a circular hyperboloid (hourglass) shape. Wire frame details are not shown since in practice the external surface would preferably be covered, such as with Dacron polyester to facilitate in-growth. A proximal fold area **2023**A and a distal fold area **2023**B are shown on opposite ends of an anterior collar **2021** and a posterior-septal collar **2022** of the frame **2010** along a horizontal axis **2011** with a front anterior wall **2016** and central channel or aperture **2014** shown, according to an embodiment.
[0229] FIG. **21** is an illustration of a cut away view of the valve **2002**. FIG. **21** shows that inner leaflet **2053** and inner frame of the flow control component are attached to the inner surface of the annular frame **2010**, with a collar portion **2020** attached to a subannular anchor portion **2032** via a wall portion **2012**. Here, the flow control component is only attached at a top edge of the frame **2010** although other non-limiting attachments are contemplated (e.g., mid-wall, multiple attachment points, etc.).
[0230] FIG. **22** is an illustration of an exploded view of a valve or valve frame **2110** according to an embodiment, having a funnel anterior collar **2121**, funnel posterior-septal collar **2122**, anterior cylinder body portion **2112**A, and posterior-septal cylinder body portion **2112**B. FIG. **22** shows one variation where the valve frame **2110** includes wire cells used to create opposing panels, which are joined using fabric strain-minimizing panels at a proximal fold area **2123**A and a distal flow area **2123**B. FIG. **22** also shows a flow control component **2150** having a three-leaflet valve **2153** mounted on an inner U-shaped wire frame **2152**.
[0231] FIG. **23** is an illustration of a side view of the valve or valve frame **2110** showing two (2) panels or walls **2116**A and **2116**B of the valve frame **2110**. The panel or wall **2116**A can include the anterior collar portion **2121** and the anterior cylinder body portion **2112**A and the panel or wall **2116**B can include the posterior-septal collar portion **2122** and the posterior-septal cylinder body portion **2112**B. FIG. **23** shows that diamond wire cells **2125**A of the frame **2110** for the collar portion **2121** may be one large diamond in height, while the lower body portion **2112**A may be constructed using two smaller diamond wire cells in height. Dashed lines illustrate where the inner flow control component is attached but not shown.
[0232] FIG. **24** is an illustration of a side view of the two-panel embodiment of the valve or valve frame **2110** in a compressed configuration.
[0233] FIG. **25** is an illustration of an exploded view of a valve or valve frame **2110** according to an embodiment, having a funnel anterior collar **2221**, funnel posterior-septal collar **2222**, anterior cylinder body portion **2212**A, and posterior-septal cylinder body portion **2212**B. FIG. **25** shows one variation where the valve frame **2210** includes wire cells used to create the entire opposing panels. FIG. **25** also shows a flow control component **2250** having a three-leaflet valve **2253** mounted on an inner U-shaped wire frame **2252**. FIG. **25** also shows a subannular tab **2230** that can be used for anchoring the frame **2210** in an annulus of a native valve.
[0234] FIG. **26** is an illustration of a side view of the valve or valve frame **2210** showing two (2) panels or walls **2216**A and **2216**B of the valve frame **2210**. FIG. **26** shows that wave wire cells **2225**B of the frame **2210** for the collar portion **2221** may be one large wave cell in height, while the lower body portion **2212**A may be constructed using one or two smaller wave wire cells in height. Dashed line illustrates where the inner flow control component is attached but not shown.
[0235] FIG. **27** is an illustration of a side view of the two-panel embodiment of the valve or valve frame **2210** in a compressed configuration.
[0236] FIG. **28** is an illustration of a side perspective view of a frame **2310** of a prosthetic valve formed by wave wire cells **2325**B. The frame **2310** has a proximal folding area **2323**A and a distal folding area **2323**B in the wave wire cells **2325**B. Dashed lines illustrate where an inner flow

control component is attached but not shown.
[0237] FIG. **29** is an illustration of a top view of the valve frame **2310** showing the proximal folding area or gap **2323**A and the distal folding area or gap **2323**B in the wave wire cells **2325**B. A central flow control component opening is shown as a horizontal linear gap **2354**.
[0238] FIG. **30** is an illustration of a side perspective view of a frame **2410** of a prosthetic valve formed by diamond wire cells **2425**A. The frame **2310** has a set of folding areas or gaps **2419** in the diamond wire cells **2425**A. Dashed lines illustrate where an inner flow control component is attached but not shown. Wire frame details are not shown since in practice the external surface would preferably be covered, such as with Dacron polyester cover **2417** to facilitate in-growth.
[0239] FIG. **31** is an illustration of a top view of the valve showing the folding areas or gaps **2419** in the generic annular support wire frame having diamond wire cells **2425**A. A central flow control component opening is shown as a three-leaflet structure **2455**.
[0240] FIG. **32**A is an illustration of a side perspective view of a frame **2510** of a prosthetic valve according to an embodiment. The frame **2510** has a set of folding areas or gaps **2519** in a generic wire cell structure where the folding gaps **2519** are covered with a fabric mesh spanning the gaps **2519**. Fabric folding panels **2519**A are illustrated on the proximal and distal sides of a lower body portion of the frame **2510**. A polyester cover **2517** for the lower body portion of the frame **2510** is also shown.
[0241] FIG. **32**B is an illustration of a side view of frame **2510** showing the lower body portion in a partially rolled configuration. FIG. **32**B shows that the lower body portion is unfurled towards the septal leaflet of the native valve.
[0242] FIG. **33**A is an illustration of a side perspective view of a frame **2610** of a prosthetic valve according to an embodiment. The fame **2610** has a flat collar portion **2620** and cylinder body portion **2612**. FIG. **33**A shows a proximal fold area **2623**A and a distal fold area **2623**B in the collar portion **2620** and a fold area **2626** in the lower body portion **2612** of the frame **2610**.
[0243] FIG. **33**B is an illustration of a side perspective view of the frame **2610** shown flattened and partially compressed. FIG. **33**B shows the two sides of the collar slide **2620** inward, compressing the fold areas **2623**A, **2623**B, to collapse the central axial opening or aperture, while flattening the lower body portion **2612** along the fold area or seam **2626**.
[0244] FIG. **33**C is an illustration of a side perspective view of the frame **2610** shown with the collar portion **2620** folded to be flattened and partially compressed and with the lower body portion **2612** rolled to be flattened and partially compressed.
[0245] FIG. **33**D is an illustration of a side perspective view of the frame **2610** shown with the collar portion **2620** folded to be flattened and partially compressed and with the lower body portion **2612** being completely compressed by rolling up to the collar portion **2620**.
[0246] FIG. **33**E is an illustration of a side perspective view of the flattened, compressed valve frame **2610** in its compressed configuration, with the lower body portion **2612** compressed by rolling and folded onto the flattened upper collar portion **2620**.
[0247] FIG. **34**A is an illustration of a side perspective view of a composite laser-cut workpiece prior to expansion into a valve frame **2710**. FIG. **34**A shows that a wire loop portion **2725**C in combination with a wire mesh or wire braid portion **2725**A can be combined in a single wire frame structure.
[0248] FIG. **34**B is an illustration of a side perspective view of the valve frame **2710** showing the composite laser-cut workpiece after expansion into the valve wireframe in an expanded configuration. FIG. **34**B shows a collar portion of the valve frame **2710** having the braid or laser-cut wire cell structure **2725**B, and a lower body portion having the wire loop structure **2725**C.
[0249] FIG. **35**A is an illustration of a side perspective view of a laser-cut orthogonal cell workpiece prior to expansion into a set of valve frame panels or walls **2816**A and **2816**B. FIG. **35**A illustrates asymmetric irregular rounded wire cells **2825**D.
[0250] FIG. **35**B is an illustration of a side perspective view of the laser-cut orthogonal workpiece

after expansion into the valve wireframe panels or walls **2816**A and **2816**B prior to assembly of the frame. FIG. **35**B shows rounded, horizontally oriented wire cells **2825**D for minimizing wire strain during folding, rolling, and compression of the assembled frame.

[0251] FIG. **36**A is an illustration of a side perspective view of a laser-cut orthogonal cell workpiece with zig-zag/diamond shape cells **2925**A prior to expansion into a valve frame panels or walls **2916**A and **2916**B.

[0252] FIG. **36**B is an illustration of a side perspective view of the laser-cut orthogonal workpiece with zig-zag/diamond shape cells **2925**A after expansion into the valve wireframe panels **2916**A, **2916**B, prior to assembly. FIG. **36**B illustrates diamond-shaped, horizontally oriented wire cells **2925**A for minimizing wire strain during folding, rolling and compression.

[0253] FIG. **37**A is an illustration of a side perspective view of valve wireframe panels or walls **3016**A and **3016**B that are stitched along the side edges **3026**A to form a three-dimensional valve frame **3010** having an arc-shape collar portion **3021**, **3022** and a cylinder body portion with an internal flow control component **3050** mounted within the cylinder body portion, and shown in a collapsed or folded configuration.

[0254] FIG. **37**B is an illustration of a top perspective view of the valve wireframe panels or walls **3016**A and **3016**B that are stitched along the side edges **3026**A to form the three-dimensional valve frame **3010** having the arc-shape collar portion **3021**, **3022** and the cylinder body portion with the internal flow control component **3050** mounted within the cylinder body portion, and shown in an expanded configuration.

[0255] FIG. **37**C is an illustration of a side perspective view of the two-panel valve frame **3010** being compressed by rolling. FIG. **37**C shows two panels, sewn along the joining (stitched, joined) edges **3026**.

[0256] FIG. **37**D is an illustration of a side perspective view of the two-panel valve frame **3010** in a rolled, compressed configuration with at least 1 turn, and up to 1.5 turns—or at least 360 degrees, and up to at least 540 degrees.

[0257] FIG. **38**A is an illustration of a top view of a single sheet of metal or metal alloy with compressible cells cut or formed into a first and second collar panel and a first and second body portion to form a wire valve frame **3110**. FIG. **38**A shows a cut and fold design. FIG. **38**A shows where the collar can be folded so that the two points A on the collar are brought together, and the lower portion can be folded so that the two points B on the lower portion are brought together to form the three-dimensional valve frame structure **3110** with partial folding to minimize the requirement for extensive sewing.

[0258] FIG. **38**B is an illustration of a top perspective view of the single sheet valve frame **3110** after folding, assembly, and attachment along the open seams.

[0259] FIG. **38**C is an illustration of a side perspective view of the single sheet valve frame **3110** after folding, assembly, and attachment along the open seams, in its expanded configuration.

[0260] FIG. **39** is an illustration of a side perspective view of a valve frame **3210** formed from a series of horizontal wave-shaped wires **3225**E connected at connection points, with an upper collar portion, and an hourglass shape for the lower body portion, in its expanded configuration. Sewing features are shown along the joining edges.

[0261] FIG. **40** is an illustration of a side perspective view of a valve frame **3310** formed from a series of (vertical) zigzag-shaped wires **3325**B connected at connection points, with an upper collar portion, and an hourglass shape for the body portion, in its expanded configuration. Sewing features are shown along the joining edges.

[0262] FIG. **41**A is an illustration of a top perspective view of a valve frame **3410**, in its expanded configuration, according to an embodiment. The valve frame **3410** has an upper collar portion formed from a series of fan-shaped asymmetric, irregular rounded cells/wires **3425**D connected circumferentially to the top peripheral edge of a lower body portion of the frame **3410**.

[0263] FIG. **41**B is an illustration of a cut away view of the valve frame **3410** showing the upper

collar portion formed from a series of fan-shaped asymmetric, irregular rounded cells/wires **3425**D connected circumferentially to the top peripheral edge of the lower body portion, and showing half of a flow control component **3450** mounted with the lower body portion.
[0264] FIG. **41**C is an illustration of a side perspective view of the upper cuff or collar portion of the frame **3410** in a partially expanded configuration, showing how the elongated fan-shape asymmetric, irregular rounded cells/wires **3425**D permit elongation and radial compression.
[0265] FIG. **41**D is an illustration of a side perspective view of a two-panel embodiment of the flow control component **3450**.
[0266] FIG. **41**E is an illustration of a side perspective view of an embodiment of the lower body portion of the frame **3410** having a braided wire cell construction **3425**B.
[0267] FIG. **41**F is an illustration of a side perspective view of an embodiment of the lower body portion of the frame **3410** having a diamond laser-cut wire cell construction **3425**A.
[0268] FIG. **41**G is an illustration of a side perspective view of an embodiment of a lower body portion of the frame **3410** having a connected-wave wire cell construction **3425**E.
[0269] FIG. **42** is an illustration of a top view of flat wire frame of metal or metal alloy having compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic valve. The arrangement and/or formation of the compressible wire cells allows the cells to compress, deform, or reconfigure when the prosthetic valve is compressed to the compressed configuration while minimizing strain within the wire valve frame. FIG. **42** shows outer wave cells **3525**B used for a collar portion of a wire frame with inner diamond cells **3525**A used for a lower body portion of the wire frame.
[0270] FIG. **43** is an illustration of a top view of a smaller sized flat wire frame of metal or metal alloy having compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic valve. FIG. **43** shows outer wave cells **3525**B used for the collar portion of the wire frame with inner diamond cells **3525**A used for the lower body portion of the wire frame.
[0271] FIG. **44** is an illustration of a side perspective view of a portion of a wire frame in a funnel configuration (heat set) showing compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **44** shows outer diamond cells **3525**A used for a collar portion of the wire frame and inner diamond cells **3525**A used for the lower body portion of the wire frame.
[0272] FIG. **45** is an illustration of a side perspective view of a portion of a wire frame in a funnel configuration (heat set) showing compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **45** shows outer diamond cells **3525**A used for a collar portion of the wire frame and inner diamond cells **3525**A used for the lower body portion of the wire frame.
[0273] FIG. **46** is an illustration of a top view down the central axis of the wire frame in a funnel configuration (heat set) showing compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **46** shows outer wave cells **3525**B used for the collar portion of the wire frame and inner diamond cells **3525**A used for the lower body portion of the wire frame.
[0274] One benefit of the two (or more) panel valve frame construction described in connection with several embodiments above is that each frame panel can be formed as a flat sheet, rather than as a braid, laser-cut tube, etc. The manufacturing process for such flat sheet components can be substantially less expensive than other techniques. For example, rather than using a laser to cut apertures in the sheet to form the wire frame structure, the sheet can be etched using, for example, photolithography and resistive masks. This technique also enables the sheet to be selectively etched to different thicknesses in different areas of the sheet, providing more design control over the mechanical or structural characteristics of different sections of the sheet (and thus of the valve frame formed from the sheet). FIG. **47**A is an illustration of a side perspective view of a metal alloy

sheet **3605**A that has been etched partially on a single side using photolithography and resistive masks. The metal alloy sheet **3605**A can be used to form a wire valve frame.
[0275] FIG. **47**B is an illustration of a side perspective view of a metal alloy sheet **3605**B that has been etched partially in a two-sided configuration using photolithography and resistive masks. The metal alloy sheet **3605**B can be used to form a wire valve frame.
[0276] As described above with reference to FIGS. **1**A and **1**B, a valve and/or valve frame can include any number of tension arms and/or anchoring members configured to mount, secure, or anchor the valve and/or valve frame within the annulus of a native valve. The tension arms can, for example, extend from the valve frame and can engage supra-annular tissue or subannular tissue. Tension arms included in the valve and/or valve frames described herein can be substantially similar in at least form and/or function to at least one of the tensions arms **131**, **132**, **133**, and/or **134** described above with reference to FIGS. **1**A and **1**B. A valve and/or valve frame can include and/or can be coupled to an anchoring member that can be used to mount or anchor the valve or valve frame in the annulus of the native valve. Anchoring members included in and/or used with the valves and/or valve members described herein can be substantially similar in at least form and/or function to the tissue anchor **190** described above with reference to FIGS. **1**A and **1**B.
[0277] FIG. **48** is an illustration of a plan view of an embodiment of a prosthetic valve with a valve frame **3710** having a distal upper tension arm **3731** and a distal lower tension arm **3732** mounted on, and anchored to, an anterior leaflet side of a native annulus. The frame **3710** includes a mechanical anchor element such as, for example, a proximal sealing cuff **3720** for anchoring on the posterior-septal side of the native annulus. The sealing cuff **3720** may be a short tab on the posterior side of the valve frame **3710** or may be a semi-circular or circular collar or cuff (e.g., similar to the cuff **120** described above with reference to FIGS. **1**A-**1**F) that engages the atrial floor to seal the annulus from perivalvular leaks. The deployment of the valve can include placing the valve frame **3710** at or near an annulus of a native valve and positioning the distal lower tension arm **3732** in a subannular position such as, for example, the RVOT. The distal upper tension arm **3731** can be placed in a supra-annular position such as, for example, in the atrium of the heart. As such, the distal upper tension arm **3731** can exert a supra-annular downward force on the annular tissue and the distal lower tension arm **132** can exert an opposing subannular upward force on an opposite side of the annular tissue. The forces act to mount or secure the valve frame **3710** within the annulus of the native valve.
[0278] FIG. **49** is an illustration of a plan view of an embodiment of a prosthetic valve with a valve frame **3810** having a distal upper tension arm **3831** and a distal lower tension arm **3832** mounted on, and anchored to, the anterior leaflet side of the native annulus. The frame **3810** includes a mechanical anchor element such as, for example, an hourglass annular sealing cuff **3820**, for anchoring on the posterior-septal side of the native annulus. The hourglass, or concave, sealing cuff **3820** may be only a short segment on the posterior side of the valve or may be a semi-circular or circular combined upper and lower collar or cuff that engages the atrial floor and the ventricular ceiling to seal the annulus from perivalvular leaks. The hourglass, or concave, sealing cuff **3820** can be formed by, for example, a proximal upper tension arm **3833** and a proximal lower tension arm **3834**. The proximal upper tension arm **3833** and the proximal lower tension arm **3834** can exert opposing forces on the annular tissue as described with the distal tension arms **3831** and **3832**. This embodiment may also include embodiments having a partial collar. This embodiment may be used in conjunction with other anchoring elements described herein such as a tissue anchor.
[0279] FIG. **50** is an illustration of a plan view of a prosthetic valve **3902** according to an embodiment. The valve **3902** includes a valve frame **3910** having a distal upper tension arm **3931** and a distal lower tension arm **3932** mounted on and anchoring to the annulus. FIG. **50** shows distal lower tension arm **3932** extending into the RVOT. The lateral, or side-loaded, delivery of the valve **3902** through the inferior vena cava provides for direct access to the native valve annulus without the need to deliver a compressed valve around a right angle turn, as is done for IVC delivery of

axially, or vertically loaded, traditional transcatheter prosthetic valves. FIG. **50** shows one embodiment where a tissue anchor **3990** such as a screw or other anchor device is used in conjunction with the tension-mounting method described herein where the distal upper and lower tension arms **3931** and **3932** on the anterior leaflet side anchor the valve **3902** in place, and a secondary anchor element (e.g., the tissue anchor **3990**) completes the securement of the valve **3902** in the annular site.

[0280] FIG. **50** shows polyester mesh cover **3917** that covers the valve frame **3910** and encircles a collapsible flow control sleeve of flow control component (not shown). FIG. **50** also shows the valve frame **3910** having Nitinol wire frame in diamond shape cells **3925**A within or covered by the biocompatible covering **3917**. In one embodiment, the frame may have a pericardial material on top and a polyester material, e.g., surgical Dacron, underneath to be in contact with the native annulus and promote ingrowth.

[0281] FIG. **51**A is an illustration of a plan view of a low profile, e.g., 10 mm in height, prosthetic valve **4002** according to an embodiment, in an expanded configuration. The valve **4002** includes a frame **4010** that has and/or that forms a wire annulus support loop. The frame **4010** includes and/or forms (or the wire loop includes and/or forms) a distal upper tension arm **4031** and a distal lower tension arm **4032** that can be formed as a unitary or integral part and covered with a biocompatible material. This embodiment shows how the low profile, side-loaded valve **4002** can having a very large diameter, 40-80 mm, without having to deliver the valve **4002** with an undesirably large delivery catheter, as would be otherwise used to deliver a large diameter valve that is delivered using the traditional, vertical or axial, orientation.

[0282] FIG. **51**B is an illustration of a top view of the valve **4002** that shows the inner two-panel sleeve or flow control component **4050** and the reciprocating collapsible aperture **4054** at the lower end for delivering blood to the ventricle.

[0283] FIG. **51**C is an illustration of a bottom-side view of the valve **4002** that shows a plan view of the inner two-panel sleeve or flow control component **4050** and the collapsible terminal aperture **4054** at the ventricular side.

[0284] FIG. **51**D is an illustration of the valve **4002** in a compressed configuration and disposed within a delivery catheter **4072**. FIG. **51**D illustrates how a large diameter valve **4002**, using side loading, can be delivered via the delivery catheter **4072**.

[0285] FIG. **51**E is an illustration of the valve **4002** in a compressed configuration being partially ejected, and partially disposed within, the delivery catheter **4072**. FIG. **51**E shows how the valve **4002** can be partially delivered for positioning in the annulus. The distal lower tension arm **4034** can be used to navigate through the native tricuspid leaflets and chordae tendineae while the valve body, the tubular frame **4010**, is still within the steerable delivery catheter **4072**.

[0286] FIG. **52**A is an illustration of a plan view of a prosthetic valve **4102** partially mounted within a native valve annulus. By using the side-loaded valve **4102** of the disclosed embodiments, the distal upper tension arm **4133** and the distal lower tension arm **4132** can be mounted against an anterior aspect of the native annulus, and valve function can be assessed before completely seating the valve **4102**. By allowing two pathways for blood flow, the first through the native valve near the posterior leaflet, and the second through the central aperture of the prosthetic valve **4102**, a practitioner can determine if the heart is decompensating or if valve function is less than optimal. FIG. **52**A also shows a proximal upper tension arm **4133** which can work in conjunction with the distal tension arms **4131** and **4132** to mount, seat, and/or anchor the valve **4102** in the native annulus.

[0287] FIG. **52**B is an illustration of a plan view of the prosthetic valve **4102** completely seated within the valve annulus. FIG. **52**B shows that the valve **4102** can be secured in place once the valve function assessment shows that the deployment is successful. Importantly, since the valve **4102** is a low profile valve, and fits easily within a standard, e.g., 8-12 mm, delivery catheter without requiring the forceful loading of typical transcatheter valves, the side-loading valve **4102**

can be easily retrieved using the same delivery catheter that is used to deploy the valve.
[0288] FIG. **53**A is an illustration of a prosthetic valve **4202** according to an embodiment in a compressed configuration within a delivery catheter **4272**. The valve **4202** includes a frame **4210** that has and/or that forms a wire annulus support loop. The frame **4210** includes and/or forms (or the wire loop includes and/or forms) a distal upper tension arm **4231** and a distal lower tension arm **4232** that can be formed as a unitary or integral part and covered with a biocompatible material. The lower and upper tension arms **4231** and **4232** are elongated to the right and the prosthetic valve **4202** is shown laterally compressed in the delivery catheter **4272**. The lateral compression is a function of the use of minimal structural materials, e.g., a minimal inner valve sleeve of flow control component **4250** (FIG. **53**C), and the relatively short height of the frame **4210**. This lateral delivery provides for a relatively large, e.g., up to 80 mm or more, prosthetic valve. The lateral delivery also avoids the need to perform a 90-degree right turn when delivering the valve **4202** using the IVC femoral route. This sharp delivery angle when delivering traditional valves has also limited the size and make up of prior valve prostheses and the side-delivery of the valve **4202** avoids such limitations.
[0289] FIG. **53**B is an illustration of a profile, or plan, view of the wire-frame **4210** of the valve **4202** in an expanded configuration. FIG. **53**B shows the distal upper tension arm **4231** is attached to the tubular frame **4210** while the distal lower tension arm **4232** is shaped in an S-shape and is connected only to the distal upper tension arm **4231**.
[0290] FIG. **53**C is an illustration of a top view of the valve **4202** disposed in a native tricuspid valve. FIG. **53**C shows the tubular frame **4210** and the inner sleeve or flow control component **4250** sewn into a central aperture **4214** of the frame **4210**, with the two (2) panels extending downward (into the page) in a ventricular direction. FIG. **53**C shows the distal upper tension arms **4231** oriented towards the anterior leaflet side of the atrial floor around the native tricuspid valve, which is shown in dashed outline.
[0291] FIG. **53**D is an illustration of a plan view and FIG. **53**E is an illustration of a cut away plan view of the valve **4202**. FIG. **53**E shows the inner panel valve sleeve or flow control component **4250** mounted within the inner space or aperture **4214** defined by the tubular frame **4210**. FIG. **53**E shows an elongated two-panel valve sleeve or flow control component **4250** that extends into the sub-annular leaflet space. The tubular frame **4210** shown in FIG. **53**E is about 10 mm in height and the valve sleeve or flow control component **4250** extends about 10 mm below the bottom of the tubular frame **4210**, resulting in a valve **4202** having a total height of 20 mm.
[0292] FIG. **53**F is an illustration of a bottom view of the valve **4202** that shows the tubular frame **4210** having an inner sleeve or flow control component **4250** sewn into the central aperture **4214**, with the two panels extending upward (out of the page) in a ventricular direction. FIG. **53**F shows the distal lower tension arm **4242** oriented towards the anterior leaflet side of the ventricular ceiling of the native tricuspid valve, which is shown in dashed outline.
[0293] FIG. **54**A is an illustration of a profile, or plan, view of a prosthetic valve **4302** according to an embodiment in an expanded configuration. The valve **4302** has a braid or laser-cut frame **4310**. FIG. **54**A shows a distal upper tension arm **4331** attached to an upper edge of the tubular frame **4310**, and a distal lower tension arm **4332** attached to a lower edge of the tubular frame **4310**.
[0294] FIG. **54**B is an illustration of a top view of the valve **4302** disposed in a native tricuspid valve. FIG. **54**B shows the tubular frame **4310** having an inner sleeve or flow control component **4350** sewn into a central aperture of the frame **4310**, with the two panels extending downward (into the page) in a ventricular direction. FIG. **54**B shows the distal upper tension arm **4331** oriented towards the anterior leaflet side of the atrial floor of the native tricuspid valve, which is shown in dashed outline.
[0295] FIG. **54**C is an illustration of a plan view and FIG. **54**D is an illustration of a cut away plan view of the valve **4302**. FIG. **54**D shows the inner panel valve sleeve or flow control component **4350** mounted within the inner space or central aperture defined by the tubular frame **4310**.

[0296] FIG. **54**E is an illustration of a bottom view of the valve **4302** that shows the tubular frame **4210** having the inner sleeve or flow control component **4350** sewn into the central aperture, with the two (2) panels extending upward (out of the page) in a ventricular direction. FIG. **54**E shows the distal lower tension arm **4334** oriented towards the anterior leaflet side of the ventricular ceiling, which is shown in dashed outline.
[0297] FIG. **55**A is an illustration of a side perspective view of a valve **4402** according to an embodiment having a circular hyperboloid (hourglass) shape, in an expanded configuration. The valve **4402** includes a frame **4410** having an extended RVOT tab **4430**. The RVOT tab **4430** can be similar to the distal lower tension arms described herein. The wire frame details are not shown since in practice the external surface would preferably be covered, such as with Dacron polyester to facilitate in-growth. The frame **4410** includes a proximal fold area **4423**A and a distal fold area **4423**B that are shown on opposite ends of an anterior collar **4421** and posterior-septal collar **4422** along a horizontal long-axis **4411**. The frame **4410** defines a central channel or aperture that accepts a flow control component.
[0298] FIG. **55**B is an illustration of a cut away view of the valve **4402** showing circular hyperboloid (hourglass) shape thereof and the RVOT tab **4430** (e.g., the distal lower tension arm). FIG. **55**B shows that an inner leaflet **4453** and flow control component inner frame (not visible) are attached to an inner surface of the annular frame **4410**, with collar portion **4420** attached to the RVOT tab or subannular anchor portion **4430** via a wall portion **4412**. Here, the flow control component is only attached at the top edge although other non-limiting attachments are contemplated, e.g., mid-wall, multiple attachment points, etc.
[0299] FIG. **56**A is an illustration of a side view of a vertically compressible valve **4502** with an internal non-extending set of leaflets (e.g., a flow control component) and compressible orthogonal (wide) wire cells and shown in an expanded configuration for implanting in a desired location in the body.
[0300] FIG. **56**B is an illustration of a side view of the vertically compressible valve **4502** shown in a compressed configuration for delivery of the compressed valve **4502** to the desired location in the body.
[0301] FIG. **57**A is an illustration of a side view of a vertically compressible valve **4602** with extended leaflets **4653** (e.g., a flow control component) and compressible orthogonal (wide) wire cells and shown in an expanded configuration for implanting in a desired location in the body.
[0302] FIG. **57**B is an illustration of a side view of the vertically compressible valve **4602** shown in a compressed configuration for delivery of the compressed valve **4602**, where the wire frame is reduced in height (vertically compressed) and the extended leaflets are rolled up.
[0303] FIGS. **58**A and **58**B are illustrations of a side perspective view and a top view, respectively, of a valve **4702** having a wire frame **4710** that is formed from a single continuous wire, with an upper collar portion, a lower body portion having an hourglass shape, and a RVOT tab or distal lower tension arm extending away from the lower edge of the lower body portion of the frame **4710**. The valve **4702** is shown in an expanded configuration.
[0304] FIG. **59** is an illustration of a side perspective view of a valve frame **4810** formed from a series of wave-shaped wires **4825**E connected at connection points, with an upper collar portion, a lower body portion having an hourglass shape, and an RVOT tab or distal lower tension arm extending away from a lower edge of the lower body portion of the frame **4810**. The valve frame **4810** is shown in an expanded configuration. Sewing features are shown along the joining edges.
[0305] FIG. **60** is an illustration of a side perspective view of a valve frame **4910** formed from a series of horizontal wave-shaped wires **4925**F connected at connection points, with an upper collar portion, a lower body portion having an hourglass shape, and an RVOT tab or distal lower tension arm extending away from a lower edge of the lower body portion of the frame **4910**. The valve frame **4910** is shown in an expanded configuration. Sewing features are shown along the joining edges.

[0306] FIG. **61** is an illustration of a top view of flat wire frame of metal or metal alloy having compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **61** shows outer diamond cells **5025**A used for a collar portion of a wire frame with inner wave cells **5025**B used for a lower body portion of the wire frame, and diamond cells **5025**A used for a subannular tab **5030** (e.g., a distal lower tension arm).
[0307] FIG. **62** is an illustration of a top view of a portion of a wire frame in a funnel configuration (heat set) showing compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **62** shows outer diamond cells **5025**A used for a collar portion of the wire frame and inner diamond cells **5025**A used for a lower body portion of the wire frame and a subannular tab **5030** (e.g., a distal lower tension arm).
[0308] FIG. **63** is an illustration of a side view of a portion of a wire frame in a funnel configuration (heat set) showing compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **63** shows outer diamond cells **5025**A used for a collar portion of the wire frame and inner diamond cells **5025**A used for a lower body portion of the wire frame and a subannular tab **5030** (e.g., a distal lower tension arm).
[0309] FIG. **64** is an illustration of a side perspective view of a portion of a wire frame in a funnel configuration (heat set) showing compressible wire cells configured in a strain minimizing orientation to facilitate orthogonal loading and delivery of a prosthetic tricuspid valve. FIG. **64** shows outer diamond cells **5025**A used for a collar portion of the wire frame and inner diamond cells **5025**A used for a lower body portion of the wire frame, and irregular shaped cells used for a subannular tab **5030** (e.g., a distal lower tension arm).
[0310] FIG. **65**A is an illustration of a top view of a prosthetic valve **5102** according to an embodiment having braid or laser-cut wire frame **5110** and shown mounted within a cross-sectional view of the atrial floor at the annulus of a native tricuspid valve.
[0311] FIG. **65**B is an illustration of a bottom view of the valve **5102** having the braid or laser-cut wire frame **5110** that includes and/or forms a distal lower tension arm **5132** and shown mounted within a cross-sectional view of the ventricular ceiling at the annulus of a native tricuspid valve. FIG. **65**B shows a two-panel valve sleeve or flow control component **5150** in an open position and disposed within a central aperture **5114** of the frame **5110**. The flow control component **5150** can be in the open position, for example, for atrial systole and ventricular diastole.
[0312] FIG. **66** is an illustration of a prosthetic valve **5202** according to an embodiment, in an expanded configuration. The valve **5202** includes a frame **5210** that has and/or that forms a wire annulus support loop, with two vertical support posts **5252** extending down the edge on opposing sides of an inner sleeve or flow control component **5250**. During compression into a delivery catheter, the posts **5252** are engineered to fold horizontally, and to elastically unfold during ejection to deploy the valve sleeve or flow control component **5250**. FIG. **66** also shows the frame **5210** with a distal upper tension arm **5231** and a distal lower tension arm **5232** that can be formed as a unitary or integral part and covered with a biocompatible material. FIG. **66** also illustrates a proximal tab **5230** that can be, for example, a tension arm and/or an anchoring post or point.
[0313] FIG. **67** is an illustration of a two-panel embodiment of an inner valve sleeve or flow control component **5350**. In some embodiments, the frame **5210** shown in FIG. **66** can be adapted to receive the flow control component **5350**.
[0314] FIGS. **68**A and **68**B are illustrations of a side perspective view and a cut away plan view, respectively, of a flow control component **5450** having two rigid support posts **5452**. FIG. **68**B shows the flow control component **5450** having the two rigid support posts **5452** mounted within the inner space or central aperture define by a tubular frame **5410**, where the frame **5410** includes a distal upper tension arm **5431** and a distal lower tension arm **5432** extending away from the frame

5410.
[0315] FIG. **69** is an illustration of a three-panel embodiment of an inner valve sleeve of flow control component **5550** according to an embodiment.
[0316] FIG. **70**A is an illustration of a three-panel embodiment of an inner valve sleeve or flow control component **5550** having three rigid support posts **5552** according to an embodiment.
[0317] FIG. **70**B is an illustration of a cut away plan view of the three panel, three post valve sleeve or flow control component **5550** mounted within the inner space or central aperture defined by a tubular frame **5510**, where the frame **5510** includes a distal upper tension arm **5531** and a distal lower tension arm **5532** extending away from the frame **5510**.
[0318] FIG. **71**A is an illustration of one embodiment of a partial cut-away interior view of a tri-leaflet embodiment of a low profile, e.g., 8-20 mm, side-loaded prosthetic valve **5702** having a frame **5710** and a flow control component **5750**. The frame **5710** includes a distal lower tension arm **5732**. The flow control component **5750** is a tri-leaflet flow control component with three rigid support posts **5752**.
[0319] FIG. **71**B is an illustration of another embodiment of a partial cut-away interior view of the tri-leaflet embodiment of the low profile, e.g., 8-20 mm, side-loaded prosthetic valve **5702** showing the flow control component **5750** in a non-cut-away view.
[0320] FIG. **71**C is an illustration of a top view of the tri-leaflet embodiment of the low profile, e.g., 8-20 mm, side-loaded prosthetic valve **5702**.
[0321] FIGS. **72**A-**72**C are various schematic illustrations of a delivery system **270** for delivering a transcatheter prosthetic valve **202** according to an embodiment. The transcatheter prosthetic valve **202** is configured to deployed in a desired location within a body (e.g., of a human patient) and to permit blood flow in a first direction through an inflow end of the transcatheter prosthetic valve **202** and to block blood flow in a second direction, opposite the first direction, through an outflow end of the transcatheter prosthetic valve **202**. For example, the transcatheter prosthetic valve **202** can be a transcatheter prosthetic heart valve configured to be deployed within the annulus of a native tricuspid valve or native mitral valve of a human heart to supplement and/or replace the functioning of the native valve.
[0322] The transcatheter prosthetic valve **202** is compressible and expandable in at least one direction perpendicular to a long-axis of the valve **202**. The valve **202** is configured to compressible and expandable between an expanded configuration for implanting at a desired location in a body (e.g., a human heart) and a compressed configuration for introduction into the body via the delivery system **270**.
[0323] In some embodiments, the prosthetic valve **202** can be similar to or substantially the same as the valve **102** described above with reference to FIGS. **1**A-**1**F. For example, FIG. **72**B shows that the valve **202** can include an annular support frame **210** and a flow control component **250**. The annular support frame **210** can be similar to the frame **110** and can include a cuff or collar portion **220** and a tubular section (e.g., a lower tubular body portion) **212**, and a guidewire collar **240**. In addition, the annular support frame **210** defines an aperture **214** that extends along or in the direction of a central axis **213** of the frame **210**. While not shown, the frame **210** and/or the valve **202** can also include one or more tension arms, anchoring tabs, and/or the like. The flow control component **250** can be similar to the flow control component **150** described above with reference to FIGS. **1**A-**1**F. The valve **202** being substantially similar to the valve **102**, is not described in further detail herein.
[0324] As shown in FIGS. **72**A-**72**C, the delivery system **270** includes a delivery catheter **272**, a secondary catheter **280**, and a guidewire **285**. The delivery system **270** can be configured to orthogonally deliver the compressed valve **202** and/or portions of the valve **202** (e.g., the compressed frame **210** or the compressed flow control component **250**) to a desired location in the body such as, for example, the annulus of a native tricuspid valve and/or the annulus of a native mitral valve of the human heart. As described in detail above with reference to the valve **102**, the

delivery system **270** can orthogonally deliver the valve **202**, which has been compressed to the compressed configuration by being compressed along the central axis **213** (FIG. **72**B) or compressed in a lateral direction (e.g., orthogonal to the central axis **213** and a central lengthwise axis **275** of the delivery catheter **272**). Such compression can result in elongation of the valve **202** along a longitudinal axis (not shown in FIGS. **72**A-**72**C), which is substantially parallel to the central lengthwise axis **275** of the delivery catheter **272**.

[0325] The delivery catheter **272** defines a lumen **274** that extends along or in the direction of the central lengthwise axis **275**. The lumen **274** of the delivery catheter **272** can have a diameter sufficient to receive the compressed valve **202** therethrough. For example, the delivery catheter **272** can be 22-34 Fr, with any suitable corresponding internal lumen diameter and/or an internal lumen diameter sufficient to receive the prosthetic valve **202** in the compressed configuration.

[0326] The guidewire **285** extends or threads through the secondary catheter **280**, the valve **202**, and the delivery catheter **272**. The guidewire **285** can be, for example, a sheathed guidewire at least partially sheathed by the secondary catheter **280**. The guidewire **285** is configured to be advanced through the anatomy of the body and placed in a desired position relative to native tissue (e.g., a native valve). In some instances, the guidewire **285** can be advanced to provide a wire path (e.g., for the delivery catheter **272**, the valve **202**, etc.) to the RVOT. The guidewire **285** extends through the guidewire collar **240** of the valve **202** to provide a wire path along which the valve **202** is advanced.

[0327] The secondary catheter **280** can be a sheath, tube, annular rod or wire, and/or the like. In some embodiments, the secondary catheter **280** is a hypotube sheath disposed about a portion of the guidewire **285** (e.g., the secondary catheter **280** and the guidewire **285** collectively form a sheathed guidewire or sheathed guidewire assembly). The secondary catheter **280** can have a relatively small size allowing the secondary catheter **280** to be advanced through the delivery catheter **272** and/or at least partially disposed in or otherwise engaged with the guidewire collar **240**. As shown in FIGS. **72**A-**72**C, the secondary catheter **280** has a lumen with an internal diameter that is greater than the guidewire **285**, allowing the guidewire **285** to pass therethrough.

[0328] The pusher **281** is disposed within the secondary catheter **280** and is configured to push on a portion of the valve **202** to advance the valve **202** through and/or out of the delivery catheter **272**. In some implementations, the pusher **281** is configured to push against a portion of the guidewire collar **240** of the valve **202**. For example, the guidewire collar **240** can allow the guidewire **285** to be advanced through the guidewire collar **240** and can block and/or substantially prevent the pusher **281** from being advanced beyond the guidewire collar **240** (or at least a portion thereof). While the pusher **281** is shown disposed in the secondary catheter **280**, in some embodiments, the secondary catheter **280** can be used as the pusher **281**. In such embodiments, the delivery system **270** need not include a separate pusher **281**.

[0329] The guidewire collar **240** of the valve (FIG. **72**B) can be any suitable element that selectively allows the guidewire **285** to be advanced therethrough while blocking or preventing the advancement of the secondary catheter **280** and/or the pusher **281** beyond the guidewire collar **240**. In some embodiments, the guidewire collar **240** can be included in, formed by, and/or attached to the cuff **220** of the frame **210**. In some embodiments, guidewire collar **240** can be included in, formed by, and/or attached to a tension arm such as, for example, a distal upper tension arm, a distal lower tension arm, and/or the like. In certain embodiments, the distal lower tension arm can form and/or can include a feature that forms the guidewire collar **240**. It may be desirable to attach the guidewire collar **240** to the distal lower tension arm since both the guidewire **285** and the distal lower tension arm are inserted into or directed toward the RVOT.

[0330] In some embodiments, the guidewire collar **240** can be a ball or feature of a tension arm that defines an aperture or lumen that is sufficiently large to allow the guidewire **285** to pass through but is not sufficiently large to allow the secondary catheter **280** and/or the pusher **281** to be advanced therethrough. As such, the secondary catheter **280** and/or the pusher **281** can be stopped

against the guidewire collar **240** by the larger circumference of the secondary catheter **280** and/or pusher **281** relative to the aperture or lumen of the guidewire collar **240**. Such an arrangement allows the secondary catheter **280** and/or pusher **281** to push on the guidewire collar **240** and thus, the tension arm (e.g., the distal lower tension arm) to which it is attached. When the guidewire collar **240** is attached to a distal tension arm, the pushing on the guidewire collar **240** is operative to pull the valve **202** through and/or out of the delivery catheter **272**. It is contemplated that the guidewire collar **240** can have any suitable configuration that allows the guidewire collar **240** to permit the advancement of the guidewire **285** while limiting, blocking, or preventing advancement of the secondary catheter **280** and/or the pusher **281**. Moreover, the release mechanism **282** can be configured to release the guidewire **285**, the secondary catheter **280** and/or the pusher **281** from the guidewire collar **240**, for example, after deployment of the valve **202**.

[0331] FIG. **72**C shows the delivery system **270** delivering the valve **202** to a native valve such as a mitral valve or pulmonary valve (or tricuspid valve or aortic valve). The guidewire **285** is advanced to through the annulus of the native valve and disposed within the ventricle (e.g., within the RVOT). The delivery catheter **272** can be advanced over the guidewire **285** and delivered to the desired location at or near the annulus. Once the delivery catheter **272** is in the desired location, the valve **202** can be advanced over the guidewire **285** and within the delivery catheter **272** by pushing on the secondary catheter **280** and/or pusher **281**. When the guidewire collar **240** is attached to a distal or anterior side of the valve **202** or frame **210**, the pushing of the secondary catheter **280** and/or pusher **281** acts like a pulling force relative to, for example, the tubular section **212** of the valve frame **210** and/or the flow control component **250** of the valve **202**. Moreover, the secondary catheter **280** and/or the pusher **281** can be used to eject the valve **202** from the delivery catheter **272**. Once ejected from the delivery catheter **272**, the valve **202** is allowed to expand to the expanded configuration and can be seated within the annulus of the native valve. In some embodiments, secondary catheter **280**, the pusher **281**, and/or the guidewire **285** can be released from the guidewire collar **240** to allow the secondary catheter **280**, the pusher **281**, and/or the guidewire **285** to be retracted and/or withdrawn. In some embodiments, the secondary catheter **280** and/or the pusher **281** can be used to push at least a proximal side of the valve **202** or valve frame **210** into the annulus, thereby completely seating and/or deploying the valve **202**. Although not shown in FIGS. **72**A-**72**C, in some embodiments the secondary catheter **280** and/or pusher **281** can be further used to deliver and/or anchor a tissue anchor to the proximal side of the valve **202** or valve frame **210**. Thus, the delivery system **270** can deliver a traditionally compressed valve or orthogonally deliver vertically and/or laterally compressed valve **202**.

[0332] FIG. **72**D is a flowchart describing a method **300** for delivering a low profile, side-loaded prosthetic valve such as any of the valves disclosed herein, according to an embodiment. The method **300** includes disposing in an atrium of the heart, a distal portion of a delivery catheter containing a frame of a prosthetic valve in a compressed configuration, directed towards the annulus of a native valve of the heart, at **302**. The valve can be any of the valves disclosed herein. For example, the valve can be similar in at least form and/or function to the valves **102** and/or **202** described above. In some embodiments, the valve can be a valve (i) where the valve has a tubular frame with a flow control component mounted within the tubular frame, (ii) where the valve or flow control component is configured to permit blood flow in a first direction through an inflow end of the valve and to block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, (iii) where the valve is compressible and expandable and has a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and (iv) where the long-axis is parallel to a length-wise cylindrical axis of a delivery catheter used to deliver the valve.

[0333] A tension arm of the prosthetic valve frame is released from the delivery catheter, **304**. The tension arm can be, for example, a distal lower tension arm of the valve frame. The arrangement of the valve within the delivery catheter can be such that the distal lower tension arm is distal to the

valve body. In other words, the compressed valve is disposed within the delivery catheter such that a long-axis (a longitudinal axis) is substantially parallel to a long-axis or length-wise axis of the delivery catheter with the distal lower tension arm extending in a distal direction from the valve body. Thus, the distal lower tension arm is generally released from the delivery catheter prior to the valve body.

[0334] A distal portion of the tension arm is disposed on the ventricle side of the annulus of the native valve while the distal end of the delivery catheter remains on the atrium side of the annulus, at **306**. The tension arm (e.g., the distal lower tension arm) can extend through the native annulus and at least partially disposed within the RVOT. In some instances, the tension arm can engage sub-annular tissue to at least partially secure the distal end portion of the valve to the native annular tissue while the remainder of the valve is maintained in a supra-annular position within the atrium side of the annulus.

[0335] The remainder of the prosthetic valve frame is released from the delivery catheter, at **308**. As described in detail above with respect to specific embodiments, releasing the remainder of the prosthetic valve allows the prosthetic valve to expanded from the compressed configuration within the delivery catheter to the expanded configuration outside of the delivery catheter and suitable for deployment into the native annulus.

[0336] The method **300** optionally may include holding the prosthetic valve frame at an angle relative to the native valve annulus, at **310**. The angle can be, for example, an oblique angle relative to the native valve annulus. In some embodiments, a delivery system or the like can include a secondary catheter or push/pull rod that can be used to (1) advance the valve through the delivery catheter and (2) temporarily hold the prosthetic valve at the angle relative to the native valve annulus. If the prosthetic valve is held at the angle, blood may be allowed to flow from the atrium to the ventricle partially through the native valve annulus around the prosthetic valve frame, and partially through the prosthetic valve, at **312**. The blood flow may be used to optionally assess valve function, at **314**. If the prosthetic valve does not appear to be functioning properly, the valve can be replaced without having to remove a fully deployed valve.

[0337] Dispose the tubular portion of the frame within the annulus of the native valve, at **316**. For example, in some embodiments, the secondary catheter or push/pull rod can be used to push at least the proximal end portion of the valve into the native annulus. In some implementations, one or more walls of the valve and/or one or more proximal or distal tension arms can be used to seat the prosthetic valve within the native annulus. For example, the tension arms can exert opposing forces that can at least partially secure the prosthetic valve to the annular tissue. In some embodiments, the tension arms and/or any other portion of the frame can form a rotational or pressure lock against the annular tissue. With the tubular portion of the frame within the annulus of the native valve, the prosthetic valve can be fully deployed.

[0338] The method **300** optionally may include anchoring the proximal portion of the frame of the prosthetic valve to tissue surrounding the native valve, at **318**. For example, the proximal portion of the frame can be anchored using any of the tissue anchors and/or anchoring methods described herein. In some implementations, the proximal portion of the frame can be anchored using a tissue anchor that engages a portion of the frame and inserted into the tissue surrounding the native valve.

[0339] The method **300** optionally may include delivering to an aperture of the prosthetic valve frame a flow control apparatus, at **320**. For example, as described above with reference to the valve **102** shown in FIGS. **1**A-**1**F, the valve can be deployed in the annulus of a native valve as a single integrated component—the valve including a valve frame and a flow control component disposed in the aperture of the valve frame. In other embodiments, however, the valve can be deployed in the annulus of a native valve in two or more independent or separate processes. In some instances, delivering the valve in two or more parts can allow the separately delivered components to be compressed into a smaller or tighter compressed configuration. In some such instances, the valve frame can be compressed and delivered to the annulus of the native valve as described in the

method **300** above. After fully seating or deploying the valve frame in the annulus of the native valve, the flow control component can be compressed and delivered to the valve frame. The flow control component can be a self-expanding valve component or can be balloon-expanded once placed in a desired position within the valve frame.

[0340] Provided below is a discussion of certain aspects or embodiments of transcatheter prosthetic valves, delivery systems, and/or delivery methods. The transcatheter prosthetic valves (or aspects or portions thereof), the delivery systems, and/or the delivery methods described below with respect to specific embodiments can be substantially similar in at least form and/or function to the valve **202** and/or corresponding aspects of the valve **202**, the delivery system **270**, and/or the delivery method **300** described above with reference to FIGS. **72**A-**72**D. Thus, certain aspects of the specific embodiments are not described in further detail herein.

[0341] FIG. **73**A is an illustration of a side view of human heart anatomy, and FIG. **73**B is an enlarged illustration of a portion of the human heart anatomy of FIG. **73**A showing the geometric relationship between the inferior vena cava (IVC), the three leaflet cusps of the tricuspid valve—anterior, posterior, septal—the RVOT, and the pulmonary artery (PA).

[0342] FIG. **74** is an illustration of a side perspective view of a side delivered valve **5802** seated with the native tricuspid annulus with collar portion **5820** of the valve **5802** (or valve frame) laying atrially above the tricuspid annulus and leaflets, lower body portion extending into and through the annulus to provide corrective hemodynamic flow from the flow control component. FIG. **74** also shows a RVOT footer tab or a distal lower tension arm **5832** disposed in the RVOT.

[0343] FIG. **75**A is an illustration of a plan view of a native right atrium of a human heart, and shows the superior vena cava (SVC), the inferior vena cava (IVC), the right atrium (RA), the tricuspid valve and annulus (TCV), the anterior leaflet (A), the posterior leaflet (P), the septal leaflet(S), the right ventricle (RV), and the right ventricular outflow tract (RVOT).

[0344] FIG. **75**B is an illustration of a prosthetic valve **5902** according to an embodiment being delivered to the tricuspid valve annulus. FIG. **75**B shows the valve **5902** having a braided/laser cut-frame **5910** with a distal lower tension arm **5932** that is being ejected from a delivery catheter **5972** and directed through the annulus and towards the right ventricular outflow tract.

[0345] FIG. **75**C is an illustration of the valve **5902** showing the braided/laser cut-frame **5910** with the distal lower tension arm **5932** and the distal upper tension arm **5931** ejected from the delivery catheter **5972** via a secondary catheter and/or pusher **5980**, the distal lower tension arm **5932** being directed through the annulus and into the RVOT, and the distal upper tension arm **5931** staying in a supra-annular position, and causing a passive, structural anchoring of the distal side of the valve **5902** about the annulus.

[0346] FIG. **75**D is an illustration of the valve **5902** showing the entire braided/laser cut-frame **5910** ejected from the delivery catheter **5972**, the distal lower tension arm **5932** being directed through the annulus and into the RVOT, the distal upper tension arm **5931** staying in a supra-annular position, and causing a passive, structural anchoring of the distal side of the valve about the annulus, and at least one tissue anchor (not shown) anchoring the proximal side of the prosthesis into the annulus tissue.

[0347] FIG. **76**A is an illustration of a prosthetic valve **6002** according to an embodiment being delivered to tricuspid valve annulus. FIG. **76**A shows a distal lower tension arm **6032** of the valve **6002** ejected from a delivery catheter and being directed through the annulus and towards the RVOT. In this example, delivery of the valve **6002** can include a valve assessment process.

[0348] FIG. **76**B shows distal lower tension arm **6032** and a distal upper tension arm **6031** ejected from the delivery catheter, the distal lower tension arm **6032** is directed through the annulus and into the RVOT, and the distal upper tension arm **6031** stays in a supra-annular position, and causing a passive, structural anchoring of the distal side of the valve **6002** about the annulus. FIG. **76**B shows that the valve **6002** can be held (e.g., by a secondary catheter (not shown)) at an oblique angle in a pre-attachment position, so that the valve can be assessed, and once valve function and

patient conditions are correct, the secondary catheter can push the proximal side of the valve **6002** from its oblique angle, down into the annulus. By allowing two pathways for blood flow, the first through the native valve near the posterior leaflet, and the second through the central aperture of the prosthetic valve **6002**, a practitioner can determine if the heart is decompensating or if valve function is less than optimal. The secondary catheter can then install one or more anchoring elements or otherwise secure the valve **6002** in the native valve.

[0349] FIG. **76**C is an illustration of the valve **6002** showing the entire braided/laser cut-frame valve **6002** ejected from the delivery catheter, the distal lower tension arm **6032** is directed through the annulus and into the RVOT, the distal upper tension arm **6031** stays in a supra-annular position, and causes a passive, structural anchoring of the distal side of the valve **6002** about the annulus, and optionally at least one tissue anchor (not shown) anchoring the proximal side of the valve **6002** into the annulus tissue.

[0350] FIG. **77**A is an illustration of a side perspective view of a valve **6102** that is vertically compressed without folding into a compressed configuration and loaded into a delivery catheter **6172**. By using horizontal rather than traditional vertical diamond shaped cells, a frame **6110** of the valve **6102** can be compressed from top to bottom. This allows for orthogonal delivery of a much larger diameter valve than can be delivered using traditional axial compression. Additionally, the orthogonal delivery provides access from the IVC to the tricuspid annulus using a subannular distal-side anchoring tab or distal lower tensioning arm **6132**. Normally, a delivery catheter would need to make a 90-120 degree right turn before expelling a traditional transcatheter axially compressed valve. In contrast, the vertically compressed valve **6102** (e.g., compressed in the direction of a central aperture or the direction of blood flow through the valve **6102**) can be directly expelled into the distal side of the tricuspid annulus.

[0351] FIG. **77**B is an illustration of a side perspective view of the valve **6102** being partially expelled or released from the delivery catheter **6172** that allows a transition from native blood flow through the native tricuspid valve and a partial flow around the prosthetic valve **6102** and into the native annulus to a partial flow through an inflow end (indicated in FIG. **77**B by the arrow labeled “Inflow”) and out of an outflow end (indicated in FIG. **77**B by the arrow labeled “Outflow”) of the prosthetic valve **6102** into the native annulus. A guide wire **6185** is shown pig-tailed into the pulmonary artery of the heart. A rigid pull rod/wire, pusher, and/or secondary catheter **6180** in some embodiments is engineered to ride over the guide wire **6185**, thus allowing the valve **6102** to be delivered exactly where intended. The distal subannular tab or distal lower tension arm **6132** is directed into the RVOT and is configured to provide anchoring for the valve **6102** while it is positioned and assessed.

[0352] FIG. **77**C is an illustration of a side perspective view of the valve **6102** being fully expelled or released from the delivery catheter **6172** into an expanded configuration. The valve **6102** is lodged using the distal tab or distal lower tension arm **6132** against the distal surface of the annulus and held using the rigid pull rod/wire or pusher **6180** at an elevated angle above the native annulus prior to complete deployment of the valve **6102**. This allows a further transition from native blood flow through the native tricuspid valve with a partial flow around the prosthetic valve **6102** and into the native annulus, and an increasing partial flow through the inflow end and out of the outflow end of the prosthetic valve **6102** into the native annulus. FIG. **77**C also shows the guide wire **6185** pig-tailed into the pulmonary artery of the heart (through the LVOT). FIG. **77**C further shows a proximal subannular anchoring tab or proximal lower tension arm (proximal tab) **6134**, which can facilitate the mounting or anchoring for the valve **6102** once entirely deployed in the native annulus.

[0353] FIG. **77**D is an illustration of a side perspective view of the valve **6102** being fully expelled or released from the delivery catheter **6172** and completely seated into the native annulus. The delivery of the valve **6102** just described allows a smooth transition from native blood flow to a full, complete flow through the prosthetic valve **6102** and thus, the native annulus. The valve **6102**

is anchored using subannular distal tab (distal lower tension arm) **6132**, the subannular proximal tab (proximal lower tension arm) **6134**, and a supra-annular (atrial) upper tension arm (distal upper tension arm) **6131**. Corrected replacement flow using the valve **6102** is shown by Inflow through the inflow end and Outflow through the outflow end of the prosthetic valve **6102** and thus, the native annulus.

[0354] FIG. **78**A is an illustration of a side perspective view of a valve **6202** that is vertically compressed without folding, into a compressed configuration and loaded into a delivery catheter **6272** and shows a flow control component **6250** in a rolled configuration. A guide wire **6285** and an RVOT tab or distal lower tension arm **6232** are shown extended into the pulmonary artery and allowing the valve **6202** to be precisely delivered.

[0355] FIG. **78**B is an illustration of a side perspective view of the valve **6202** being partially expelled or released from the delivery catheter **6272**, with inner leaflets **6253** of the flow control component **6250** partially unfurled and extended. FIG. **78**B shows a transition from native blood flow through the native tricuspid valve to a partial flow around the prosthetic valve **6202** and into the native annulus to a partial flow through an inflow end (indicated in FIG. **78**B by the arrow labeled “Inflow”) and out of an outflow end (indicated in FIG. **78**B by the arrow labeled “Outflow”) of the prosthetic valve **6202** into the native annulus. A rigid pull rod/wire, pusher, and/or secondary catheter **6280** in some embodiments is engineered to ride over the guide wire **6285**. The RVOT tab or distal lower tension arm **6232** is directed into the RVOT and is configured to provide anchoring for the valve **6202** while it is positioned and assessed. The valve **6202** has a distal mid-wall arch above the RVOT tab or distal lower tension arm **6232** for engaging the native annulus.

[0356] FIG. **78**C is an illustration of a side perspective view of the valve **6202** being fully expelled or released from the delivery catheter **6272** into an expanded configuration, with the inner leaflets **6253** of the flow control component **6250** a fully unfurled and extended. The valve **6202** is lodged using the distal tab or distal lower tension arm **6232** against the distal surface of the annulus and held elevated using the rigid puller/pusher or secondary catheter **6280** at an angle above the native annulus prior to complete deployment. This allows a further transition from native blood flow through the native tricuspid valve with a partial flow around the prosthetic valve **6202** and into the native annulus, and an increasing partial flow through the inflow end and out of the outflow end of the prosthetic valve **6202** into or through the native annulus. FIG. **78**C shows the distal mid-wall arch engaging the distal native annulus and shows a proximal mid-wall arch raised above the native annulus in preparation for a smooth transition to prosthetic flow when the valve **6202** is fully seated in the native annulus.

[0357] FIG. **78**D is an illustration of a side perspective view of the valve **6202** being fully expelled or released from the delivery catheter **6272** and completely seated into the native annulus. The delivery of the valve **6202** just described allows a smooth transition from native blood flow to a full, complete flow through the prosthetic valve **6202** and thus, the native annulus. The valve **6202** is anchored using subannular distal tab or distal lower tension arm **6232**, a subannular proximal tab or proximal lower tension arm **6234**, and a supra-annular (atrial) tab or distal upper tension arm **6231**. Corrected replacement flow through unfurled and extended leaflets **6253** is shown by Inflow through the inflow end and Outflow through the outflow end of the prosthetic valve **6202** and thus, the native annulus.

[0358] FIG. **79**A is an illustration of a side view of a valve **6302** in a compressed configuration within a delivery catheter **6372** according to an embodiment. FIG. **79**A shows how a central tube/wire or secondary catheter **6380** can be distally attached to a distal edge, RVOT tab, or distal lower tension arm **6332** and by pushing on the rigid tube/wire or secondary catheter **6380**, the compressed valve **6202** can be pulled from the proximal end of the catheter **6372** to the distal deployment end of the delivery catheter **6372**. This pulling action avoids pushing the valve **6302** out of the delivery catheter **6372**, which may cause additional radial expansion and radial forces

that can damage the valve **6302** when it is compressed within the delivery catheter **6372**.
[0359] FIG. **79**B is an illustration of a side view of the valve **6302** being partially compressed and partially released from the delivery catheter **6372** and shows how blood flow can begin to transition. The gradual, smooth transition from native flow to flow through the prosthetic valve **6302** by pulling on the valve **6302** using the rigid pusher or secondary catheter **6380** attached to the distal subannular anchoring tab or distal lower tension arm **6332** avoids the sphincter effect where the heart is cut off from the flow, resulting in a dry pump action, which can cause heart failure. When the valve **6302** is partially open (partially released) exposing only a part of a collar portion **6320** of a frame of the valve **6302** on a small fraction of right atrial blood flow going through the prosthetic valve **6302**, the washing effect provides for a smooth transition to a larger volume going through the valve **6302**.
[0360] FIG. **79**C is an illustration of a side view of the valve **6302** being partially compressed and partially released from the delivery catheter **6372** and shows how blood flow can begin its transition. The gradual, smooth transition from native flow to flow into the valve **6302** through an inflow end (indicated in FIG. **79**C by the arrow labeled “Inflow”) and out of an outflow end (indicated in FIG. **79**C by the arrow labeled “Outflow”) of the prosthetic valve **6302** by pulling from the distal subannular anchoring tab or distal lower tension arm **6332** avoids the sphincter effect where the heart is cut off from the flow, resulting in a dry pump action, and causing heart failure. When the valve is partially open exposing only a part of the collar portion **6320** on a small fraction of right atrial blood flow initially going through the prosthetic valve **6302**, with an increasing amount transitioning from flow around the valve **6302** to flow going through the valve **6302**, the washing effect provides for a smooth transition to a larger volume going through the valve **6302**.
[0361] FIG. **79**D is an illustration of a side view of valve **6302** being fully expanded or uncompressed into the expanded configuration and orthogonally released from the delivery catheter **6372**, and still releasably attached to the distal pull wire/deployment control wire or hypotube (secondary catheter) **6380** via the distal tab/RVOT tab or distal lower tension arm **6332**. The collar portion **6320** and lower body portion **6312** of the frame are fully expanded, permitting functioning of the flow control component **6350**. FIG. **79**D shows that the valve can be positioned or re-positioned by using the rigid pull wire **310**. Since the blood flow is not blocked, an interventionist is allowed the opportunity and time to ensure correct orientation of the valve **6302**, especially where the distal tab (mitral)/RVOT tab (tricuspid) or distal lower tension arm **6332** is used to assist in anchoring. Once proper orientation is achieved, the valve **6302** can be slowly seated into the native tricuspid annulus, providing a smooth blood flow transition from the native flow to the prosthetic flow. FIG. **79**D also shows a release mechanism **6382** for releasing the rigid pull device or secondary catheter **6380** from the valve body or distal lower tension arm **6332** by pulling on a trigger wire that is attached to a release hook, lock, bead, or other release mechanism.
[0362] FIG. **79**E is an illustration of a side view of the valve **6302** being fully expanded or uncompressed showing transition to all blood flow through the flow control component **6350** of the valve **6302** and no flow around the valve **6302** during or resulting from atrial sealing of an anterior collar portion **6321** and a posterior-septal collar portion **6322** against the atrial floor.
[0363] FIG. **80**A is an illustration of a side view of a valve **6402** being rolled into a compressed configuration within a delivery catheter **6472** and being advanced by a distal rigid pull wire/draw-wire or secondary catheter **6480** (or far-side push-pull wire) attached to a leading edge of a collar **6420** of a valve frame **6410**.
[0364] FIG. **80**B is an illustration of a side view of valve **6402** being partially unrolled and deployed from the delivery catheter **6472** by action of the pushing rod or secondary catheter **6480** on the distal upper edge of the collar **6420**.
[0365] FIG. **80**C is an illustration of a side view of the valve **6402** being partially unrolled and deployed from the delivery catheter **6472**, and shows the pushing rod or secondary catheter **6480**

maintaining connection to the valve **6401** while an anterior collar portion **6421** is unrolled and leaflets **6453** of a flow control component are uncovered.

[0366] FIG. **80**D is an illustration of a side view of valve **6402** being completely released and unrolled into the expanded configuration where the rigid pull device or secondary catheter **6480** is used to position the valve **6402** within the native annulus and obtain a good perivalvular seal via the anterior collar portion **6421** and a posterior-septal collar portion **6422** to transition to blood flow through the leaflets **6453**. FIG. **80**D also shows the release mechanism **6482** for releasing the rigid pull device or secondary catheter **6480** from the valve body or collar **6420** by pulling on a trigger wire that is attached to a release hook, lock, bead, or other release mechanism.

[0367] FIG. **80**E is an illustration of a side view of a valve **6502** according to an embodiment. FIG. **80**E shows that the valve **6502** can have a combination wire cell frame construction as described above with reference to FIG. **34**A and can be compressed into a compressed configuration within a delivery catheter **6572**, and shows that a draw/pulling wire or secondary catheter **6580** can be attached to a forward end of the compressed valve **6502** and can be pushed to pull the valve **6502** through and/or out of the delivery catheter **6572**. FIG. **80**E also shows the valve **6502** and the draw/pulling wire or secondary catheter **6580** being positioned over a guidewire **6585**.

[0368] FIG. **81**A is an illustration of a side or plan transparent view of a delivery catheter **6672** loaded with a side-delivered (orthogonal) valve **6602** in a compressed configuration. The valve **6602** has a frame with a tension arm (e.g., a distal lower tension arm) **6632**, a guidewire collar element **6640** attached to the tension arm **6632**, and a guidewire **6685** extending through the guidewire collar element **6640** with a guidewire sheath or secondary catheter **6680** pushing against the guidewire collar element **6640**. The enlarged inset shows a non-limiting example of the guidewire collar element **6640** attached to the tension arm **6632** with the guidewire **6685** extending through an aperture defined by the guidewire collar element **6640** and the hypotube sheath or secondary catheter **6680** stopped against the guidewire collar element **6640** by the larger circumference of the guidewire collar element **6640**, permitting pushing on the tension arm (e.g., the distal lower tension arm) **6632** to pull the valve **6602** through and/or out of the delivery catheter **6672**.

[0369] FIG. **81**B is another non-limiting example of a guidewire collar element **6640**A attached to the tension arm **6632** with the guidewire **6685** extending through the aperture of the guidewire collar element **6640**A and the hypotube sheath or secondary catheter **6680** stopped by the larger circumference of the hypotube sheath or secondary catheter **6680** relative to the aperture defined by the guidewire collar element **6640**A, permitting pushing on the tension arm (e.g., the distal lower tension arm) **6632** to pull the valve **6602** out of the delivery catheter **6672**. FIG. **81**B shows the tension arm **6632** being substantially hollow or annular, defining a lumen that extends therethrough. The guidewire collar element **6640**A is shown as a structure (e.g., a rounded structure) that constricts the lumen that extends through the tension arm **6632**, the hypotube sheath or secondary catheter **6680** having a circumference that is larger than the constriction permitting pushing on the tension arm (e.g., the distal lower tension arm) **6632** to pull the valve **6602** through and/or out of the delivery catheter **6672**.

[0370] FIG. **81**C is another non-limiting example of a guidewire collar element **6640**B attached to the tension arm **6632** with the guidewire **6685** extending through the aperture of the guidewire collar element **6640**B and the hypotube sheath or secondary catheter **6680** stopped by the guidewire collar element **6640**B as it slides over the guidewire **6685**—the guidewire is in the lumen of the hypotube sheath or secondary catheter **6680**—by the larger circumference of the hypotube sheath or secondary catheter **6680** relative to the aperture defined by the guidewire collar element **6640**B, permitting pushing on the tension arm (e.g., the distal lower tension arm) **6632** to pull the valve **6602** through and/or out of the delivery catheter **6672**.

[0371] FIG. **81**D is another non-limiting example of a guidewire collar element **6640**C attached to the tension arm **6632** with the guidewire **6685** extending through the aperture of the guidewire

collar element **6640**C and the hypotube sheath or secondary catheter **6680** stopped by the larger circumference of the hypotube sheath or secondary catheter **6680** relative to the guidewire collar element **6640**C, permitting pushing on the tension arm (e.g., the distal lower tension arm) **6632** to pull the valve **6602** through and/or out of the delivery catheter **6672**.

[0372] FIGS. **82**A-**82**C are various schematic illustrations of a delivery system **470** for delivering a transcatheter prosthetic valve **402** according to an embodiment. The transcatheter prosthetic valve **402** is configured to deployed in a desired location within a body (e.g., of a human patient) and to permit blood flow in a first direction through an inflow end of the transcatheter prosthetic valve **402** and to block blood flow in a second direction, opposite the first direction, through an outflow end of the transcatheter prosthetic valve **402**. For example, the transcatheter prosthetic valve **402** can be a transcatheter prosthetic heart valve configured to be deployed within the annulus of a native tricuspid valve or native mitral valve of a human heart to supplement and/or replace the functioning of the native valve.

[0373] The transcatheter prosthetic valve **402** is compressible and expandable in at least one direction perpendicular to a long-axis of the valve **402**. The valve **402** is configured to compressible and expandable between an expanded configuration for implanting at a desired location in a body (e.g., a human heart) and a compressed configuration for introduction into the body via the delivery system **470**.

[0374] In some embodiments, the prosthetic valve **402** can be similar to or substantially the same as the valve **102** described above with reference to FIGS. **1**A-**1**F. For example, FIG. **82**B shows that the valve **402** can include an annular support frame **410** and a flow control component **450**. The annular support frame **410** can be similar to the frame **110** and can include a cuff or collar portion **420** and a tubular section (e.g., a lower tubular body portion) **412**, and a guidewire collar **440**. In addition, the annular support frame **410** (referred to herein as "frame") defines an aperture **414** that extends along or in the direction of a central axis **413** of the frame **410**. While not shown, the frame **410** and/or the valve **402** can also include one or more tension arms, anchoring tabs, and/or the like. The flow control component **450** can be similar to the flow control component **150** described above with reference to FIGS. **1**A-**1**F. The valve **402** being substantially similar to the valve **102**, is not described in further detail herein.

[0375] As shown in FIGS. **82**A-**82**C, the delivery system **470** includes a delivery catheter **472**, a capsule **476**, a secondary catheter **480**, and a guidewire **485**. The delivery system **470** can be configured to orthogonally deliver the compressed valve **402** and/or portions of the valve **402** (e.g., the compressed frame **410** or the compressed flow control component **450**) to a desired location in the body such as, for example, the annulus of a native tricuspid valve and/or the annulus of a native mitral valve of the human heart. As described in detail above with reference to the valve **102**, the delivery system **470** can orthogonally deliver the valve **402**, which has been compressed to the compressed configuration by being compressed along the central axis **413** (FIG. **82**B) or compressed in a lateral direction (e.g., orthogonal to the central axis **413** and a central lengthwise axis **475** of the delivery catheter **472**). Such compression can result in elongation of the valve **402** along a longitudinal axis (not shown in FIGS. **82**A-**82**C), which is substantially parallel to the central lengthwise axis **475** of the delivery catheter **472**.

[0376] The delivery catheter **472** defines a lumen **474** that extends along or in the direction of the central lengthwise axis **475**. The lumen **474** of the delivery catheter **472** can have a diameter sufficient to receive the compressed valve **402** therethrough. For example, the delivery catheter **472** can be 22-34 Fr.

[0377] The capsule **476** is configured to facilitate placement into the delivery catheter **472** of the valve **402** in the compressed configuration. FIG. **82**A shows the valve **402** and at least a portion of the secondary catheter **480**, the pusher **481**, the release mechanism **482**, and the guidewire **485** disposed within the capsule **476**, which in turn, is positioned within or at the proximal end portion of the delivery catheter **472**. As described in detail above, the valve **402** can be compressed from a

configuration in which a circumference of the valve **402** in a plane orthogonal to the lengthwise axis **475** of the delivery catheter **472** is greater than the circumference or diameter of the lumen **474** of the delivery catheter **472**. The capsule **476** can be configured to compress the valve **402** to the compressed configuration, or to receive the valve **402**, which has already been compressed to the compressed configuration, such that the circumference of the compressed valve **402** within the capsule **476** is less than the circumference or diameter of the lumen **474** of the delivery catheter **472**.

[0378] The capsule **476** can be any suitable capsule, catheter, compression member, and/or device configured to compress the valve **402** into the compressed configuration or to receive the valve **402**, which has already been compressed to the compressed configuration. In some embodiments, the capsule **476** can be a compression catheter or sleeve configured to exert a compression force (e.g., squeeze) the valve **402**. In some embodiments, the capsule **476** can be configured to maintain the valve **402** in a rolled or folded configuration (e.g., compressed configuration) prior to the valve **402** being delivered into the delivery catheter **472**. In some embodiments, the delivery system **470** can include a tapering or funnel fixture that can compress the valve **402** to the compressed configuration, which can then be inserted into the capsule **476**. In some embodiments, the capsule **476** can be configured to deliver the valve **402** to the proximal end of the delivery catheter **472** and once delivered, can be removed and/or the valve **402** can be ejected from the capsule **476** into the delivery catheter **472**. In other embodiments, the valve **402** can remain within the capsule **476**, which are advanced, collectively, through the delivery catheter **472**.

[0379] The guidewire **485** extends or threads through the secondary catheter **480**, the valve **402**, and the delivery catheter **472**. The guidewire **485** can be, for example, a sheathed guidewire at least partially sheathed by the secondary catheter **480**. The guidewire **485** is configured to be advanced through the anatomy of the body and placed in a desired position relative to native tissue (e.g., a native valve). In some instances, the guidewire **485** can be advanced to provide a wire path (e.g., for the delivery catheter **472**, the valve **402**, etc.) to the RVOT. The guidewire **485** extends through the guidewire collar **440** of the valve **402** to provide a wire path along which the valve **402** is advanced.

[0380] The secondary catheter **480** can be a sheath, tube, annular rod or wire, and/or the like. In some embodiments, the secondary catheter **480** is a hypotube sheath disposed about a portion of the guidewire **485** (e.g., the secondary catheter **480** and the guidewire **485** collectively form a sheathed guidewire or sheathed guidewire assembly). The secondary catheter **480** can have a relatively small size allowing the secondary catheter **480** to be advanced through the delivery catheter **472** and/or at least partially disposed in or otherwise engaged with the guidewire collar **440**. As shown in FIGS. **82**A-**82**C, the secondary catheter **480** has a diameter that is greater than the guidewire **485**, allowing the guidewire **485** to pass therethrough.

[0381] The pusher **481** is disposed within the secondary catheter **480** and is configured to push on a portion of the valve **402** to advance the valve **402** through and/or out of the delivery catheter **472**. In some implementations, the pusher **481** is configured to push against a portion of the guidewire collar **440** of the valve **402**. For example, the guidewire collar **440** can allow the guidewire **485** to be advanced through the guidewire collar **440** and can block and/or substantially prevent the pusher **481** from being advanced beyond the guidewire collar **440** (or at least a portion thereof). While the pusher **481** is shown disposed in the secondary catheter **480**, in some embodiments, the secondary catheter **480** can be used as the pusher **481**. In such embodiments, the delivery system **470** need not include a separate pusher **481**.

[0382] The guidewire collar **440** of the valve (FIG. **82**B) can be any suitable element that selectively allows the guidewire **485** to be advanced therethrough while blocking or preventing the advancement of the secondary catheter **480** and/or the pusher **481** beyond the guidewire collar **440**. In some embodiments, the guidewire collar **440** can be included in, formed by, and/or attached to the cuff **420** of the frame **410**. In some embodiments, guidewire collar **440** can be included in,

formed by, and/or attached to a tension arm such as, for example, a distal upper tension arm, a distal lower tension arm, and/or the like. In certain embodiments, the distal lower tension arm can form and/or can include a feature that forms the guidewire collar **440**. It may be desirable to attach the guidewire collar **440** to the distal lower tension arm since both the guidewire **485** and the distal lower tension arm are inserted into or directed toward the RVOT.

[0383] In some embodiments, the guidewire collar **440** can be a ball or feature of a tension arm that defines an aperture or lumen that is sufficiently large to allow the guidewire **485** to pass through but is not sufficiently large to allow the secondary catheter **480** and/or the pusher **481** to be advanced therethrough. As such, the secondary catheter **480** and/or the pusher **481** can be stopped against the guidewire collar **440** by the larger circumference of the secondary catheter **480** and/or pusher **481** relative to the aperture or lumen of the guidewire collar **440**. Such an arrangement allows the secondary catheter **480** and/or pusher **481** to push on the guidewire collar **440** and thus, the tension arm (e.g., the distal lower tension arm) to which it is attached. When the guidewire collar **440** is attached to a distal tension arm, the pushing on the guidewire collar **440** is operative to pull the valve **402** through and/or out of the delivery catheter **472**. It is contemplated that the guidewire collar **440** can have any suitable configuration that allows the guidewire collar **440** to permit the advancement of the guidewire **485** while limiting, blocking, or preventing advancement of the secondary catheter **480** and/or the pusher **481**. Moreover, the release mechanism **482** can be configured to release the guidewire **485**, the secondary catheter **480** and/or the pusher **481** from the guidewire collar **440**, for example, after deployment of the valve **402**.

[0384] FIG. **82**C shows the delivery system **470** delivering the valve **402** to a native valve such as a mitral valve or pulmonary valve (or tricuspid valve or aortic valve). The guidewire **485** is advanced to through the annulus of the native valve and disposed within the ventricle (e.g., within the right ventricle outflow tract. The delivery catheter **472** can be advanced over the guidewire **485** and delivered to the desired location at or near the annulus. The valve **402** can be placed in the compressed configuration (e.g., by rolling, folding, and/or a combination thereof) and can be disposed within the capsule **476**. Once the delivery catheter **472** is in the desired location and the compressed valve **402** is in the capsule **476**, the capsule **476** can be used to deliver the compressed valve **402** into the lumen **474** of the delivery catheter **472**.

[0385] FIG. **82**A shows the capsule **476** delivering the compressed valve **402** into the proximal end of the delivery catheter **472**. In some instances, once the valve **402** is in the lumen **474** of the delivery catheter **472**, the capsule **476** can be removed and/or the valve **402** can be ejected from the capsule **476**. In other embodiments, the valve **402** can remain in the capsule **476** as the valve **402** is advanced through the delivery catheter **472**. The valve **402** can be advanced over the guidewire **485** and within the delivery catheter **472** by pushing on the secondary catheter **480** and/or pusher **481**. When the guidewire collar **440** is attached to a distal or anterior side of the valve **402** or frame **410**, the pushing of the secondary catheter **480** and/or pusher **481** acts like a pulling force relative to, for example, the tubular section **412** of the valve frame **410** and/or the flow control component **450** of the valve **402**.

[0386] FIG. **82**C shows the valve **402** partially ejected from the delivery catheter **472** and completely ejected from the capsule **476**. The ejecting of the valve **402** from the capsule **476** and the delivery catheter **472** can be a single integrated process or step or can be performed in any number of independent processes and/or steps. Alternatively, the capsule **476** can be removed once the valve **402** is delivered into the lumen **474** of the delivery catheter **472**.

[0387] The secondary catheter **480** and/or the pusher **481** can be used to eject the valve **402** from the delivery catheter **472**. Once ejected from the delivery catheter **472**, the valve **402** is allowed to expand to the expanded configuration and can be seated within the annulus of the native valve. In some embodiments, secondary catheter **480**, the pusher **481**, and/or the guidewire **485** can be released from the guidewire collar **440** to allow the secondary catheter **480**, the pusher **481**, and/or the guidewire **485** to be retracted and/or withdrawn. In some embodiments, the secondary catheter

480 and/or the pusher **481** can be used to push at least a proximal side of the valve **402** or valve frame **410** into the annulus, thereby completely seating and/or deploying the valve **402**. Although not shown in FIGS. **82**A-**82**C, in some embodiments the secondary catheter **480** and/or pusher **481** can be further used to deliver and/or anchor a tissue anchor to the proximal side of the valve **402** or valve frame **410**. Thus, the delivery system **470** can deliver a traditionally compressed valve or orthogonally deliver a vertically and/or laterally compressed valve **402**. Moreover, the delivery system **470** includes the capsule **476**, which can maintain the valve **402** in the compressed configuration at least until the valve **402** is delivered into the delivery catheter **472**.

[0388] FIG. **82**D is a flowchart describing a method **500** for delivering a compressible prosthetic valve such as any of the prosthetic valves described herein, according to an embodiment. The method **500** includes advancing over a guidewire a delivery catheter to dispose a distal end of the delivery catheter at a desired location within a body, at **502**. The desired location within the body can be, for example, an annulus of a native valve within the human heart. Prior to advancing the delivery catheter, the guidewire can be advanced into the desired location and placed, for example, within a right ventricle outflow tract or in another desired position relative to the annulus.

[0389] A valve capsule is mounted onto a proximal end of the guidewire, where the valve capsule contains a prosthetic valve in a compressed configuration and having a guidewire collar with an aperture therethrough having an internal diameter larger than the diameter of the guidewire, with the guidewire disposed through the aperture, at **504**. The arrangement of the prosthetic valve, guidewire collar, guidewire, and capsule can be substantially similar to the arrangement described above with reference to the delivery system **470**. In some embodiments, the valve capsule can be configured to place and/or to maintain the prosthetic valve in the compressed configuration prior to the prosthetic valve being delivered and/or loaded into the delivery catheter.

[0390] The valve capsule is loaded into a proximal end of the delivery catheter, at **506**. The valve capsule can have an outer diameter or circumference that is smaller than the diameter or circumference of the lumen of the delivery catheter, thereby allowing the valve capsule to be disposed within the lumen. Moreover, the valve capsule can maintain the prosthetic valve in the compressed configuration and the loading of the valve capsule similarly loads the prosthetic valve into the proximal end of the delivery catheter.

[0391] Proximal to the prosthetic valve, a pusher is disposed over the guidewire, wherein the pusher has an outside diameter larger than the inside diameter of the aperture in the guidewire collar, at **508**. The pusher can be similar to the pusher **481** described above with reference to FIGS. **82**A-**82**C. In some embodiments, the pusher can be a secondary catheter or the like that can form a sheath of the guidewire. In other embodiments, the pusher can be inserted into or at least partially disposed within the secondary catheter.

[0392] The prosthetic valve is advanced distally from the valve capsule into and through the lumen of the delivery catheter to the distal end of the delivery catheter, at **510**. In some embodiments, the loading and/or delivery of the valve capsule into the proximal end of the delivery catheter can begin to eject the prosthetic valve from the valve capsule as the valve capsule is moved relative to or within the delivery catheter. In other embodiments, the prosthetic valve can remain within the valve capsule until the prosthetic valve is at or near the distal end of the delivery catheter. In some embodiments, the valve capsule can be a compression catheter or sleeve that can be slid off or relative to the prosthetic valve to allow the prosthetic valve to move distally from the valve capsule. As described above with reference to the delivery system **470**, the prosthetic valve can be advanced distally by pushing on the pusher and/or the second catheter, which in turn, can push or pull the prosthetic valve in the distal direction through the delivery catheter.

[0393] The prosthetic valve is deployed from the distal end of the delivery catheter to the desired location, at **512**. As described above, the pusher or secondary catheter can be used to eject the prosthetic valve from the distal end of the delivery catheter. Moreover, the prosthetic valve can similarly be advanced relative to or ejected from the valve capsule. Thus, when the prosthetic valve

is disposed outside of and distal to the delivery catheter (e.g., within the atrium of the heart), the prosthetic valve can be allowed to expand to an expanded configuration suitable for deployment into the annulus of the native valve. In some instances, the pusher and/or the secondary catheter can be used to push the prosthetic valve into the annulus of the native valve, and the prosthetic valve can form a seal with the native annular tissue when deployed therein.

[0394] Provided below is a discussion of certain aspects or embodiments of transcatheter prosthetic valves, delivery systems, and/or delivery methods. The transcatheter prosthetic valves (or aspects or portions thereof), the delivery systems, and/or the delivery methods described below with respect to specific embodiments can be substantially similar in at least form and/or function to the valve **402** and/or corresponding aspects of the valve **402**, the delivery system **470**, and/or the delivery method **500** described above with reference to FIGS. **82**A-**82**D. Thus, certain aspects of the specific embodiments are not described in further detail herein.

[0395] FIGS. **83**A-**83**F illustrate a process for delivery of an orthogonal transcatheter prosthetic valve **6702** to the tricuspid annulus of the human heart. FIG. **83**A is an illustration of a first step of the delivery process in which a guidewire **6785** with a hypotube sheath or secondary catheter **6780** is delivered to the RVOT. The guidewire **6785** has a diameter of about 0.035 in (or about 0.889 mm).

[0396] FIG. **83**B shows a delivery catheter **6772** being advanced over the guidewire **6785** to and through the native tricuspid annulus to the right ventricle.

[0397] FIG. **83**C shows the valve **6702** in a compressed configuration disposed within a capsule/compression catheter **6776**. The capsule **6776** is loaded into a proximal end of the delivery catheter **6772** and the valve **6702** is withdrawn from the capsule **6776** into the delivery catheter **6772**, with the sheathed guidewire **6785** threaded through the valve **6702** and providing a wire path to the RVOT, planned deployment location. In another embodiment, the capsule **6776** with the valve **6702** disposed therein can be advanced through at least part of the delivery catheter **6772**. The guidewire **6785** can extend through a guidewire collar element **6740** of the valve **6702** while the larger circumference of the hypotube sheath or secondary catheter **6780** relative to an aperture of the guidewire collar element **6740** blocks passage of the hypotube sheath or secondary catheter **6780** through the guidewire collar element **6740**.

[0398] FIG. **83**D shows the valve **6702** being expelled and/or released out of the delivery catheter **6772** into the expanded configuration and deployed into the native annulus by pushing on the hypotube sheath or secondary catheter **6780** against the guidewire collar element **6740** to pull the valve **6702** through the delivery catheter **6772** and into position in the native tricuspid annulus. The tension arm (e.g., the distal lower tension arm) **6732** is used to position the expanded valve **6702** in the native annulus.

[0399] FIG. **83**E shows the secondary catheter **6780**, or steerable catheter, being used to push the proximal side of the valve **6702** into position within the native annulus.

[0400] FIG. **83**F shows withdrawal of the delivery system (e.g., the guidewire **6785** and the delivery catheter **6772**) and anchoring of a proximal side (e.g., a posterior-septal side) of the valve **6702** to the annular tissue. FIG. **83**F shows the expanded valve **6702** with an atrial sealing collar facing the atrium, a valve body (e.g., a lower tubular body portion) deployed within the native annulus and extending from atrium to ventricle, the anchoring tension arm or distal lower tension arm **6732** extending subannularly into the RVOT area, and the guidewire collar/ball **6740** at a distal end of the tension arm **6732**. The guidewire **6785** and the delivery catheter **6772** are being withdrawn.

[0401] FIGS. **84**A-**84**F illustrate a process for delivery of an orthogonal transcatheter prosthetic valve **6802** to the tricuspid annulus of the human heart. FIG. **84**A is an illustration of a first step of the delivery process in which a guidewire **6885** is advanced from the femoral artery, through the inferior vena cava (IVC), to the right atrium. The guidewire **6885** is an 8 Fr guidewire (or about 2.667 mm in diameter).

[0402] FIG. **84**B shows a balloon catheter **6889** advanced over the guidewire **6885** through the native annulus and into the RVOT to expand and push aside native valve and leaflet tissue, chordae tendineae that might tangle the transcatheter delivery of the valve **6802**.
[0403] FIG. **84**C shows a guidewire **6885** with a hypotube sheath or secondary catheter **6880** delivered to the RVOT. The guidewire **6885** has a diameter of about 0.035 in (or about 0.889 mm).
[0404] FIG. **84**D shows a delivery catheter **6872** being advanced over the guidewire **6885** to and through the native tricuspid annulus to the right ventricle.
[0405] FIG. **84**E shows the valve **6802** in a compressed configuration disposed within a capsule/compression catheter **6876**. The capsule **6876** is loaded into a proximal end of the delivery catheter **6872** and the compressed valve **6802** is advanced through the delivery catheter **6872**, with the sheathed guidewire **6885** threaded through the valve **6802** and providing a wire path to the RVOT, planned deployment location.
[0406] FIG. **84**F shows the valve **6802** advanced though the delivery catheter **6872**, expelled, expanded to the expanded configuration, and at least partially deployed into the native annulus by pushing on the outer sheath or secondary catheter **6880** of the guidewire **6885** to pull the valve **6802**, pulling from a guidewire collar **6840** included in or coupled to a distal end of a tension arm (e.g., a distal lower tension arm) **6832**, through the delivery catheter **6872** and into position in the native annulus. The tension arm **6832** is used to position the valve **6802**.
[0407] FIG. **84**G shows the hypotube sheath or secondary catheter **6880**, or steerable catheter, being used to push the proximal side of the valve **6802** nearest the IVC or access point into position within the tricuspid annulus.
[0408] FIG. **84**H shows withdrawal of the delivery system (e.g., the guidewire **6885** and the delivery catheter **6872**) and anchoring of a proximal side (e.g., a posterior-septal side) of the valve **6802** to the annular tissue, and anchoring of the distal side of the valve **6802** using the distal subannular anchoring tension arm **6832**. The guidewire **6885** and the delivery catheter **6872** are withdrawn.
[0409] FIGS. **85**A-**85**F illustrate a process for delivery of an orthogonal transcatheter prosthetic valve **6902** to the tricuspid annulus of the human heart. FIG. **85**A is an illustration of a first step of the delivery process and shows the compressed side-deliverable valve **6902** disposed in a delivery catheter **6972** and advanced therethrough using a pushing sheath or rod or secondary catheter **6980**. The delivery catheter **6972** is advanced over a guidewire **6985** to the native annulus by following the track of the guidewire **6985**, which is at least partially disposed in a lumen of the pushing sheath or secondary catheter **6980**.
[0410] FIG. **85**B shows pushing on the outer sheath or secondary catheter **6980** along with the guidewire **6985** threaded through a guidewire collar element **6940** included in and/or coupled to a tension arm (e.g., a distal lower tension arm) **6932** of the valve **6902** to pull the valve **6902** up the delivery catheter **6972** and into position, partially expelling the valve **6902** with the tension arm **6932** being placed into the RVOT and the distal side of the valve **6902** lodged against the native annular wall.
[0411] FIG. **85**C shows the valve **6902** fully expelled from the delivery catheter **6972** into the expanded configuration and the pushing catheter or secondary catheter **6980** extending from the delivery catheter **6972** being used to push a proximal side of the valve **6902** into position within the native tricuspid annulus.
[0412] FIG. **85**D shows how the tension arm (e.g., the distal lower tension arm) **6932** is used to position the valve **6902** while the pushing catheter or secondary catheter **6980** is used to push the proximal side of the valve **6902** into position within the native annulus to allow a proximal subannular anchoring tab (proximal tab) or proximal lower tension arm **6934** to engage and secure the valve **6902** against the native tissue.
[0413] FIG. **85**E shows how the pushing catheter and/or secondary catheter **6980** can be used to deliver a tissue anchor **6990** used to secure the proximal side of the valve **6902** to the native

annular tissue.
[0414] FIG. **85**F shows withdrawal of the delivery system (e.g., the secondary catheter **6980**, the guidewire **6985**, and the delivery catheter **6972**) and anchoring of the proximal side of the valve **6902** to the native annular tissue via the tissue anchor **6990**. The secondary catheter **6980** can be used to push the tissue anchor **6990** into the native annular tissue to secure the tissue anchor **6990** to the native annular tissue.
[0415] FIGS. **86**A-**86**F illustrate a process for delivery of a transcatheter prosthetic valve **7002** to the tricuspid annulus of the human heart. FIG. **86**A is an illustration of a first step of the delivery process in which a guidewire **7085** with a hypotube sheath or secondary catheter **7080** is delivered to the RVOT through the superior vena cava (SVC). The guidewire **7085** has a diameter of about 0.035 in (or about 0.889 mm).
[0416] FIG. **86**B shows a delivery catheter **7072** being advanced over the guidewire **7085** to and through the native tricuspid annulus to the right ventricle.
[0417] FIG. **86**C shows the valve **7002** in a compressed configuration disposed within a capsule/compression catheter **7076**. The capsule **7076** is loaded into a proximal end of the delivery catheter **7072** and the valve **7002** is withdrawn from the capsule **7076** into the delivery catheter **7072** for further advancement or the capsule **7076** is used to advance the valve **7002** within the delivery catheter **7072**, with the sheathed guidewire **7085** threaded through the valve **7002** and providing a wire path to the RVOT, planned deployment location. The guidewire **7085** can extend through a guidewire collar element **7040** of the valve **7002** while the larger circumference of the hypotube sheath or secondary catheter **7080** relative to an aperture of the guidewire collar element **7040** blocks passage of the hypotube sheath or secondary catheter **7080** through the guidewire collar element **7040**. The guidewire collar element **7040** can be coupled to a tension arm (e.g., a distal lower tension arm) **7032**.
[0418] FIG. **86**D shows the valve **7002** advanced up and expelled out of the delivery catheter **7072** into the expanded configuration and deployed into the native annulus by pushing on the outer sheath or secondary catheter **7080** to pull the valve **7002** by the guidewire collar element/ball **7040** up the delivery catheter **7072** and into position. The tension arm or distal lower tension arm **7032** is used as a mount for the guidewire collar element/ball **7040**, to position the valve **7002** during deployment, and to provide subannular anchoring on the distal side.
[0419] FIG. **86**E shows the pushing catheter or secondary catheter **7080** extending from the delivery catheter **7072** and being used to push the proximal side of the valve **7002** into position within the native annulus.
[0420] FIG. **86**F shows withdrawal of the delivery system (e.g., the guidewire **7085** and the delivery catheter **7072**) and anchoring of a proximal side of the expanded valve **7002** to the native annular tissue. FIG. **86**F shows the expanded valve **7002** with an atrial sealing collar facing the atrium, a valve body (e.g., a lower tubular body portion) deployed within the native annulus and extending from atrium to ventricle, the anchoring tension arm or distal lower tension arm **7032** extending subannularly into the RVOT area, and the guidewire collar/ball **7040** at a distal end of the tension arm **7032**. The guidewire **7085**, the secondary catheter **7080**, and the delivery catheter **7072** are withdrawn.
[0421] FIG. **87**A is an illustration of a trans-septal (femoral-IVC) delivery of a low profile, e.g., 8-20 mm, side-loaded prosthetic mitral valve **7102** FIG. **87**A shows the valve **7102** partially housed within a delivery catheter **7172**, and partially ejected for deployment into the native mitral annulus.
[0422] FIG. **87**B is an illustration of the low profile, side-loaded, vertically compressed prosthetic mitral valve **7102** shown housed in a compressed configuration within the delivery catheter **7172**.
[0423] FIG. **87**C is an illustration of the low profile, side-loaded prosthetic mitral valve **7102** shown partially housed within the delivery catheter **7172** and partially laterally ejected from the delivery catheter **7172** and positioned for deployment against the anterior side of the native mitral annulus. FIG. **87**C shows the valve **7102** partially expanded, with a flow control component **7150**

of the valve **7102** beginning to unfurl or expand.
[0424] FIG. **87**D is an illustration of the low profile, side-loaded prosthetic mitral valve **7102** shown ejected from the delivery catheter **7172** into the expanded configuration and positioned against the anterior side of the native mitral annulus. FIG. **87**D shows a secondary catheter **7180** that can be pushed to pull the valve **7102** through the delivery catheter **7172** and to eject the valve **7102** from the delivery catheter **7172**. FIG. **87**D shows the valve **7102** in an expanded configuration, with the flow control component **7150** of the valve **7102** being unfurled and expanded.
[0425] FIG. **87**E is an illustration of a side or plan view of a low profile, side-loaded prosthetic valve **7102** shown deployed into the native mitral annulus. FIG. **87**E shows the valve **7102** in the expanded configuration, with the flow control component **7150** of the valve **7102** being unfurled and expanded, and shows the delivery system (e.g., the delivery catheter **7172** and the secondary catheter **7180**) withdrawn.
[0426] FIG. **88**A is an illustration of a side perspective view of a valve **7202** according to an embodiment, partially delivered to a native annulus. The valve **7202** is a rotational lock valve embodiment where the prosthetic valve **7202** is delivered to the native annulus with an off-set sub-annular tension arm/tab (e.g., a distal lower tension arm) **7232** positioned below the native annulus, and an off-set supra-annular tension arm/tab (e.g., a distal upper tension arm) **7231** positioned above the native annulus, while the valve **7202** (or at least a tubular valve frame **7210** thereof) is partially rolled off-set from the annular plane about a longitudinal axis.
[0427] FIG. **88**B is an illustration of a side perspective view of a valve **7202** showing the prosthetic valve **7202** delivered to the native annulus with the off-set sub-annular tension arm/tab (e.g., the distal lower tension arm) **7232** positioned below the native annulus, and the off-set supra-annular tension arm/tab (e.g., the distal upper tension arm) **7231** positioned above the native annulus, while the valve **7202** (or at least the tubular valve frame **7210**) is partially rolled into a functional or fully deployed position parallel to the annular plane. Once the valve **7202** is rolled into position, and the tension arms **7231** and **7232** are locked against the supra-annular and subannular tissues, respectively. The valve **7202** can also be further anchored using traditional anchoring elements as disclosed herein. FIG. **88**B also shows a flow control component
[0428] FIG. **89**A is an illustration of a prosthetic valve **7302** according to an embodiment being delivered to tricuspid valve annulus. FIG. **89**A shows a wire-frame distal lower tension arm **7332** of the valve **7302** or valve frame being ejected from the delivery catheter **7372** and being directed through the annulus and towards the RVOT. FIG. **89**A shows an embodiment of an accordion-compressed low profile valve **7302** and shows the distal lower tension arm **7332** directed towards the anterior leaflet for placement into the RVOT while the valve **7302** is in the compressed configuration within the delivery catheter **7372** or substantially within the delivery catheter **7372**.
[0429] FIG. **89**B shows the wire-frame distal lower tension arm **7332** and a distal upper tension arm **7331** ejected from the delivery catheter **7372**, the distal lower tension arm **7332** is directed through the native annulus and into the RVOT, and the distal upper tension arm **7331** stays in a supra-annular position, causing a passive, structural anchoring of a distal side of the valve **7302** about the annulus. FIG. **89**B also shows a steerable anchoring catheter or secondary catheter **7380** attached to a proximal anchoring tab **7330**. While the valve **7302** is held in the expanded configuration in a pre-seating position, the valve **7302** can be assessed, and once valve function and patient conditions are correct, the steerable anchoring catheter **7380** can be used to push a proximal side of the valve **7302** from its oblique angle relative to a native annular plane, down into the annulus. The steerable anchoring catheter or secondary catheter **7380** can then be used to install one or more anchoring elements **7390**.
[0430] FIG. **89**C shows the entire valve **7302** ejected from the delivery catheter **7372**, the wire-frame distal lower tension arm **7332** directed through the annulus and into the RVOT, and the wire-frame distal upper tension arm **7331** staying in a supra-annular position, and causing a passive,

structural anchoring of the distal side of the valve **7302** about the annulus, and at least one tissue anchor **7390** anchoring the proximal side of the valve **7302** into the annulus tissue.

[0431] FIGS. **90**A-**90**C show a plan view of a tissue anchor **7490** having a head **7491**A and a screw **7491**B that can be inserted and/or threaded into the native annular tissue. The tissue anchor **7490** includes a floating radio-opaque marker **7492** at a distal end of the tissue anchor **7490** (e.g., at an end of the screw **7491**B) and in contact with the atrial surface of the annular tissue. FIG. **90**B shows the screw **7491**B of the tissue anchor **7490** being advanced into the annular tissue with the radio-opaque marker **7492** threaded onto the tissue anchor **7490** and maintaining position on the atrial surface of the annular tissue. FIG. **90**C shows the tissue anchor **7490** completely advanced into the annular tissue such that the tissue anchor **740** and the threaded floating radio-opaque marker **7492** are now adjacent, indicating the desired depth, tension, and/or plication of the tissue anchor **7490** with respect to the annular tissue.

[0432] FIGS. **91**A-**91**D illustrate a plan view of various tissue anchor configurations. FIG. **91**A shows a tissue anchor **7590** according to an embodiment having a straight thread and a constant pitch. FIG. **91**B shows a tissue anchor **7690** according to an embodiment having a straight thread and a variable pitch. FIG. **91**C shows a tissue anchor **7790** according to an embodiment having a tapered thread and a constant pitch. FIG. **91**D shows a tissue anchor **7890** according to an embodiment having a sunken taper thread and a variable pitch.

[0433] FIGS. **92**A-**92**D illustrate a process for clipping and/or anchoring a lower profile prosthetic valve **7902** to annular tissue such as, for example, a proximal or anterior side of the native annulus. FIG. **92**A shows the valve **7902** being inserted into the native valve annulus and the valve **7902** having an integral anchor delivery conduit or channel **7997** with a tissue anchor **7990** disposed in a lumen of anchor delivery conduit or channel **7997** and an anchor delivery catheter or pusher **7998** attached to the tissue anchor **7990**.

[0434] FIG. **92**B shows the valve **7902** completely deployed within the native valve annulus and the integral anchor delivery conduit or channel **7997** with the anchor **7990** disposed in the lumen of the channel **7997** and the anchor delivery catheter or pusher **7998** attached to the anchor **7990**.

[0435] FIG. **92**C shows the anchor **7990** being pushed out of the lumen of the anchor delivery conduit or channel **7997** and into the annular tissue. The anchor delivery catheter or pusher **7998** can be used to advance the anchor **7990** through the anchor delivery conduit or channel **7997**.

[0436] FIG. **92**D shows the anchor **7990** in a locked position after being pushed out of the lumen of the delivery conduit or channel **7997** (e.g., via the anchor delivery catheter or pusher **7998**) and into the annular tissue, thus anchoring the proximal side of the low profile valve **7902** to the proximal or anterior side of the native annular tissue.

[0437] FIGS. **93**A-**93**E illustrate a process for clipping and/or anchoring a lower profile prosthetic valve **8002** to annular tissue such as, for example, a proximal or anterior side of the native annulus. FIG. **93**A shows the valve **8002** completely deployed within the native valve annulus. FIG. **93**A also shows delivery of an attachment wire **8093** via an anchor delivery catheter or pusher **8098** with a clip or anchor **8090** housed within the lumen of the anchor delivery catheter **8098**. The attachment wire **8093** is attached to a proximal or anterior side of the prosthetic valve **8002**. The attachment wire **8093** is configured to engage or couple to the clip or anchor **8090** to couple the valve **8002** to the clip or anchor **8090**.

[0438] FIG. **93**B shows the anchor delivery catheter **8098** inserted into an intra-annular space and shows the attachment wire **8093** attached to the proximal or anterior side of the valve **8002**. The clip or anchor **8090** is housed within the lumen of the anchor delivery catheter **8098** and is not shown.

[0439] FIG. **93**C shows a receiver element or portion **8094** of the clip or anchor **8090** ejected from the anchor delivery catheter **8098** and positioned behind tissue to be captured. The receiver element or portion **8094** is engaged with or connected to the attachment wire **8093**.

[0440] FIG. **93**D shows an anchoring element or portion **8095** of the clip or anchor **8090** piercing

the annular tissue behind which the receiver element or portion **8094** is positioned. The anchoring element or portion **8095** is inserted through the annular tissue and into the receiver element or portion **8094** of the clip or anchor **8090**. The clip or anchor **8090** or at least the receiving element or portion **8094** of the clip or anchor **8090** are attached to the low profile valve **8002** via the attachment wire **8093**.

[0441] FIG. **93**E shows the anchor element or portion **8095** of the clip or anchor **8090** extending through the annular tissue. The receiver element or portion **8094** of the clip or anchor **8090** and the anchor element or portion **8095** of the clip or anchor **8090** are connected to each other and to the annular tissue and connected by the attachment wire **8093** to the low profile valve **8002**. The anchor delivery catheter **8098** is withdrawn and the clip or anchor **8090** remains.

[0442] FIG. **94** is a flowchart showing a method **8100** for orthogonal delivery of an implantable prosthetic valve to a desired location in the body according to an embodiment. The method **8100** includes providing a compressible and expandable prosthetic valve, at **8101**. The compressible and expandable prosthetic valve can be any of the valves disclosed herein. For example, the compressible and expandable prosthetic valve can be a valve (i) where the valve has a tubular frame with a flow control component mounted within the tubular frame, (ii) where the valve or flow control component is configured to permit blood flow in a first direction through an inflow end of the valve and to block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, (iii) where the valve is compressible and expandable and has a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and (iv) where the long-axis is parallel to a length-wise cylindrical axis of a delivery catheter used to deliver the valve. A delivery catheter is advanced to the desired location in the body, at **8102**. The compressible and expandable prosthetic valve is delivered, at **8103**, wherein the compressible and expandable prosthetic valve has a height of about 5-60 mm and a diameter of about 25-80 mm. The valve is compressible to a compressed configuration during introduction or delivery into the body using a delivery catheter. The compressible and expandable prosthetic valve is released from the delivery catheter, at **8104**, wherein the valve is expandable to an expanded configuration after being released from the delivery catheter for implanting the valve in the desired location in the body.

[0443] FIG. **95** is a flowchart showing a method **8200** for orthogonally loading a compressible and expandable prosthetic valve into a delivery catheter according to an embodiment. The method **8200** includes providing a compressible and expandable prosthetic valve, at **8201**. The compressible and expandable prosthetic valve can be any of the valves disclosed herein. For example, the compressible and expandable prosthetic valve can be a valve (i) where the valve has a tubular frame with a flow control component mounted within the tubular frame, (ii) where the valve or flow control component is configured to permit blood flow in a first direction through an inflow end of the valve and to block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, (iii) where the valve is compressible and expandable and has a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, (iv) where the long-axis is parallel to a length-wise cylindrical axis of a delivery catheter used to deliver the valve, and (v) where the valve has a height of about 5-60 mm and a diameter of about 25-80 mm. The compressible and expandable prosthetic valve is loaded into a tapering fixture or funnel attached to a delivery catheter, to compress the valve to a compressed configuration for introduction into the body using the delivery catheter for implanting at a desired location in the body, at **8202**.

[0444] As described above with reference to FIGS. **1**A and **1**B, a transcatheter prosthetic valve can include a valve frame and a flow control component that are integral components or that are separate components coupled prior to delivery to the desired location in the body. Any of the prosthetic valves described herein, however, can include a valve frame and a flow control component that are separate components that are delivered separately and coupled or mounted

within the desired location in the body. For example, a valve frame such as those described herein can be compressed and delivered to the desired location in the body via a delivery catheter. The frame can be released from the delivery catheter and deployed, for example, in the annulus of the native valve. The frame is in the expanded configuration once released from the delivery catheter, and thus, is deployed in the annulus of the native valve in the expanded configuration. A flow control component such as any of those described herein can then be delivered separately (e.g., via the delivery catheter or a separate or secondary delivery catheter) and mounted into the deployed frame. In some implementations, such an arrangement can allow for a commercially available flow control components, which are deployed within any of the frames described herein, which have been previously and/or separately deployed in the native annulus.

[0445] Provided below is a discussion of certain aspects or embodiments of transcatheter prosthetic valves, delivery systems, and/or delivery methods. The transcatheter prosthetic valves (or aspects or portions thereof), the delivery systems, and/or the delivery methods described below with respect to specific embodiments can be substantially similar in at least form and/or function to the valve **102** and/or corresponding aspects of the valve **102**, the delivery system used to deliver the valve **102**, and/or the delivery methods described above with reference to FIGS. **1**A-**1**F. Thus, certain aspects of the specific embodiments are not described in further detail herein.

[0446] FIG. **96**A is an illustration of an open cross-section view of a low profile, side-loaded prosthetic valve frame **8310** and shows an example of a commercially available valve or flow control component **8350** mounted within a central aperture **8314** defined by an inner surface of frame **8310**.

[0447] FIG. **96**B is an illustration of valve frame **8310** having a braid or laser-cut construction. FIG. **96**B shows a longer distal lower tension arm **8332** for extending sub-annularly towards the RVOT (described in detail above), and a shorter distal upper tension arm **8331** for extending over the atrial floor (described in detail above). The tubular frame **8310** shown in FIG. **96**B is about 10 mm in height and the commercially available valve sleeve or flow control component **8350** received by the frame **8310** can extend about 10 mm below the bottom of the tubular frame **8310** when received therein, resulting in a valve having a total height of 20 mm.

[0448] FIG. **96**C is an illustration of the valve frame **8310** having the braid or laser-cut construction and the commercially available valve sleeve or flow control component **8350** in a compressed configuration within a delivery catheter **8372**. FIG. **96**C shows a secondary steerable catheter **8380** attached to the valve frame **8310** and used for ejecting, positioning, and anchoring the valve frame **8310** within the native annulus. The secondary catheter **8380** can also be used to retrieve a failed deployment of the valve frame **8310**. The valve frame **8310** can be delivered to the native annulus with the valve sleeve or flow control component **8350** previously mounted therein such that the valve frame **8310** and flow control component **8350** are delivered together or can be delivered in separate processes.

[0449] FIG. **96**D is an illustration of the valve frame **8310** having a braid or laser-cut construction shown partially compressed within the delivery catheter **8372**, and partially ejected from the delivery catheter **8372**. FIG. **96**D shows that while the valve frame **8310** is still compressed the distal lower tension arm **8332** can be manipulated through the leaflets and chordae tendineae to find a stable anterior-side lodgment for the distal side of the valve frame **8310**. FIG. **96**D also shows that the valve frame **8310** without the valve sleeve or flow control component **8350** showing that the valve frame **8310** can be delivered to the native annulus prior to and/or separate from the delivery of the flow control component **8350**.

[0450] FIG. **96**E is an illustration of the valve frame **8310** having the braid or laser-cut construction and engaging the tissue on the anterior side of the native annulus with the curved distal sidewall of the tubular frame **8310** sealing around the native annulus. FIG. **96**E shows the valve frame **8310** held by the steerable secondary catheter **8380** at an oblique angle while valve frame **8310** function is assessed. FIG. **96**E shows that the flow control component **8350** has not been delivered to the

native annulus.
[0451] FIG. **96**F is an illustration of a prosthetic valve having the braid or laser-cut tubular frame **8310** fully deployed into the tricuspid annulus. The distal side of the valve frame **8310** is shown engaging the tissue on the anterior side of the native annulus with the curved distal sidewall of the tubular frame **8310** sealing around the native annulus, and with the proximal sidewall tension-mounted into the posterior side of the native annulus. FIG. **96**F shows the valve sleeve or flow control component **8350** delivered to the native annulus (after the delivery of the valve frame **8310**) and mounted in the valve frame **8310**. The valve sleeve or flow control component **8350** can be a commercially available flow control component.
[0452] FIG. **97**A is an illustration of a valve frame **8410** according to an embodiment being delivered to tricuspid valve annulus. FIG. **97**A shows the valve frame **8410** having the braided/laser cut-wire frame construction with a distal lower tension arm **8432** that is ejected from a delivery catheter **8472** and directed through the annulus and towards the RVOT.
[0453] FIG. **97**B shows the valve frame **8410** partially disposed within the delivery catheter **8472** with the distal lower tension arm **8432** and the distal upper tension arm **8431** ejected from the delivery catheter **8472**. The distal lower tension arm **8432** is directed through the annulus and into the RVOT. The distal upper tension arm **8431** is shown staying in a supra-annular position, and causing a passive, structural anchoring of a distal side of the valve frame **8410** about the annulus. FIG. **97**B shows that a steerable anchoring catheter or secondary catheter **8480** can hold the valve frame **8410** at an oblique angle in a pre-attachment position, so that the valve frame **8410** can be assessed, and once valve frame function and patient conditions are correct, the steerable anchoring catheter or secondary catheter **8480** can push the proximal side of the valve frame **8410** from its oblique angle, down into the native annulus. The steerable anchoring catheter or secondary catheter **8480** can then optionally install one or more anchoring elements.
[0454] FIG. **97**C is an illustration of a valve frame **8410** showing the entire braided/laser cut-frame **8410** ejected from the delivery catheter **8410**. The distal lower tension arm **8432** is directed through the annulus and into the RVOT. The distal upper tension arm **8431** stays in a supra-annular position, and causes a passive, structural anchoring of the distal side of the valve frame **8410** about the annulus. At least one tissue anchor (not shown) can be used to anchor the proximal side of the valve frame **8410** into the annulus tissue. FIG. **97**C shows how the opening or aperture of the valve frame **8410** can allow blood to flow through the aperture and can then have a commercial valve sleeve or flow control component **8450** secondarily delivered and deployed into the aperture and secured to valve frame **8410**.
[0455] FIG. **98**A is an illustration of a valve frame **8510** according to an embodiment being delivered to tricuspid valve annulus. FIG. **98**A shows the frame **8510** having a braided/laser cut-wire frame construction with a distal lower tension arm ejected from a delivery catheter (not shown) and being directed toward and/or through the native annulus and towards the RVOT. Delivery of the valve frame **8510** can also include a valve or valve frame assessment process.
[0456] FIG. **98**B shows the braided/laser cut-wire frame **8510** with the distal lower tension arm and a distal upper tension arm ejected from a delivery catheter. The distal lower tension arm is directed through the annulus and into the RVOT. The distal upper tension arm stays in a supra-annular position, and causes a passive, structural anchoring of the distal side of the valve frame **8510** about the annulus. The valve frame **8510** can be held at an oblique angle in a pre-attachment position (e.g., via a steerable anchoring catheter or secondary catheter, not shown), so that the valve frame **8510** can be assessed, and once valve frame function and patient conditions are correct, the proximal side of the valve frame **8510** can be pushed from its oblique angle, down into the native annulus.
[0457] FIG. **98**C shows the entire braided/laser cut-frame valve frame **8510** ejected from the delivery catheter, with the distal lower tension arm directed through the annulus and into the RVOT and the distal upper tension arm staying in a supra-annular position, and causing a passive,

structural anchoring of the distal side of the valve frame **8510** about the annulus. Although not shown, at least one tissue anchor can be used to anchor the proximal side of the valve frame **8510** into the annulus tissue. FIG. **98**C shows how a commercial valve sleeve or flow control component **8550** can be secondarily deployed into the opening or aperture of the frame **8510**.

[0458] FIG. **99**A is an illustration of a commercial valve sleeve or flow control component **8650** that can be mounted within any of the frames disclosed herein.

[0459] FIG. **99**B is an illustration of the commercial valve sleeve or flow control component **8650** showing that the flow control component **8650** can be mounted within the any of the frames disclosed herein using and/or having two rigid support posts **8652**.

[0460] FIG. **99**C is an illustration of a commercial valve sleeve or flow control component **8750**A that can be mounted within any of the frames disclosed herein. The flow control component **8750**A is shown as a three-panel embodiment.

[0461] FIG. **99**D is an illustration of the commercial valve sleeve or flow control component **8750**B that can be mounted within any of the frames disclosed herein. The flow control component **8750**B is shown as a three-panel embodiment having three rigid support posts **8752**.

[0462] FIG. **100** is an illustration of the heart and shows an approximate location of the valves, the left and right atrium, the left and right ventricles, and the blood vessels that enter and exit the chambers of the heart.

[0463] FIG. **101**A is an illustration of a low profile, e.g., 8-20 mm, side-loaded valve frame **8810** shown in a vertically compressed configuration and housed within a delivery catheter **8872**.

[0464] FIG. **101**B shows the valve frame **8810** partially compressed and partially housed within a delivery catheter **8872**, and partially laterally ejected from the delivery catheter **8872** and positioned for deployment against the anterior side of the annulus of a native valve, such as the tricuspid valve or mitral valve.

[0465] FIG. **101**C shows the valve frame **8810** ejected from the delivery catheter **8872** and positioned against the anterior side of the native annulus. The valve frame **8510** can be held at an oblique angle in a pre-attachment position via a steerable anchoring catheter or secondary catheter **8880**, so that the valve frame **8510** can be assessed, and once valve frame function and patient conditions are correct, the proximal side of the valve frame **8810** can be pushed from its oblique angle, down into the native annulus via the steerable anchoring catheter or secondary catheter **8880**.

[0466] FIG. **101**D shows the valve frame **8810** deployed into the native annulus of a heart valve.

[0467] FIGS. **101**E-**101**G illustrate side views of a valve or flow control component **8850** that can be inserted into the deployed frame **8810**. FIG. **101**E shows two alternate versions of flow control component **8850**, secondarily deliverable by a suitable respective delivery catheter. In the embodiment on the left in FIG. **101**E, the flow control component is self-expanding, and is delivered from the lumen of the delivery catheter and allowed to expand into the lumen or aperture of the valve frame **8810**. In the embodiment on the right in FIG. **101**E, the flow control component is a commercially-approved transcatheter balloon expandable flow control component **8850**, that is delivered on a balloon catheter **8889**, on which it can be expanded into the lumen or aperture of the valve frame **8810**. FIG. **101**F shows that the self-expanding embodiment of the valve or flow control component **8850** is deployed in the valve frame **8810** and allowed to expand to an expanded configuration within the lumen or aperture of the frame **8810**. FIG. **101**G shows that the balloon expandable valve or flow control component **8850** can be vertically deployed into the central lumen or aperture of the already (laterally, horizontally, orthogonally) deployed valve frame **8810**.

[0468] FIGS. **102**A-**102**D illustrate a process for delivering a co-axial transcatheter prosthetic valve **8902** to the annulus of a native valve of the human heart. FIG. **102**A shows the valve **8902** in a co-axial compressed configuration being loaded using a compression capsule or compression catheter **8976** into a distal end of a delivery catheter **8972**. FIG. **102**A shows a hypotube or sheath (secondary catheter **8980**), a guidewire **8985** threaded through a guidewire collar **8940** coupled to, for example, a distal tension arm. The compression capsule or catheter **8976** is configured to

compress the co-axial prosthetic valve to a size suitable for insertion into the delivery catheter **8972**.

[0469] FIG. **102**B shows the co-axial compressed valve **8902** being delivered to the distal end of the delivery catheter **8972**, with the hypotube or secondary catheter **8980** and sheathed guidewire **8985** threaded through or disposed within a channel-type guidewire collar **8940** attached, for example, to a distal tension arm. The guidewire collar **8940** can include and/or form a constriction or other feature configured to permit advancement of the guidewire **8985** through the guidewire collar **8940** and to block advancement of the secondary catheter **8980**, which can be used to advance the valve **8902** within the delivery catheter **8972**.

[0470] FIG. **102**C shows the co-axial compressed valve **8902** partially expelled from the delivery catheter **8972**, with a distal tension arm and/or the channel-type guidewire collar **8940** being positioned into the ventricular outflow tract of the native valve (e.g., the RVOT). The distal tension arm can form and/or define the channel-type guidewire collar **8940**, thereby combining the functions or features.

[0471] FIG. **102**D shows that, once positioned, the self-expanding valve **8902** can be completely expelled from the delivery catheter **8972** and deployed as a prosthetic valve similar to any of those disclosed herein.

[0472] FIGS. **103**A-**103**G illustrate a process for delivering a co-axial transcatheter prosthetic valve **9002** to the annulus of the tricuspid valve of the human heart. FIG. **103**A is an illustration of a first step of the delivery process in which a guidewire **9085** with a hypotube sheath or secondary catheter **9080** is delivered to the RVOT through the superior vena cava (SVC). The guidewire **9085** has a diameter of about 0.035 in (or about 0.889 mm).

[0473] FIG. **103**B shows a delivery catheter **9072** being advanced through the SVC over the guidewire **9085** to and through the native tricuspid annulus to the right ventricle.

[0474] FIG. **103**C shows the valve **9002** in a compressed configuration within a compression capsule **9076**. The capsule **9076** can be used to compress the valve **9002** to an extent that the compressed valve **9002** fits within the delivery catheter **9072**. FIG. **103**C shows the capsule **9076** is loaded into the proximal end of the delivery catheter **9072** and the valve **9002** is withdrawn/delivered from the capsule **9076** into the delivery catheter **9072**, with sheathed guidewire **9085** threaded through the valve **9002** and providing a wire path to the RVOT, planned deployment location.

[0475] FIG. **103**D shows the valve **9002** advanced up the delivery catheter **9072** and deployed into the native annulus by pushing on the outer hypotube sheath or secondary catheter **9080** to pull the valve **9002** up the delivery catheter **9072** and into position. FIG. **103**D shows a tension arm **9030** of the valve **9002** is used to position the valve **9002** in the native annulus.

[0476] FIG. **103**E shows a steerable balloon catheter **9089** being used to push the proximal side of the valve **9002** in the expanded configuration into position within the native annulus.

[0477] FIG. **103**F shows balloon expansion of the co-axial valve **9002** in the native annulus. The proximal side of the valve **9002** can be anchored to the annular tissue.

[0478] FIG. **103**G shows withdrawal of the delivery system (e.g., the delivery catheter **9072**, the secondary catheter **9080**, the guidewire **9085**, etc.). The proximal side of the expanded valve **9002** is anchored to the annular tissue using any of the anchoring methods described herein.

[0479] FIGS. **104**A-**104**F illustrate a process for delivering a co-axial balloon-expandable transcatheter prosthetic valve **9102** to the tricuspid annulus of the human heart. FIG. **104**A shows a delivery catheter **9172** advanced over a guidewire **9185** to be deployed to the native annulus.

[0480] FIG. **104**B shows the co-axial balloon-expandable valve **9102** in a compressed configuration within a compression capsule **9176**. The capsule **9176** can be used to compress the valve **9102** to an extent that the compressed valve **9102** fits within the delivery catheter **9172**. FIG. **104**B shows the capsule **9176** is loaded into the proximal end of the delivery catheter **9172** and the valve **9102** is withdrawn/delivered from the capsule **9176** into the delivery catheter **9172**, with the

sheathed guidewire **9085** threaded through the valve **9102** and providing a wire path to the RVOT, planned deployment location. FIG. **104**B shows the valve **9102** including a channel-type guidewire collar **9140** through which the guidewire **9185** is threaded.

[0481] FIG. **104**C shows the co-axial valve **9102** being delivered to the proximal end of the delivery catheter **9172**, with the sheathed guidewire **9185** threaded through the tension arm and/or guidewire collar **9140**. The guidewire collar **9140** can couple to or can at least partially form a distal tension arm. The guidewire collar **9140** can include and/or form a constriction or other feature configured to permit advancement of the guidewire **9185** through the guidewire collar **9140** and to block advancement of a hypotube sheath or secondary catheter **9180**, which can be used to advance the valve **9102** within the delivery catheter **9172**.

[0482] FIG. **104**D shows the co-axial valve **9102** partially expelled from the delivery catheter **9172** into the expanded configuration, with the distal tension arm and/or guidewire collar **9140** being positioned into the RVOT. FIG. **104**D shows a balloon catheter **9189** connected to the valve **9102**.

[0483] FIG. **104**E shows that, once positioned and expanded by the balloon catheter **9189**, the balloon-expanded co-axial valve **9102** can be completely deployed into the inner circumference of the native annulus to function as a prosthetic valve. FIG. **104**F shows the deployed valve **9102** with the delivery system (e.g., the delivery catheter **9172**, secondary catheter **9180**, guidewire **9185**, balloon catheter **9189**, etc.) withdrawn.

[0484] FIG. **104**F is an illustration of step **6** of a 6-step process for delivery of a co-axial prosthetic valve **143** to the tricuspid annulus. FIG. **104**F shows the deployed valve.

[0485] Example—One embodiment of an orthogonally delivered transcatheter prosthetic valve has a tubular frame with a flow control component mounted within the tubular frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, wherein the long-axis of the compressed configuration of the valve is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve has a height of about 5-60 mm and a diameter of about 25-80 mm. Importantly, this heart valve substitute does not have a traditional valve configuration, can be delivered to the heart using the inferior vena cava (IVC/femoral transcatheter delivery pathway compressed within a catheter, and expelled from the catheter to be deployed without open-heart surgery.

[0486] Example—In another embodiment of a transcatheter valve, comprises: a cylindrical tubular frame having a height of about 5-60 mm and an outer diameter of about 25-80 mm, said tubular frame comprised of a braid, wire, or laser-cut wire frame having a substantially circular central aperture, said tubular frame partially covered with a biocompatible material; a collapsible flow control component disposed within the central aperture, said sleeve having a height of about 5-60 mm and comprised of at least two opposing leaflets that provide a reciprocating closable channel from a heart atrium to a heart ventricle; an upper tension arm attached to a distal upper edge of the tubular frame, the upper tension arm comprised of stent, segment of tubular frame, wire loop or wire frame extending from about 10-30 mm away from the tubular frame; a lower tension arm extending from a distal side of the tubular frame, the lower tension arm comprised of stent, segment of tubular frame, wire loop or wire frame extending from about 10-40 mm away from the tubular frame; and at least one tissue anchor to connect the tubular frame to native tissue.

[0487] Example—In another embodiment of a transcatheter valve, there is provided a feature wherein the sleeve is shaped as a conic cylinder, said top end having a diameter of 30-35 mm and said bottom end having a diameter of 8-20 mm.

[0488] Example—In another embodiment of a transcatheter valve, there is provided a feature wherein the cover is comprised of polyester, polyethylene terephthalate, decellularized pericardium, or a layered combination thereof.

[0489] Example—In an embodiment, there is also provided a method for orthogonal delivery of implantable prosthetic valve to a desired location in the body, wherein the method includes (i) advancing a delivery catheter to the desired location in the body and delivering an expandable prosthetic valve to the desired location in the body by releasing the valve from the delivery catheter, wherein the valve comprises a tubular frame having a flow control component mounted within the tubular frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, wherein the long-axis of the compressed configuration of the valve is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve has a height of about 5-60 mm and a diameter of about 25-80 mm.

[0490] Example—In an embodiment, there is also provided a method for orthogonally loading an implantable prosthetic valve into a delivery catheter, where the method includes loading an implantable prosthetic valve sideways into a tapering fixture or funnel attached to a delivery catheter, wherein the valve comprises a tubular frame having a flow control component mounted within the tubular frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, wherein the long-axis of the compressed configuration of the valve is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve has a height of about 5-60 mm and a diameter of about 25-80 mm.

[0491] Example—In an embodiment, there is also provided a method for orthogonally loading an implantable prosthetic valve into a delivery catheter, where the method includes (i) loading an implantable prosthetic valve into a tapering fixture or funnel attached to a delivery catheter, wherein the valve comprises a tubular frame having a flow control component mounted within the tubular frame and configured to permit blood flow in a first direction through an inflow end of the valve and block blood flow in a second direction, opposite the first direction, through an outflow end of the valve, wherein said loading is perpendicular or substantially orthogonal to the first direction, wherein the valve is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the first direction, wherein the long-axis of the compressed configuration of the valve is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve has a height of about 5-60 mm and a diameter of about 25-80 mm.

[0492] Example—The transcatheter prosthetic heart valve may be percutaneously delivered using a transcatheter process via the femoral through the IVC, carotid, sub-xiphoid, intercostal access across the chest wall, and trans-septal to the mitral annulus through the fossa ovalis. The device is

delivered via catheter to the right or left atrium and is expanded from a compressed shape that fits with the internal diameter of the catheter lumen. The compressed valve is loaded external to the patient into the delivery catheter and is then pushed out of the catheter when the capsule arrives to the atrium. The cardiac treatment technician visualizes this delivery using available imaging techniques such as fluoroscopy or ultrasound, and in an embodiment, the valve self-expands upon release from the catheter since it is constructed in part from shape-memory material, such as Nitinol®, a nickel-titanium alloy used in biomedical implants.

[0493] In another embodiment, the valve may be constructed of materials that requires balloon-expansion after the capsule has been ejected from the catheter into the atrium.

[0494] The atrial collar/frame and the flow control component are expanded to their functional diameter, as they are deployed into the native annulus, providing a radial tensioning force to secure the valve. Once the frame is deployed about the tricuspid annulus, fasteners secure the device about the native annulus. Additional fastening of the device to native structures may be performed, and the deployment is complete. Further adjustments using hemodynamic imaging techniques are contemplated to ensure the device is secure, is located and oriented as planned, and is functioning as a substitute or successor to the native tricuspid valve.

[0495] Example—One embodiment of an orthogonally delivered transcatheter prosthetic valve frame has a tubular frame, wherein the valve frame is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the central, cylindrical axis of the native annulus, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the central, cylindrical axis of the native annulus, wherein the long-axis of the compressed configuration of the valve is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve has a height of about 5-60 mm and a diameter of about 25-80 mm. This heart valve frame can be delivered to the heart using the inferior vena cava (IVC/femoral transcatheter delivery pathway compressed within a catheter and expelled from the catheter to be deployed without open-heart surgery.

[0496] Example—In another embodiment of a transcatheter valve frame, a cylindrical tubular frame is provided having a height of about 5-60 mm and an outer diameter of about 25-80 mm, said tubular frame comprised of a braid, wire, or laser-cut wire frame having a substantially circular central aperture, said tubular frame partially covered with a biocompatible material; an upper tension arm attached to a distal upper edge of the tubular frame, the upper tension arm comprised of stent, segment of tubular frame, wire loop or wire frame extending from about 10-30 mm away from the tubular frame; a lower tension arm extending from a distal side of the tubular frame, the lower tension arm comprised of stent, segment of tubular frame, wire loop or wire frame extending from about 10-40 mm away from the tubular frame; and at least one tissue anchor to connect the tubular frame to native tissue.

[0497] Example—In an embodiment, there is also provided a method for orthogonal delivery of implantable prosthetic valve frame to a desired location in the body, where the method includes (i) advancing a delivery catheter to the desired location in the body and delivering an expandable prosthetic valve frame to the desired location in the body by releasing the valve frame from the delivery catheter, wherein the valve frame is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the central, cylindrical axis of the native annulus, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the central, cylindrical axis of the native annulus, wherein the long-axis of the compressed configuration of the valve frame is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve frame has a height of about 5-60 mm and a diameter of about

25-80 mm.
[0498] Example—In an embodiment, there is also provided a method for orthogonally loading an implantable prosthetic valve frame into a delivery catheter, where the method includes loading an implantable prosthetic valve frame sideways into a tapering fixture or funnel attached to a delivery catheter, wherein the valve frame is compressible to a compressed configuration for introduction into the body using a delivery catheter for implanting at a desired location in the body, said compressed configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the central, cylindrical axis of the native annulus, and expandable to an expanded configuration having a long-axis oriented at an intersecting angle of between 45-135 degrees to the central, cylindrical axis of the native annulus, wherein the long-axis of the compressed configuration of the valve frame is substantially parallel to a lengthwise cylindrical axis of the delivery catheter, wherein the valve frame has a height of about 5-60 mm and a diameter of about 25-80 mm.
[0499] Example—The transcatheter prosthetic heart valve may be percutaneously delivered using a transcatheter process via the femoral through the inferior vena cava (IVC), superior vena cava (SVC), jugular vein, brachial vein, sub-xiphoid, intercostal access across the chest wall, and trans-septal through the fossa ovalis. The device is delivered via catheter to the right or left atrium and is expanded from a compressed shape that fits with the internal diameter of the catheter lumen. The compressed valve is loaded external to the patient into the delivery catheter and is then pushed out of the catheter when the capsule arrives to the atrium. The cardiac treatment technician visualizes this delivery using available imaging techniques such as fluoroscopy or ultrasound, and in an embodiment the valve frame self-expands upon release from the catheter since it is constructed in part from shape-memory material, such as Nitinol®, a nickel-titanium alloy used in biomedical implants.
[0500] In another embodiment, the valve frame may be constructed for use with balloon-expansion after the capsule has been ejected from the catheter into the atrium. The atrial collar/frame is expanded to their functional diameter, and deployed into the native annulus, providing a radial tensioning force to secure the valve frame. Once the frame is deployed about the tricuspid annulus, fasteners secure the device about the native annulus. Additional fastening of the device to native structures may be performed, and the deployment is complete. Further adjustments using hemodynamic imaging techniques are contemplated in order to ensure the device is secure, is located and oriented as planned, and is functioning.
[0501] Example—Compression methods. In another embodiment, there is provided a method of compressing, wherein the implantable prosthetic heart valve is rolled or folded into a compressed configuration using at least one of (i) unilaterally rolling into a compressed configuration from one side of the annular support frame; (ii) bilaterally rolling into a compressed configuration from two opposing sides of the annular support frame; (iii) flattening the annular support frame into two parallel panels that are substantially parallel to the long-axis, and then rolling the flattened annular support frame into a compressed configuration; and (iv) flattening the annular support frame along a vertical axis to reduce a vertical dimension of the valve from top to bottom.
[0502] Many modifications and variations can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. Functionally equivalent methods and apparatuses within the scope of the disclosure, in addition to those enumerated herein, will be apparent to those skilled in the art from the foregoing descriptions. Such modifications and variations are intended to fall within the scope of the appended claims. The present disclosure is to be limited only by the terms of the appended claims, along with the full scope of equivalents to which such claims are entitled. It is to be understood that this disclosure is not limited to particular methods, reagents, compounds, compositions, or biological systems, which can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting.

[0503] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods described above indicate certain events occurring in certain order, the ordering of certain events may be modified. Additionally, certain of the events may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.
[0504] Where schematics and/or embodiments described above indicate certain components arranged in certain orientations or positions, the arrangement of components may be modified. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made. Any portion of the apparatus and/or methods described herein may be combined in any combination, except mutually exclusive combinations. The embodiments described herein can include various combinations and/or sub-combinations of the functions, components, and/or features of the different embodiments described.

Claims

1. A prosthetic heart valve, comprising: a valve frame having a central axis and defining an aperture extending along the central axis, the valve frame having a tension arm extending laterally therefrom; and a flow control component mounted within the aperture and configured to permit blood flow in a first direction along the central axis and to block blood flow in a second direction, opposite the first direction, the valve frame having an expanded configuration with a first height along the central axis and a first lateral width along a lateral axis perpendicular to the central axis, the valve frame having a compressed configuration with a second height along the central axis that is less than the first height and a second lateral width along the lateral axis that is less than the first lateral width, the prosthetic heart valve configured to be disposed in an annulus of a native heart valve between an atrium of a heart and a ventricle of the heart when the valve frame is in the expanded configuration such that a portion of the valve frame including the tension arm is disposed below the annulus in the ventricle.
2. The prosthetic heart valve of claim 1, wherein the valve frame in the expanded configuration has a first longitudinal length along a longitudinal axis that is perpendicular to the central axis and the lateral axis, the valve frame in the compressed configuration has a second longitudinal length along the longitudinal axis that is greater than the first longitudinal length.
3. The prosthetic heart valve of claim 1, wherein the valve frame includes two panels, the valve frame configured to be changed from the expanded configuration to the compressed configuration by folding the valve frame along the lateral axis so that the two panels are approximately parallel.
4. The prosthetic heart valve of claim 3, wherein the valve frame is further configured to be changed to the compressed configuration by compressing the valve frame vertically by flattening the folded valve frame along the central axis.
5. The prosthetic heart valve of claim 4, wherein the valve frame forms a plurality of wire cells having an orientation and cell geometry configured to minimize strain associated with the valve frame being compressed along the central axis.
6. The prosthetic heart valve of claim 1, wherein the tension arm is a distal subannular tension arm extending laterally from a distal side of the valve frame, the valve frame further having a proximal subannular tension arm extending laterally from a proximal side of the valve frame.
7. The prosthetic heart valve of claim 1, wherein the valve frame includes an atrial collar attached to an upper edge of the valve frame.
8. A method of delivering a prosthetic heart valve to an annulus of a native heart valve between a ventricle and an atrium of a heart, the prosthetic heart valve having a valve frame and a flow control component mounted within the valve frame that is configured to permit blood flow in a direction along a central axis of the valve frame, the method comprising: disposing in an atrium of a heart a distal portion of a delivery catheter, the delivery catheter having disposed within a lumen

thereof the prosthetic heart valve in a compressed configuration such that a distal subannular tension arm is disposed toward a distal end of the delivery catheter; advancing at least a distal portion of the prosthetic heart valve beyond the distal end of the delivery catheter to place at least a portion of the distal subannular tension arm on a ventricle side of the annulus while at least a proximal subannular portion of the valve frame remains on an atrium side of the annulus; and seating the prosthetic heart valve in the annulus.

9. The method of claim 8, wherein prior to the seating of the prosthetic heart valve in the annulus, the method further comprising: holding the prosthetic heart valve at an angle relative to the annulus of the native valve; and allowing blood to flow from the atrium to the ventricle both through the native valve and through the prosthetic heart valve to allow assessment of the function of the native valve and the prosthetic heart valve.

10. The method of claim 8, wherein the seating of the prosthetic heart valve in the annulus includes disposing the prosthetic heart valve in the annulus such that the proximal subannular portion of valve frame is disposed on the ventricle side of the annulus.

11. The method of claim 8, wherein the seating of the prosthetic heart valve in the annulus includes exerting a force on an atrial collar of the valve frame to push the proximal subannular portion of the valve frame into the annulus.

12. The method of claim 8, further comprising: compressing the valve frame along the central axis and along a lateral axis perpendicular to the central axis to place the prosthetic heart valve in the compressed configuration; inserting the prosthetic heart valve in the compressed configuration into the lumen of the delivery catheter such that a longitudinal axis of the valve frame is parallel to a lengthwise cylindrical axis of the lumen of the delivery catheter, the longitudinal axis of the valve frame being perpendicular to each of the central axis and the lateral axis; and advancing the prosthetic heart valve in the compressed configuration through the lumen of the delivery catheter.

13. The method of claim 8, wherein prior to the seating of the prosthetic heart valve in the annulus, the method further comprising: releasing a remainder of the prosthetic heart valve from the lumen of the delivery catheter, the prosthetic heart valve configured to transition from the compressed configuration to an expanded configuration in response to the releasing, the seating of the prosthetic heart valve in the annulus includes seating the prosthetic heart valve in the annulus when the prosthetic heart valve is in the expanded configuration.

14. A method for preparing a prosthetic heart valve for delivery into a patient by a delivery catheter having a lumen, the prosthetic heart valve having a valve frame defining an aperture that extends along a central axis and a flow control component mounted within the aperture, the method comprising: transitioning the prosthetic heart valve from an expanded configuration to a compressed configuration by: compressing the valve frame laterally along a lateral axis of the valve frame that is perpendicular to the central axis such that a lateral width of the valve frame is less than a lumen diameter, and compressing the valve frame vertically along the central axis such that a height of the valve frame is less than the lumen diameter; and inserting the prosthetic heart valve in the compressed configuration into the lumen of the delivery catheter such that a longitudinal axis of the valve frame is substantially parallel to a lengthwise cylindrical axis of the lumen of the delivery catheter, the longitudinal axis of the valve frame being perpendicular to each of the central axis and the lateral axis.

15. The method of claim 14, wherein the valve frame forms a plurality of wire cells having an orientation and cell geometry configured to minimize strain associated with the valve frame being compressed along the central axis.

16. The method of claim 15, wherein the valve frame includes two panels, the compressing the valve frame laterally includes folding the valve frame laterally so that the two panels are approximately parallel.

17. The method of claim 15, wherein the compressing the valve frame laterally includes folding the valve frame along a distal fold area of the valve frame and along a proximal fold area of the valve

frame.

18. The method of claim 14, wherein the lateral width and the height of the prosthetic heart valve in the compressed configuration are a first lateral width and a first height, respectively, the prosthetic heart valve in the expanded configuration having a second lateral width along the lateral axis that is greater than the lumen diameter and a second height along the central axis that is greater than the lumen diameter.

19. The method of claim 14, wherein the valve frame has a tension arm that extends laterally from a distal subannular portion of the valve frame, the inserting the prosthetic heart valve in the compressed configuration into the lumen of the delivery catheter is such that the tension arm is disposed towards a distal end of the delivery catheter.

20. The method of claim 14, wherein the valve frame has a tension arm that extends laterally from a distal subannular portion of the valve frame, the inserting the prosthetic heart valve in the compressed configuration into the lumen of the delivery catheter is such that the tension arm is distal to the central axis of the valve frame.