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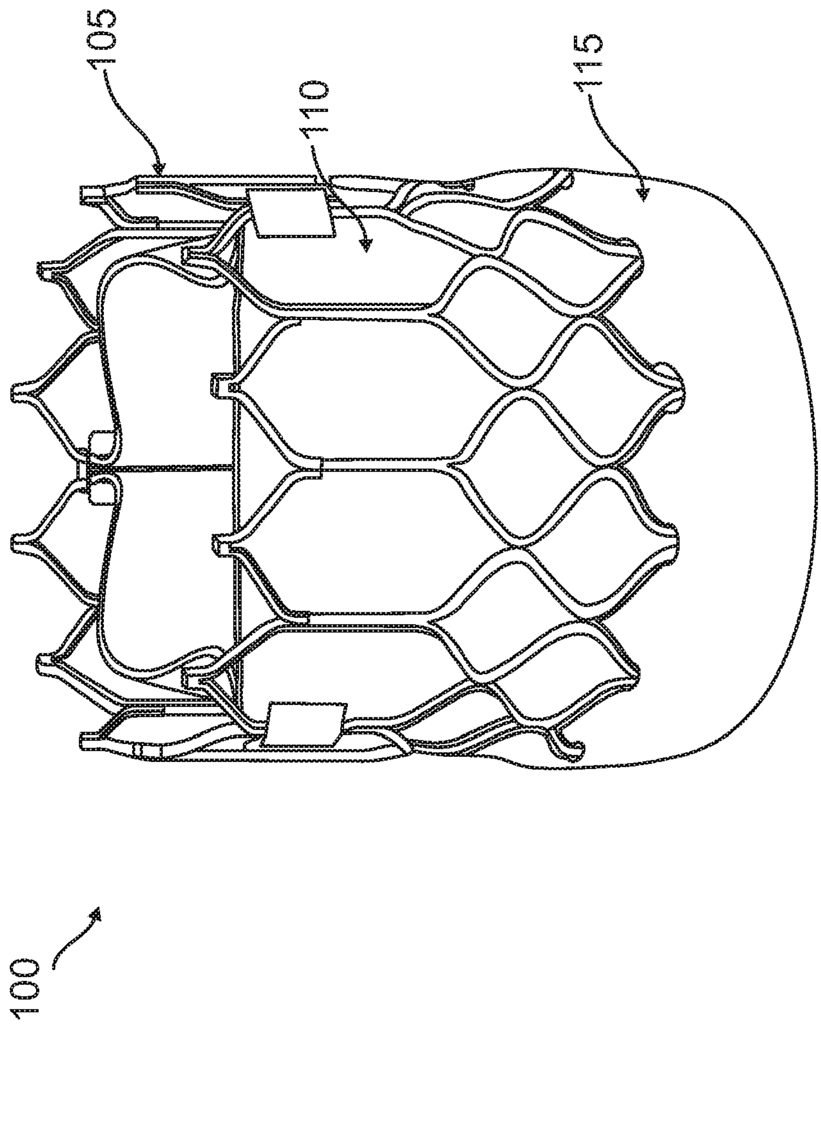

FIG. 1
(Prior Art)

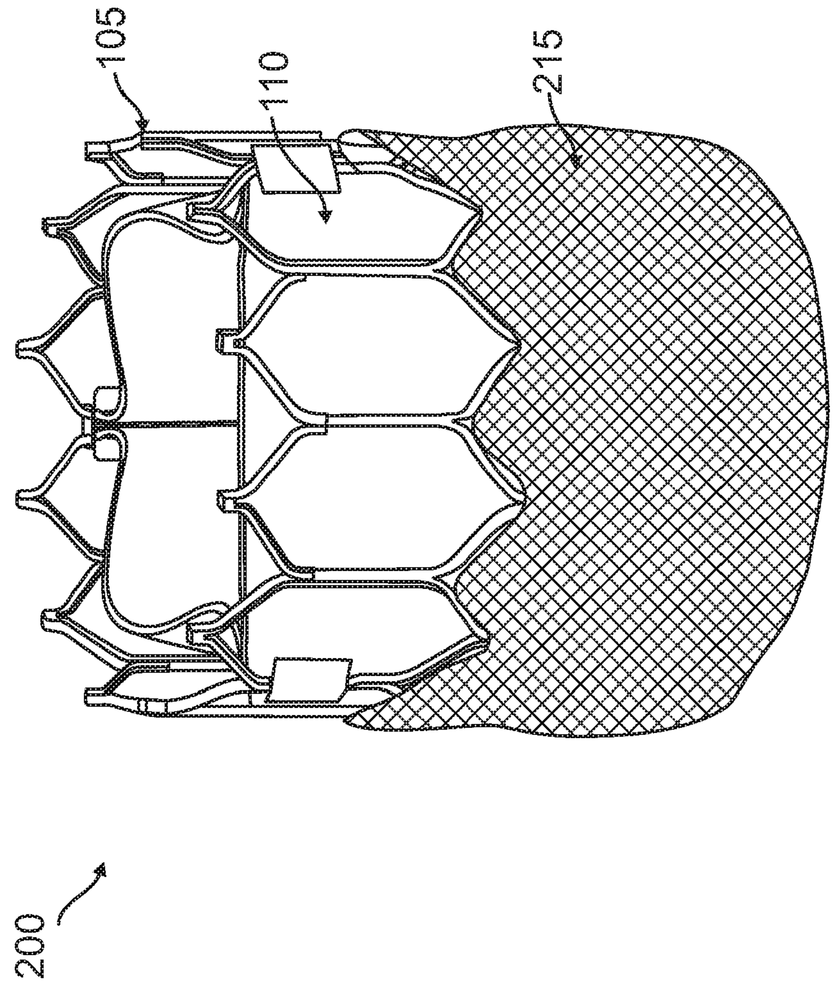

FIG. 2

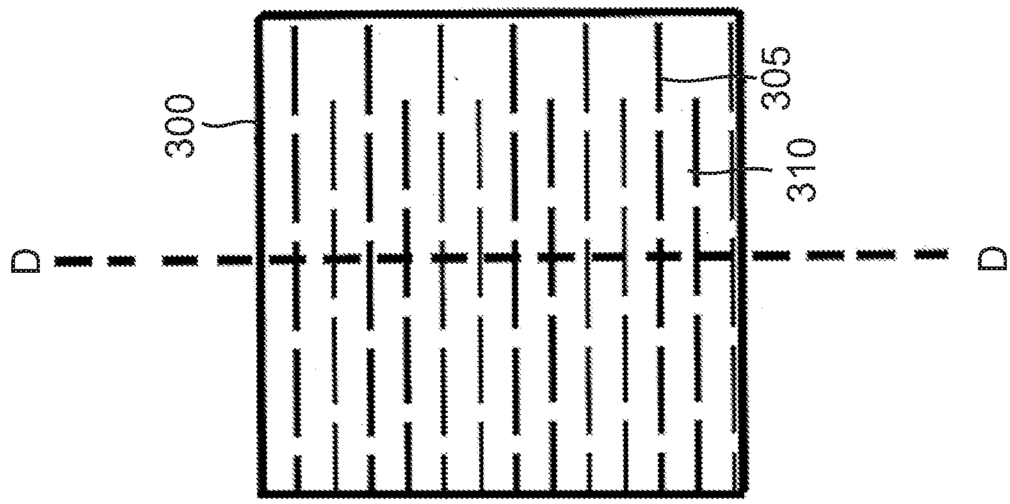

FIG. 3A

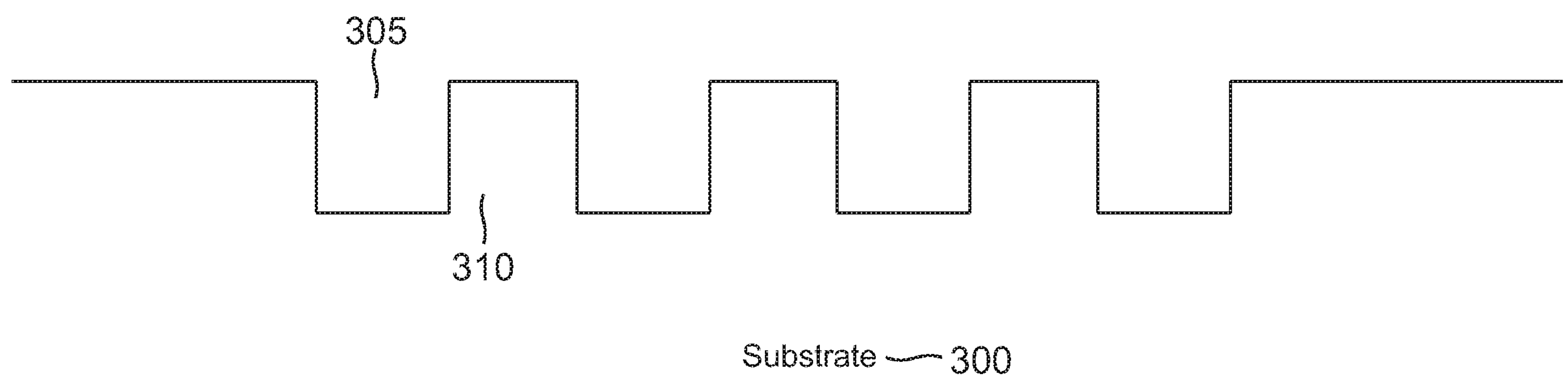

FIG. 3B

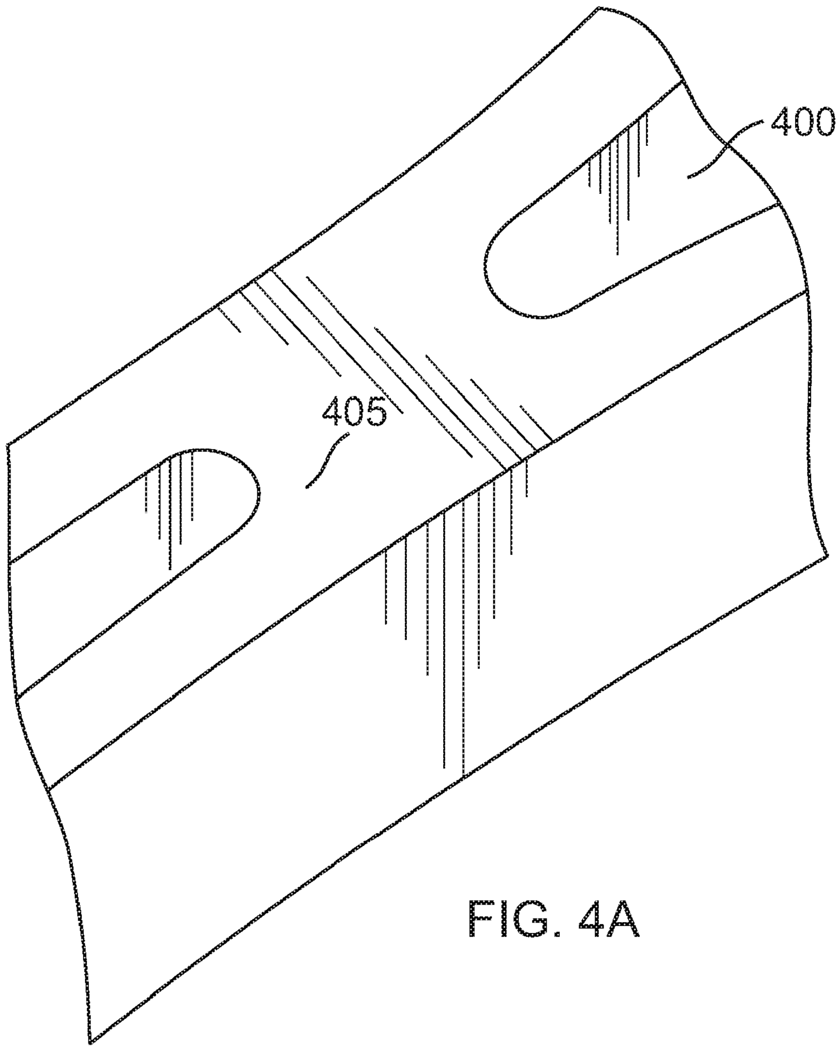

FIG. 4A

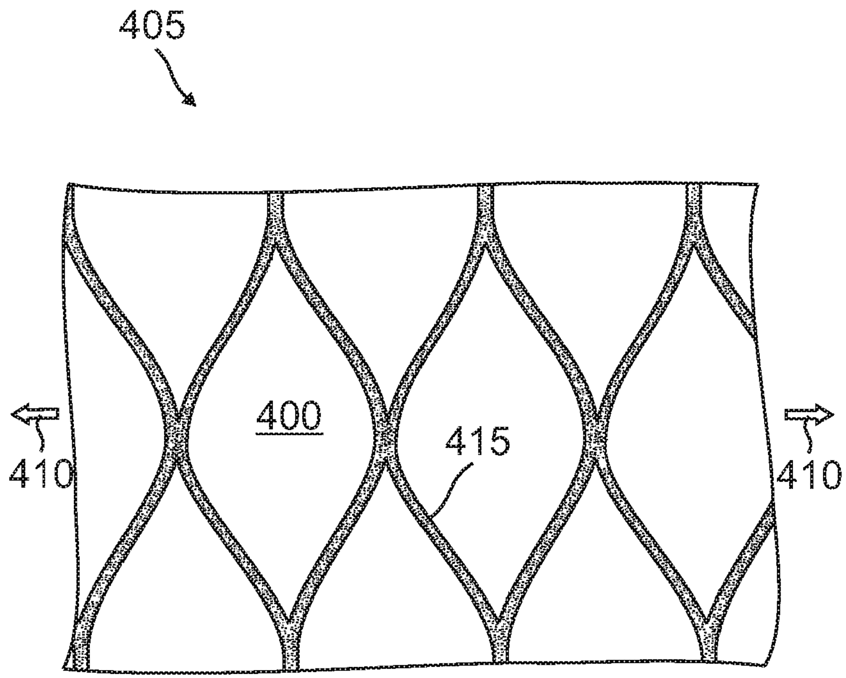

FIG. 4B

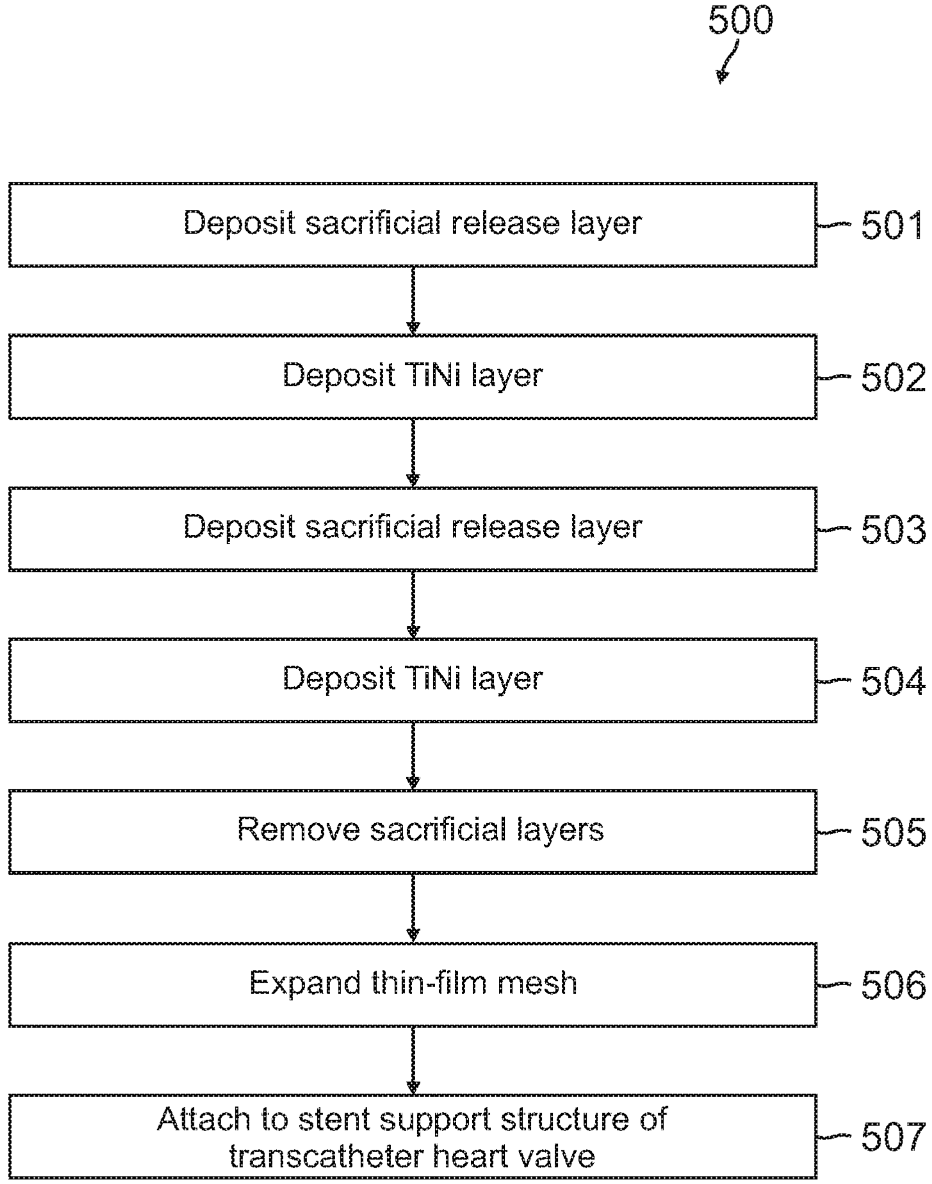
500
Deposit sacrificial release layer
501
Deposit TiNi layer
502
Deposit sacrificial release layer
503
Deposit TiNi layer
504
Remove sacrificial layers
505
Expand thin-film mesh
506
Attach to stent support structure of transcatheter heart valve
507

FIG. 5

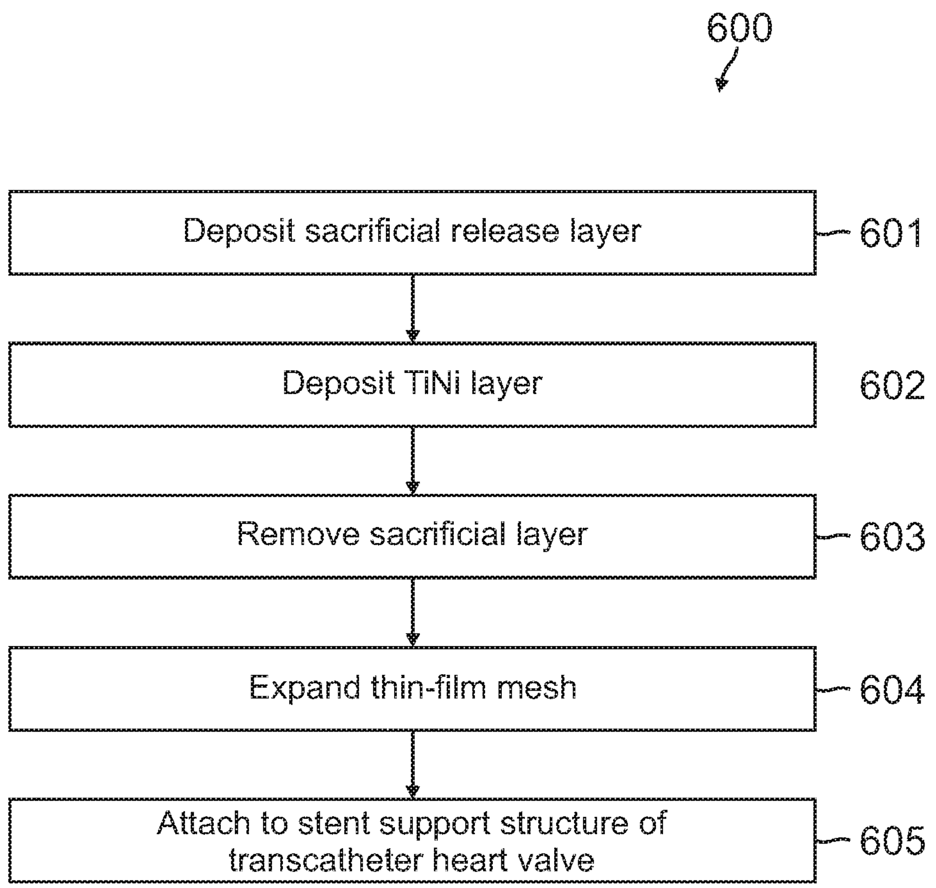
600
Deposit sacrificial release layer
601
Deposit TiNi layer
602
Remove sacrificial layer
603
Expand thin-film mesh
604
Attach to stent support structure of transcatheter heart valve
605

FIG. 6

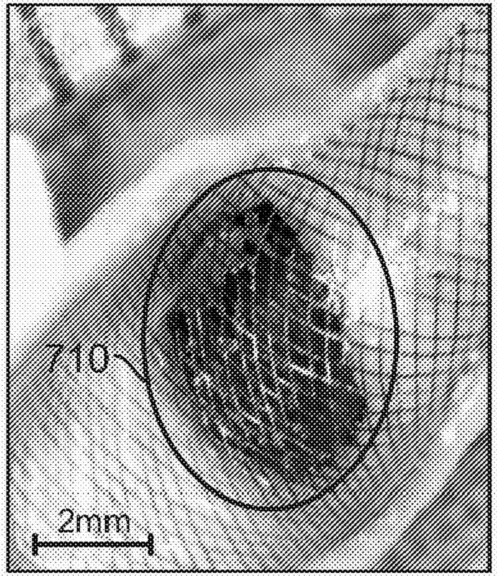

FIG. 7A

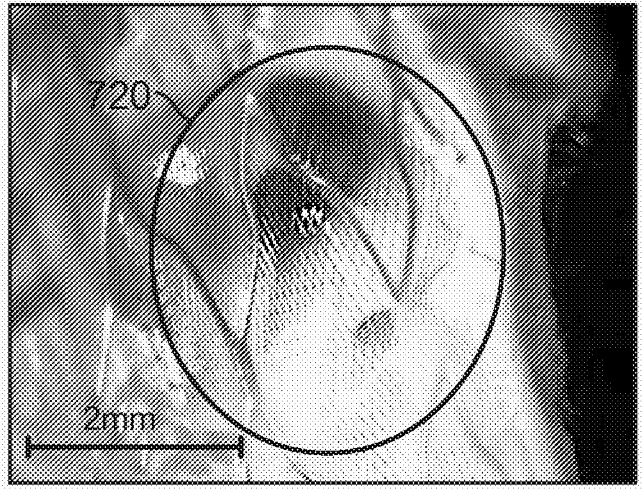

FIG. 7B

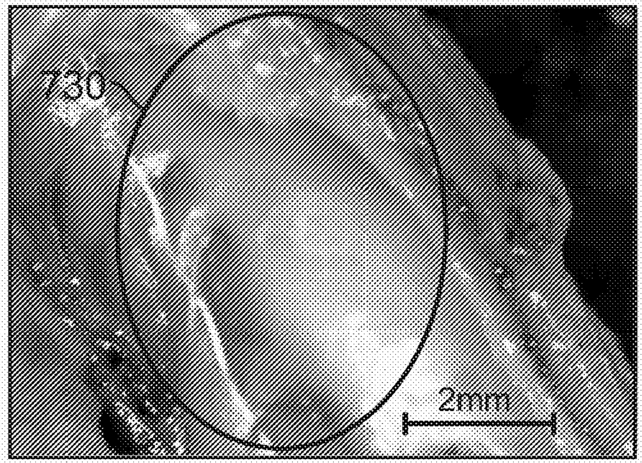

FIG. 7C

THIN-FILM TRANSCATHETER HEART VALVE

[0001] The present application claims the benefit of U.S. Provisional Application No. 62/337,801, filed on May 17, 2016, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure generally relates to transcatheter heart valves and, more particularly, to transcatheter heart valves that include a fenestrated thin-film.

BACKGROUND

[0003] Transcatheter aortic valve replacement (TAVR) is well-established as the standard of care for patients with severe symptomatic aortic stenosis who are not candidates for surgery. In these procedures, the diseased valve is not removed but is instead crushed by a superimposed stent-based, bioprosthetic valve. A known complication of the procedure is paravalvular leak (PVL), where there is an incomplete seal between the aortic annulus and the bioprosthetic valve. PVL is common post transcatheter valve placement with a reported incidence between 50% and 85%. Further it is known that moderate to severe PVL is an independent predictor of mortality in the post-operative period to 30 days, as well as at 1 and 2-year follow-up.

[0004] Thus, there is a need for an improved transcatheter valve that can reduce the incidence of PVL.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] Figure 1 is a perspective view of a conventional transcatheter heart valve.

[0006] Figure 2 is a perspective view of a thin-film transcatheter heart valve according to an embodiment of the present disclosure.

[0007] Figure 3A is a plan view of an etched semiconductor wafer for making a thin-film mesh cover for a transcatheter heart valve.

[0008] Figure 3B is a cross-sectional view of the wafer of Figure 3A along lines D:D.

[0009] Figure 4A is a perspective view of a portion of a thin-film mesh cover prior to expansion.

[0010] Figure 4B is a plan view of a portion of a thin-film mesh cover after expansion.

[0011] Figure 5 illustrates a method for forming the thin-film mesh cover of Figure 2 using a three-dimensional thin-film mesh.

[0012] Figure 6 illustrates a method for forming the thin-film mesh cover of Figure 2 using a two-dimensional thin-film mesh.

[0013] Figure 7A is an image showing results of a conventional braided stent implanted at a model aneurysm in a rabbit.

[0014] Figure 7B is an image showing results of a thin-film Nitinol covered stent with a lower pore density implanted at a model aneurysm in a rabbit.

[0015] Figure 7C is an image showing results of a thin-film Nitinol covered stent with a higher pore density implanted at the model aneurysm in a rabbit.

[0016] Embodiments of the present disclosure and their advantages are best understood by referring to the detailed description that follows. It should be appreciated that like reference numerals are used to identify like elements illustrated in one or more of the figures, in which the showings therein are for purposes of illustrating the embodiments and not for purposes of limiting them.

DETAILED DESCRIPTION

[0017] One or more embodiments of the present disclosure provide improved transcatheter heart valves that incorporate a fenestrated thin-film covering and related methods. The thin-film covering facilitates incorporation of the prosthetic valve into the surrounding tissue. Better incorporation of the valve into the surrounding tissue advantageously reduces the incidence of paravalvular leak (PVL), which is a significant improvement over conventional transcatheter heart valves.

[0018] As used herein, a thin-film mesh (also referred to as a fenestrated thin-film or a fenestrated thin-film sheet) is defined to be less than 100 microns in thickness (e.g., between 2 and 30 microns in thickness). An example thin-film mesh comprises fenestrated thin-film Nitinol (TFN), although other thin-film mesh materials may be used to form the transcatheter heart valve disclosed herein. The following discussion is thus directed to transcatheter heart valves including thin-film Nitinol without loss of generality. Example fenestrated thin-film Nitinol is disclosed in commonly-assigned International Application No. PCT/US2014/61836 (the "PCT application"), filed October 22, 2014, which in turn claims the benefit of U.S. Provisional Application No. 61/894,826, filed October 28, 2013. The contents of both of these applications are hereby incorporated by reference in their entirety.

[0019] To form a thin-film mesh, Nitinol (NiTi) may be sputtered onto patterned silicon wafers. The patterned mesh may then be removed using a lift-off process by etching away a sacrificial layer such as a chromium layer to form a two-dimensional (2D) thin-film mesh. A sheet of fenestrated thin-film Nitinol may be disposed about a transcatheter heart valve and attached, for example, by soldering, by an adhesive (e.g., glue), by fastening with a wire or string, and/or by stitches.

[0020] Alternatively, this lift-off process is combined with multiple-layer depositions of Nitinol separated by layers of sacrificial material to fabricate cylindrical a thin-film mesh, which are three-dimensional (3D) in the sense that two layers are joined together along their longitudinal edges such that the resulting joined layers may be opened up to form a cylinder. For example, the three-dimensional fabrication techniques disclosed in the PCT application may be used to manufacture a circumferential ring of thin-film Nitinol, which would then be attached to the transcatheter heart valve.

[0021] A conventional transcatheter heart valve 100 is shown in Figure 1A. Transcatheter heart valve includes a stent support structure 105 that may either be self-expandable or balloon expandable, a bioprosthetic valve 110, and an outer covering 115 (also referred to as an outer cover). Stent support structure 105 may be composed of an alloy frame (e.g., Nitinol alloy frame, a cobalt chromium frame, or other alloy frame). Outer covering 115 may be composed of a polymer such polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE), or other polymer. Outer covering 115 may also be composed a biologically derived tissues such as decellularized pericardium from a porcine or bovine source. When implanted in a patient, outer covering 115 sits in the patient's aortic annulus. A problem with conventional transcatheter heart valves 100 is that outer coverings 115 made of polymers (e.g., PET, PTFE, or other polymer) or biologically derived tissues are impermeable or only semi-permeable membranes and, thus, do not sufficiently endothelialize or facilitate robust tissue in-growth. This may be responsible for the high incidence of PVL observed in transcatheter heart valves.

[0022] To prevent or substantially eliminate the risk of PVL, a thin-film mesh covering 215 (also referred to as a thin-film mesh cover or a thin-film mesh addition) is attached to stent support structure 105, as shown by thin-film transcatheter heart valve 200 in Figure 2. Thin-film mesh covering 215 replaces outer covering 115 of conventional transcatheter heart valve 100. Accordingly, thin-film transcatheter heart valve 200 includes stent support structure 105, bioprosthetic valve 110, and thin-film mesh covering 215. Thin-film mesh covering 215 facilitates rapid tissue in-growth and endothelialization of endovascular implants. Advantageously, robust tissue in-growth facilitates improved integration with the valve annulus and decreases the incidence of PVL. In other embodiments, thin-film transcatheter heart valve 200 includes both outer covering 115 and thin-film mesh covering 215, with thin-film mesh covering 215 disposed on the outer surface of outer covering 115 (not shown).

[0023] In one example, thin-film mesh covering 215 is attached to stent support structure 105 by soldering (e.g., soldering with a low temperature solder), by fastening with a wire or string, by an adhesive (e.g., glue), or by stitches. In another example, thin-film mesh covering 215 is attached to stent support structure 105 by a wire or string. In other examples, thin-film mesh covering 215 is attached to stent support structure 105 using other fastening methods as appropriate.

[0024] In one embodiment, thin-film mesh covering 215 may be formed using a deep-reactive ion etched semiconductor wafer as described in the PCT application. Figure 3A is a plan view of a substrate such as an etched wafer 300 formed by using a deep reactive-ion etching (DRIE) process. Grooves 305 are separated by lands 310. Rows of grooves 305 are displaced with respect to adjacent rows of grooves 305 such that a groove 305 in one row is longitudinally displaced by approximately 50 % with regard to the neighboring grooves in the immediately-adjacent grooves. Figure 3B illustrates a cross-section of etched wafer 300. Grooves 305 are separated by lands 310. The width of lands 310 may be 1 to 30 microns (e.g., between 4 and 30 microns, between 4 and 20 microns, between 1 and 20 microns, approximately 10 microns, etc.) in some embodiments. Similarly, the width of grooves 305 may be 1 to 30 microns (e.g., between 4 and 30 microns, between 4 and 20 microns, between 1 and 20 microns, approximately 10 microns, etc.). The longitudinal extent of each groove 305 may range from a few microns to approximately 500 microns (e.g., between 100 microns and 500 microns, between 100 microns and 400 microns, between 100 microns and 300 microns, between 150 microns and 400 microns, etc.).

[0025] Nitinol may then be deposited on etched wafer 300 to a thickness of approximately 1 to 30 microns (e.g., between 4 and 30 microns, between 4 and 20 microns, between 2 and 20 microns, approximately 10 microns, etc.) and then lifted off. Grooves 305 will then be duplicated on the resulting patterned thin-film Nitinol sheet as corresponding longitudinally-extending fenestrations. The resulting patterns of fenestrations may also be denoted as a fiche in that the fenestrations are in collapsed form prior to an expansion of the

Nitinol sheet. Just like a microfiche, each fiche or pattern of fenestrations effectively codes for the resulting fenestrations when the stent cover is expanded to fully open up the fenestrations.

[0026] This may be better appreciated with regard to Figure 4A, which shows two fenestrations 400 in a portion of a thin-film mesh 405 prior to expansion. In Figure 4B, mesh 405 is expanded in the lateral direction 410 (also referred to as the axis of expansion of mesh 405) orthogonal to the longitudinal axis of fenestrations 400 (also referred to as the longitudinal direction or long axis of fenestrations 400) such that fenestrations 400 open up into a "chain-link" fence pattern of diamond-shaped fenestrations. It will be appreciated that other fenestration shapes may be used in alternative embodiments. In some embodiments, the expansion may extend mesh 405 in a range from 100% to 800%. Thin-film mesh 405 as fabricated (prior to expansion) has fenestrations 400 that duplicate grooves 305 of wafer 300, and struts 415 that duplicate lands 310 of wafer 300. Accordingly, prior to expansion, the longitudinal extent of each fenestration 400 may range from a few microns to approximately 500 microns (e.g., between 100 microns and 500 microns, between 100 microns and 400 microns, between 100 microns and 300 microns, between 150 microns and 400 microns, etc.). After expansion, the longitudinal extent of each fenestration 400 decreases (e.g., between 5% and 20 %) while the width of each fenestration 400 increases (e.g., between 100 to 800%). Struts 415 may have a thickness of between 1 and 30 microns (e.g., between 4 and 30 microns, between 4 and 20 microns, between 2 and 20 microns, approximately 10 microns, etc.) prior to and after expansion.

[0027] Thin-film mesh covering 215 may include fenestrations having a longitudinal axis that is parallel to the longitudinal axis of stent support structure 105 (also referred to as the longitudinal direction of stent support structure 105). Accordingly, thin-film mesh covering 215 may be fabricated to be expandable in the radial direction. When thin-film mesh covering 215 is expanded, a radius of the circular cross-section of thin-film mesh covering 215 may be equal or approximately equal to a radius of the circular cross-section of stent support structure 105. Alternatively, thin-film mesh covering 215 may include fenestrations having a longitudinal axis that is orthogonal to the longitudinal axis of stent support structure 105. Accordingly, thin-film mesh covering 215 may be expandable in the longitudinal axis of stent support structure 105.

[0028] The resulting high pore density, fenestrations per square mm, (e.g., between 81 and 1075 pores per mm^2, between 134 and 227 pores per mm^2, between 81 and 227 pores per mm^2, etc.) and low metal coverage (e.g., between 19 and 66%, between 24 and 36%, between 19% and 36%, etc.) is very advantageous with regard to promoting a planar deposition of fibrin followed by a rapid endothelialization. In this fashion, thin-film mesh covering 215 shown in Figure 2 is incorporated into the blood vessel endothelial lining, which thus seals the end of thin-film transcatheter heart valve to prevent PVL.

[0029] Thin-film meshes such as thin-film mesh 405, orientation of fenestrations, and various parameters for thin-film meshes relating to fenestrations such as fenestrations 405, struts such as struts 415, pore density, percent metal coverage, strut angle, and other features of the thin-film meshes may be implemented in accordance with the techniques described in U.S. Provisional Application No. 62/148,689, previously referenced herein.

[0030] In addition to prevention of PVL, the biological seal of the endothelium also serves to anchor thin-film transcatheter heart valve 200. As the body incorporates the thin-film Nitinol elements of thin-film transcatheter heart valve 200 into the vessel wall, thin-film transcatheter heart valve 200 is stabilized mechanically, thereby mitigating the issue of migration. Notably, this is accomplished without damage to the vessel wall or adjacent structures.

[0031] Data from an animal model have demonstrated that the placement of a thin film of Nitinol over a branch vessel (i.e., over the ostium of the lumbar artery where it branches from the abdominal aorta) advantageously does not impede adequate flow in the branch vessel, as described in Ding et al., Preclinical Testing of a Novel Thin Film Nitinol Flow-Diversion Stent in a Rabbit Elastase Aneurysm Model, American Journal of Neuroradiology, 2016; 37(3):497-501, which is incorporated herein by its entirety. Therefore, a thin-film covered transcatheter heart valve could safely cover the ostium of a coronary artery in the proximal aorta without fear of occlusion.

[0032] Figure 5 illustrates a method 500 for forming thin-film transcatheter heart valve 200 using a three-dimensional thin-film mesh.

[0033] At step 501, a first sacrificial layer (e.g., a lift-off or release layer) of Cr (or other sacrificial or barrier layers) is deposited on a silicon substrate (e.g., silicon wafer substrate 300), for example, in a sputtering chamber while the substrate is held at high vacuum or under ultra-high vacuum, using e-beam evaporation or PECVD. When subsequently etched away, the lift-off layer may release the finished product such as thin-film mesh covering 215 from the substrate (e.g., silicon wafer substrate 300) and may thus be referred to as a release layer. The lift-off layer may be 1700 to 3000 Angstroms of sputter-deposited chromium. Step 501 and one or more of subsequent steps 502 through 504 may all be performed while the substrate continues to be held under a vacuum in a sputtering chamber and without removing the vacuum (or removing the substrate wafer or device from the vacuum chamber) until all depositions are completed.

[0034] Prior to the deposition of the lift-off layer, the substrate may first (e.g., before deposition) be prepared in step 501 by etching (using, for example, dry etching or DRIE) grooves or trenches that will correspond to fenestrations 400 of the web fiche pattern or other surface features that may correspond to structures (e.g., mesh fenestrations) of a finished product such as thin-film mesh covering 215.

[0035] At step 502, a first layer of NiTi may be deposited using one or more sputtering or other techniques. An example thickness of this first layer (as well as the second layer of NiTi) is between 2 and 30 microns in thickness (e.g., 3 to 5 microns).

[0036] At step 503, a second sacrificial layer of Cr (or other sacrificial or barrier layers) may be deposited on the silicon substrate (e.g., silicon wafer substrate 300), for example, in a sputtering (or vacuum) chamber while the substrate continues to be held at high vacuum or under ultra-high vacuum, using e-beam evaporation or PECVD. A shadow mask may be placed over the substrate and the previously deposited layers such as the release layer and the first NiTi layer prior to depositing the second sacrificial layer to protect covered (or blocked) areas from deposition of the second Cr sacrificial layer (or other sacrificial or barrier layers). The shadow mask may be removed from the substrate and the accumulated deposited layers after depositing the second sacrificial layer.

[0037] In some embodiments, an aluminum bonding layer is applied using a reverse mask to prevent formation of an oxidized surface layer on the first NiTi layer. It will be appreciated that bonding of one NiTi layer onto another can be problematic if an oxidized surface layer is formed on the first NiTi layer because this surface layer inhibits the bonding of one NiTi layer to another. The reverse mask (as implied by the name) is the complement of the shadow mask used to form the second sacrificial layer. In other words, the reverse mask covers the second sacrificial layer and exposes the uncovered areas of the first NiTi layer. Aluminum may then be sputtered through the reverse mask to form the bonding layer. Since the bonding layer is applied, the first NiTi layer may be exposed to the atmosphere between the masking with the shadow mask and the subsequent masking with the reverse mask. In this fashion, manufacturing costs are lowered in that the applications of the masks is greatly aided by performing the mask applications outside of the vacuum chamber using, for example, conventional semiconductor pick-and-place equipment. Alternatively, the first NiTi layer may be maintained in a vacuum or an ultra-high vacuum until a second layer of NiTi is deposited, including during the application and removal of the shadow mask.

[0038] At step 504, a second layer of NiTi may be deposited using one or more sputtering or other techniques. At this step, deposition of the second layer of NiTi may result in the second layer of NiTi bonding to the first layer of NiTi at those areas left exposed by the second sacrificial layer, forming, for example, bonds at the edges of thin-film mesh covering 215.

[0039] In embodiments in which the bonding layer is utilized, wafer 300 may be heated to approximately 500 to 600 degrees prior to removal of the lift-off and sacrificial layers at step

506. Such heating partially melts the aluminum, which then becomes very reactive despite the formation of some aluminum oxides. The molten un-oxidized aluminum is very reactive and chemically bonds to the NiTi layers, resulting in a very secure bond, despite the formation of an oxidized NiTi surface on the first NiTi layer.

[0040] At step 505, removal of the sacrificial layers (e.g., the first sacrificial or release layer and the second sacrificial layer) may be performed using a wet etch and may be performed after allowing the vacuum chamber to repressurize or after removing substrate 300 from the vacuum chamber. Etching the sacrificial layers may release thin-film mesh covering 215 from the substrate and may remove interior layers such as the second sacrificial layer. The etch may comprise soaking silicon substrate wafer 300 and the deposited layers in a solution, for example, of Cr etch, and may create a lumen where sacrificial layers are removed between the first and second NiTi layers that are joined at the edges.

[0041] At step 506, thin-film mesh covering 215 is expanded such that fenestrations 400 open up into a "chain-link" fence pattern of diamond-shaped fenestrations. Further processing may be performed, such as shaping thin-film mesh covering 215 including, for example, shaping thin-film mesh covering 215 into a more cylindrical shape by insertion of a mandrel into the lumen. With thin-film mesh covering 215 in the desired shape, the NiTi layers may be crystallized. Steps 501-506 are further described in the PCT application.

[0042] At step 507, thin-film mesh covering 215 is attached to stent support structure 105 to form a thin-film transcatheter heart valve such as thin-film transcatheter heart valve 200 of Figure 2. Thin-film mesh covering 215 may be attached to stent support structure 105 by soldering, by an adhesive such as glue, by fastening with a wire or string, by stitches, and/or other fastening methods as appropriate. Thin-film transcatheter heart valve 200 may then be implanted in a patient using a transcatheter heart valve delivery system.

[0043] Figure 6 illustrates a method 600 for forming thin-film transcatheter heart valve 200 using two-dimensional thin-film meshes.

[0044] At step 601, a sacrificial layer (e.g., a lift-off or release layer) of Cr (or other sacrificial or barrier layers) is deposited on a silicon substrate (e.g., silicon wafer substrate 300), for example, in a sputtering chamber while the substrate is held at high vacuum or under ultra-high vacuum, using e-beam evaporation or PECVD. Prior to the deposition of the lift-off layer, the substrate may first (e.g., before deposition) be prepared in step 601 by etching (using, for example, dry etching or DRIE) grooves or trenches that will correspond to fenestrations 400 of the web fiche pattern or other surface features that may correspond to structures (e.g., mesh fenestrations) of a finished product such as thin-film mesh covering 215.

[0045] At step 602, a layer of NiTi may be deposited using one or more sputtering or other techniques. An example thickness of this first layer (as well as the second layer of NiTi) is between 2 and 30 microns in thickness (e.g., 3 to 5 microns).

[0046] At step 603, removal of the sacrificial layers may be performed using a wet etch and may be performed after allowing the vacuum chamber to repressurize or after removing substrate 300 from the vacuum chamber. Etching the sacrificial layers may release thin-film mesh covering 215 from the substrate. The etch may comprise soaking silicon substrate wafer 300 and the deposited layers in a solution, for example, of Cr etch.

[0047] At step 604, thin-film mesh covering 215 is expanded such that fenestrations 400 open up into a "chain-link" fence pattern of diamond-shaped fenestrations. Further processing may be performed, such as shaping thin-film mesh covering 215 including, for example, shaping thin-film mesh covering 215 into a more cylindrical shape by annealing on a mandrel. With thin-film mesh covering 215 in the desired shape, the NiTi layers may be crystallized.

[0048] At step 605, thin-film mesh covering 215 is attached to stent support structure 105 to form a thin-film transcatheter heart valve such as thin-film transcatheter heart valve 200 of Figure 2. Thin-film mesh covering 215 may be attached to stent support structure 105 by soldering, by an adhesive such as glue, by fastening with a wire or string, or other fastening methods as appropriate. Thin-film transcatheter heart valve 200 may then be implanted in a patient using a transcatheter heart valve delivery system.

[0049] Thin-film mesh covering 215 formed using the techniques described herein is planar with regard to the wire intersections. In that regard, the columnar fenestrations may be expanded into diamond shapes (e.g., having a length of approximately 300 microns and a width of approximately 150 microns). In contrast, the resulting wire forming the diamond-shaped fenestrations is only 2 to 30 microns in thickness. Each "corner" of the diamond-shaped fenestration is thus relatively flat such that a null region with regard to fluid flow is formed at each corner. This may be better appreciated with regard to Figure 4B, which shows the diamond-shaped fenestrations that result upon expansion. As shown in the close-up view in Figure 4A, for the adjacent longitudinal ends of two diamond-shaped fenestrations 400, the thin-film mesh 405 forms flat interstices that are advantageously conducive to the desired clotting process so that flow diversion of aneurysm is safely achieved. Such interstices are absent in a conventional wire mesh because of the weaving of the relatively coarse wire.

[0050] Endovascular implants that include thin-film Nitinol meshes facilitate robust endothelialization and tissue in-growth and, as such, thin-film Nitinol meshes may be advantageously used to improve transcatheter heart valves. A conventional braided stent, a thin-film Nitinol covered stent with a lower pore density, and a thin-film Nitinol covered stent with a higher pore density were tested by implanting in model aneurysms created in rabbits. The animals were then sacrificed after several weeks and the degree of aneurysm neck healing was examined by removing the arterial vessel segments containing the devices and the model aneurysms for pathological analysis. For the pathological analysis, the arterial vessels were cut along their long axis generating two approximately equal halves, with one half containing the model aneurysm. The sections with the model aneurysm were analyzed with light microscopy. The sections of the devices and micromesh covering the aneurysm neck region was the primary area of interest.

[0051] Figure 7A is an image showing results of the conventional braided stent 4 weeks after implanting at the model aneurysm in a rabbit. The conventional braided stent had a pore density of about 14 pores/mm^2 as implanted.

[0052] Figure 7B is an image showing results of the thin-film Nitinol covered stent having a lower pore density 8 weeks after implanting at the model aneurysm in a rabbit. The thin-film Nitinol was fabricated with a slit length of approximately 300 μm. The thin-film Nitinol had a pore density of approximately 70 pores/mm^2 as implanted. The thin-film Nitinol had a pore density may range from 38 to 70 pores/mm^2 when the strut angle (angle between two struts) is between 30 and 90 degrees. The thin-film Nitinol had a percent metal coverage of between 14% and 21%, and an edge density of between 23 mm of edge per mm^2 of surface area and 42 mm of edge per mm^2 of surface area.

[0053] Figure 7C is an image showing results of the thin-film Nitinol covered stent having a higher pore density 8 weeks after implanting at the model aneurysm in a rabbit. The thin-film Nitinol of this device was fabricated with a slit length of approximately 150 μm. The thin-film Nitinol had a pore density of approximately 150 pores/mm^2 as implanted. The pore density of the thin-film Nitinol may range from 134 to 227 pores/mm^2 when the strut angle is between 30 and 90 degrees. The thin-film Nitinol had a percent metal coverage of between 24% and 36%, and an edge density of between 40 mm of edge per mm^2 of surface area and 68 mm of edge per mm^2 of surface area.

[0054] The aneurysm neck area 720 of the low-pore density thin-film Nitinol covered stent and the aneurysm neck area 730 of the high-pore density thin-film Nitinol covered stent both had robust endothelialization and tissue in-growth compared to the aneurysm neck area 710 of the conventional braided stent. Further, the aneurysm neck area 730 of the high-pore density thin-film Nitinol covered stent had improved endothelialization and tissue in-growth compared to the aneurysm neck area 720 of low-pore density thin-film Nitinol covered stent.

Advantageously, thin-film mesh cover 215 composed of thin-film Nitinol having a pore density of between 50 and 500 pores/mm^2 (e.g., between 50 and 250 pores/mm^2) will facilitate rapid incorporation of a thin-film incorporated transcatheter heart valve such as thin-film transcatheter heart valve 200 into surrounding tissue.

[0055] Embodiments described herein illustrate but do not limit the disclosure. It should also be understood that numerous modifications and variations are possible in accordance with the principles of the present disclosure. Accordingly, the scope of the disclosure is best defined only by the following claims.

CLAIMS

1. A method comprising:

forming a fenestrated thin-film sheet; and

attaching the fenestrated thin-film sheet to a stent support structure to form a thin-film-incorporated transcatheter heart valve;

wherein the fenestrated thin-film sheet, when expanded, has a density of between 50 and 500 pores/mm^2 .

2. The method of claim 1, further comprising:

attaching a bioprosthetic valve to the stent support structure.

3. The method of claim 1, further comprising:

attaching an outer cover to the stent support structure.

4. The method of claim 1, wherein the fenestrated thin-film sheet comprises Nitinol, and wherein the forming of the fenestrated thin-film sheet comprises:

deep reactive ion etching a pattern of grooves on a surface of a substrate, the grooves corresponding to fenestrations in a desired Nitinol structure;

depositing a lift-off layer on the grooved substrate surface;

depositing a first Nitinol layer over the lift-off layer;

lifting off the fenestrated thin-film sheet by etching, wherein the etching removes the lift-off layer; and

expanding the fenestrated thin-film sheet to expand the fenestrations.

5. The method of claim 4, wherein the forming of the fenestrated thin-film sheet comprises forming a two-dimensional fenestrated thin-film mesh, and wherein the attaching the fenestrated thin-film sheet comprises rolling the two-dimensional fenestrated thin-film sheet about the stent support structure.

6. The method of claim 4, wherein the forming of the fenestrated thin-film sheet further comprises:

depositing a sacrificial layer over the first Nitinol layer; and

depositing a second Nitinol layer over the sacrificial layer;

wherein the etching further removes the sacrificial layer, and wherein the forming of the fenestrated thin-film sheet comprises forming a three-dimensional tubular fenestrated thin-film sheet having a circular cross-section with a radius that is approximately equal to a radius of a circular cross-section of the stent support structure.

7. The method of claim 4, wherein:

the depositing comprises depositing the first Nitinol layer having a thickness of between 2 and 30 microns such that the fenestrated thin-film sheet has a thickness of between 2 and 30 microns; and

the deep reactive ion etching the pattern of the grooves comprises forming the grooves having a length of between 100 microns and 500 microns such that each fenestration of the thin-film sheet has a length of between 100 and 500 microns before the expanding, each row of grooves being spaced apart from an adjacent row of grooves by between 4 and 30 microns such that each strut of the thin-film sheet has a width of between 4 microns and 30 microns.

8. The method of claim 1, wherein the attaching of the thin-film sheet comprises attaching the thin-film sheet to an outer surface of the stent support structure by low-temperature soldering and/or by using an adhesive.

9. The method of claim 4, wherein the expanding comprises expanding the fenestrated thin-film sheet such that the fenestrated thin-film sheet has the density of between 50 and 500 pores/mm^2.

10. The method of claim 9, further comprising:

implanting the thin-film-incorporated transcatheter heart valve at a heart valve site of a patient.

11. A transcatheter heart valve, comprising:

a stent support structure extending along a longitudinal axis and having a circular cross-section;

a bioprosthetic valve; and

a fenestrated thin-film mesh cover having a circular cross-section and attached to the stent support structure;

wherein the fenestrated thin-film mesh cover has a density of between 50 and 500 pores/mm^2.

12. The transcatheter heart valve of claim 11, further comprising an outer cover.

13. The transcatheter heart valve of claim 11, wherein the outer cover comprises a polymer outer cover or a decellularized pericardium outer cover.

14. The transcatheter heart valve of claim 11, wherein the fenestrated thin-film mesh cover comprises a fenestrated thin-film Nitinol sheet.

15. The transcatheter heart valve of claim 11, wherein the fenestrated thin-film mesh cover comprises a two-dimensional fenestrated thin-film sheet.

16. The transcatheter heart valve of claim 11, wherein the fenestrated thin-film mesh cover comprise a three-dimensional fenestrated thin-film sheet.

17. The transcatheter heart valve of claim 11, wherein the fenestrated thin-film mesh cover has a thickness of between 2 and 20 microns.

18. The transcatheter heart valve of claim 11, wherein each fenestration of the fenestrated thin-film mesh cover has a length of between 100 and 500 microns along a long axis of the fenestration.

19. The transcatheter heart valve of claim 11, wherein each strut of the fenestrated thin-film mesh cover has a width of between 4 microns and 30 microns.