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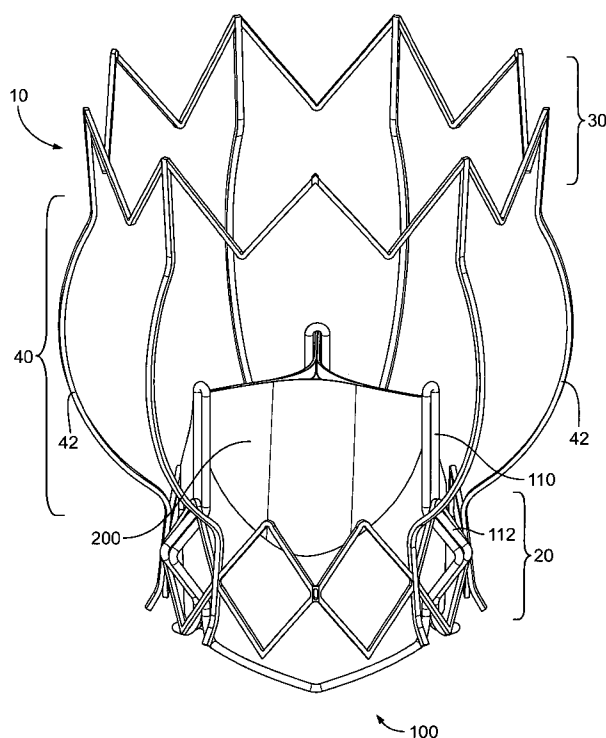


FIG. 1B

(57) Abstract: Prosthetic heart valve apparatus is adapted for delivery into a patient in a circumferentially collapsed condition, followed by circumferential re-expansion at the implant site in the patient. The apparatus includes an annular anchoring structure that can be implanted in the patient first. The apparatus further includes an annular valve support structure, which supports a flexible leaflet structure of the valve. The support and leaflet structures are initially separate from the anchoring structure, but they can be implanted in the patient by interengagement of the support structure with the already-implanted anchoring structure.



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TWO-STAGE COLLAPSIBLE/EXPANDABLE
PROSTHETIC HEART VALVES AND ANCHORING SYSTEMS

[0001] This application claims the benefit of U.S.
provisional patent application 60/995,812, filed
5 September 28, 2007, which is hereby incorporated by
reference herein in its entirety.

Background of the Invention

[0002] This invention relates to collapsible
prosthetic heart valves and valve anchoring systems for
10 use in less invasive approaches to heart valve
replacement (or at least effective replacement).

[0003] Prosthetic heart valves are known that can be
circumferentially collapsed for delivery into a patient
via means that are less invasive than full open-chest,
15 open-heart surgery. When such a valve reaches the
implant site in the patient, the valve
circumferentially re-expands and becomes an operating
valve implant in the patient.

[0004] A prosthetic valve of the type described
20 above may need to include a number of concentric layers
of material and structure. For example, such a valve
typically includes flexible leaflets inside an annular
frame structure. Additional layers of material may be

- 2 -

needed for such purposes as buffering (protecting) the leaflets from excessive contact with the frame structure and/or promoting ingrowth of tissue from the patient's surrounding body tissue structures. The
5 frame structure must be strong enough to securely hold the prosthetic valve in place at the implant site in the patient.

[0005] The above requirements for a strong structure and a structure that includes several concentric layers
10 of material can be inconsistent with the desire to circumferentially collapse the prosthetic valve to a relatively small diameter for less invasive delivery into the patient.

Summary of the Invention

15 **[0006]** In accordance with certain possible aspects of the invention, a prosthetic heart valve system may be deployed into a patient in two sequential steps. The system includes a collapsible/expandable anchoring platform (frame) and a collapsible/expandable valve
20 with integrated leaflets (tissue, polymer, or other appropriate materials).

[0007] The system works by delivering and deploying (implanting) the anchoring platform first to provide a landing site for the collapsible/expandable valve,
25 which is delivered next. The valve and anchoring platform have interlocking features that facilitate securement of the valve to the already-implanted anchoring platform. The anchoring platform also has features to secure itself to the native anatomy. There
30 are several advantages to this approach that will be described later in this specification.

- 3 -

[0008] One of the desired features for minimally invasive (e.g., percutaneous, transapical, transseptal) approaches is low profile (i.e., relatively small diameter or circumferential size) of the valve/delivery system. Many have attempted to reduce this profile. However, this may result in trade-offs with respect to valve performance. With the two-step approach of this invention, the profile of each system component does not have to be stacked on top of the other. By placing (implanting) the two system components in series, the device (valve, anchoring frame, and delivery system) profiles can be significantly reduced without trade-offs in performance to any of the system components. There are other benefits to this approach that will be highlighted later in this specification.

[0009] Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

20 Brief Description of the Drawings

[0010] FIG. 1a is a simplified isometric or perspective view of an illustrative embodiment of apparatus in accordance with the invention.

[0011] FIG. 1b is similar to FIG. 1a, but shows the addition of more structure to the apparatus.

[0012] FIG. 2a is a simplified elevational view of an illustrative embodiment of one component from FIGS. 1a and 1b in accordance with the invention.

[0013] FIG. 2b is a simplified, partial, elevational view of the FIG. 2a component from a different angle.

[0014] FIG. 2c is a simplified top view of the component of FIGS. 2a and 2b.

[0015] FIG. 2d is a simplified perspective or isometric view of the component of FIGS. 2a-c.

[0016] FIG. 3a is a view similar to FIG. 2a, but for another illustrative embodiment in accordance with the invention.

[0017] FIG. 3b is a simplified perspective or isometric view of the FIG. 3a structure.

[0018] FIG. 4a is a view similar to FIG. 3a, but for another illustrative embodiment in accordance with the invention.

[0019] FIG. 4b is a simplified, partial, elevational view of the FIG. 4a structure from a different angle.

[0020] FIG. 4c is a simplified perspective or isometric view of the structure shown in FIGS. 4a and 4b.

[0021] FIG. 5a is a simplified perspective or isometric view of a structure like that shown in FIG. 2a in another operating condition in accordance with the invention.

[0022] FIG. 5b is a simplified, partial, elevational view of what is shown in FIG. 5a.

[0023] FIG. 5c is a simplified elevational view of the FIGS. 5a-b structure from another angle.

[0024] FIG. 5d is a simplified top view of the FIGS. 5a-c structure.

[0025] FIG. 6a is a simplified isometric or perspective view of an illustrative embodiment of another component from FIGS. 1a and 1b in accordance with the invention.

[0026] FIG. 6b is another simplified isometric or perspective view of the FIG. 6a structure from another angle.

- 5 -

[0027] FIG. 7a is a view similar to FIG. 6b for another illustrative embodiment in accordance with the invention.

5 [0028] FIG. 7b is a simplified top view of the structure shown in FIG. 7a.

[0029] FIG. 7c is a simplified, partial, elevational view of the structure shown in FIGS. 7a-b.

10 [0030] FIG. 8a is a view generally similar to FIG. 1a, but shows an illustrative embodiment of how the FIG. 1a components may be assembled in accordance with the invention.

15 [0031] FIG. 8b is a simplified elevational view of the FIG. 8a structure, but shows another illustrative embodiment of how the FIG. 1a components may be assembled in accordance with the invention.

[0032] FIG. 9a is similar to FIG. 5a.

[0033] FIG. 9b is similar to FIG. 8a, but shows the structure from another angle.

20 [0034] FIG. 9c is similar to FIG. 1a, but shows the structure from another angle.

[0035] FIG. 10a is a simplified, partial, elevational view of an illustrative embodiment of use of structure like that shown in FIGS. 3a-b in accordance with the invention.

25 [0036] FIG. 10b is a view somewhat like FIG. 10a for another illustrative embodiment of the invention.

30 [0037] FIG. 11a is a simplified perspective or isometric view of an illustrative embodiment of components that can be used in accordance with the invention.

[0038] FIG. 11b is similar to FIG. 11a, but shows the structure from another angle.

- 6 -

[0039] FIG. 11c is a simplified elevational view of the FIGS. 11a-b structure.

[0040] FIG. 11d is similar to FIG. 11c, but shows the structure from another angle.

5 [0041] FIG. 12a is somewhat like FIG. 11a, but shows an illustrative use of the FIG. 12a structure with an illustrative embodiment of another component in accordance with the invention.

10 [0042] FIG. 12b is a simplified elevational view of the FIG. 12a structure.

[0043] FIG. 13a is a simplified top view of another illustrative embodiment of a component in accordance with the invention.

15 [0044] FIG. 13b is a simplified isometric or perspective view of the FIG. 13a structure.

[0045] FIG. 13c is a simplified, partial, isometric or perspective view showing an illustrative use of the FIGS. 13a-b structure in accordance with the invention.

20 [0046] FIG. 14 is similar to FIG. 6a for an illustrative embodiment with other possible components added.

[0047] FIG. 15 is similar to FIG. 7c for an illustrative embodiment with other possible components added.

25 Detailed Description

[0047] FIG. 1a shows an illustrative embodiment of an anchoring frame 10 and a valve support frame 100, assembled together, but without any of the other components that a valve in accordance with this invention typically includes. Components 10 and 100 are typically made of a highly elastic metal such as nitinol, but can also be made from stainless steel.

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- 7 -

Each of these components may be laser-cut from a tube and then processed to its final shape and dimensions. Each of components 10 and 100 is preferably a continuous annular (ring) structure. Each of components 10 and 100 is annularly, preferably elastically compressible to a smaller annular or circumferential size for delivery into a patient through instrumentation that can be less invasive than full open-chest, open-heart surgery. For example, delivery of the collapsed structures can be through a tube such as a catheter, a trocar, a laparoscopic instrument, or the like. When each component reaches the implant site in the patient, that component can be released to (preferably) elastically re-expand to the approximate size shown in FIG. 1a. This causes the re-expanded component (and any other components carried by that component) to implant itself in the patient. Anchoring structure 10 is delivered into and implanted in the patient first. Then valve support structure 100 (with valve 200 (FIG. 1b) mounted inside it) is delivered into the patient and implanted inside the already-implanted anchoring structure 10.

[0048] Anchoring structure 10 is primarily responsible for holding the valve in place in the patient, in addition to anchoring itself to native anatomy of the patient. Valve support structure 100 includes features that interengage or interlock with features of anchoring structure 10 to hold valve support structure 100 in place relative to anchoring structure 10. In the embodiment shown in FIGS. 1a-b these interlocking features include radial outward projections 112 on the commissure posts 110 of valve support structure 100 fitting into closed-perimeter,

- 8 -

open-center cells 22 in the annulus inflow portion 20 of anchoring structure 10.

[0049] Annulus inflow portion 20 of anchoring structure 10 is typically implanted in or near the patient's native valve annulus. This is the reason for referring to this portion of structure 10 as the annulus inflow portion. ("Inflow" is a term that is used with reference to the direction of blood flow through the prosthetic valve when the valve is in use in a patient. "Outflow" is similarly used with reference to the direction of blood flow through the prosthetic valve.) The embodiment shown in FIGS. 1a-1b is especially adapted for use as a prosthetic aortic valve. Annulus inflow portion 20 is therefore implanted in or near the patient's native aortic valve annulus. An aortic outflow portion 30 of anchoring structure 10 then resides in the patient's aorta. Portions 20 and 30 are connected to one another by connecting strut structure 40, which passes through the patient's valsalva sinus. The connecting struts 42 of structure 40 bulge radially out into the outwardly bulging lobes of the valsalva sinus to help hold the valve in place in the patient.

[0050] Valve or leaflet structure 200 (mounted inside valve support structure 100) typically includes three flexible leaflets that come together to close the valve as shown in FIG. 1b. This occurs when blood pressure above the valve as viewed in FIG. 1b is greater than blood pressure below the valve. When blood pressure below the valve exceeds blood pressure above the valve, the leaflets of the valve are pushed aside to open the valve and allow blood to flow upward through the valve. Suitable materials for leaflets 200

- 9 -

include biological tissue, metal (e.g., thin nitinol), flexible polymers or mesh-reinforced polymers, and the like.

[0051] Again, not all components of a finished and implanted valve are shown in FIG. 1b. For example, other layers of material such as tissue, polymer, fabric, buffer material, or the like can be included for such purposes as cushioning other components, promoting tissue ingrowth, etc.

[0052] FIGS. 2a-d show an illustrative embodiment of a valve support structure 100 by itself from several directions. (FIG. 1b shows only part of that structure.) A possible feature brought out by these FIGS. is the scalloped inflow edge of structure 100. (Again, inflow refers to the direction of blood flow through the valve when in use in a patient.) The anchoring frame 10 may also be similarly scalloped. By "scalloped" it is meant that the inflow edge is relatively high near the base of at least one (preferably all) of the commissures of the patient's native heart valve, and also the commissures 110 of the prosthetic valve. A typical high area is pointed to from the reference letter H. Elsewhere the inflow edge can be relatively low (pointed to from the reference letter L). "High" means that such a portion of the inflow edge is closer to the geometric plane defined by the distal free ends or tips of commissure posts 110. "Low" means that such a portion of the inflow edge is farther from that geometric plane. Making one or more portions of the inflow edge high as described above helps the implanted valve avoid impinging on the patient's native mitral valve and other structures in

- 10 -

the heart that are adjacent the aortic valve (e.g., conduction system pathways and the AV node).

[0053] FIGS. 3a-b show another illustrative embodiment of a valve support structure 100 by itself
5 from different directions. A possible feature brought out by these FIGS. is the provision of what may be called spread elbows for outward projections 112. This means that the two members that make up each commissure post 110 diverge from one another in the annular
10 direction where they extend radially out to form a projection 112. This can help to improve stability of engagement between structures 10 and 100 in an implanted valve.

[0054] FIGS. 3a-b (and also other FIGS.) illustrate
15 the concept that valves of this invention can employ what may be termed independent flexing commissure posts 110. At least above outward projections 112, commissure posts 110 can be free of contact with anchoring structure 10 when components 10 and 100 are
20 interlocked together. Commissure posts 110 are therefore cantilevered to their free end tips and can accordingly flex independently of one another and other stent-like structure (e.g., 10) of the valve. This can help relieve stress on valve structure 200 and has many
25 other potential benefits.

[0055] FIGS. 4a-c show another illustrative embodiment of a valve support structure 100 in accordance with the invention. In this embodiment each commissure post 110 is effectively a single member.
30 Also, the inflow edge is inverted in the up-down direction as compared, for example, to the inflow edge of the structures 100 shown in earlier FIGS.

- 11 -

[0056] FIGS. 5a-d show several views of an annularly or circumferentially compressed or collapsed valve support structure 100 in accordance with the invention. FIG. 5b is only partial, and FIG. 5d is a top view.

5 [0057] FIGS. 6a-b show two views of an illustrative embodiment of anchoring structure 10 by itself.

[0058] FIGS. 7a-c show several views of an illustrative embodiment of what may be referred to as a short anchoring structure 10. This latter type of anchoring structure includes only annulus inflow portion 20 and truncated struts 42 extending up from annulus inflow portion 20 into a portion of the patient's valsalva sinus.

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[0059] FIGS. 8a-b show two ways of implanting component 100 into component 10 in a patient. (Component 10 is assumed to be already implanted at the desired location in the patient.) In FIG. 8a valve frame structure 100 is delivered into anchoring structure 10 from the inflow end of structure 10. In FIG. 8b valve frame 100 is delivered into anchoring structure 10 from the outflow end of structure 10.

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[0060] FIGS. 9a-c show an illustrative embodiment of delivery of valve support structure 100 into anchoring structure 10 in accordance with the invention. In FIG. 9a valve support structure 100 is annularly compressed for delivery into the patient. In FIG. 9b structure 100 is released to re-expand as it approaches the inflow end of already-implanted structure 10. In FIG. 9c structure 100 is pushed into structure 10 via the inflow end of structure 10. Structure 100 latches into structure 10 by means of projections 112 on structure 100 projecting radially out into cells 22 in structure 10.

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[0061] FIGS. 10a-b show details of the interlocking engagement between outward projections 112 on structure 100 and cells 22 in structure 10. FIG. 10a shows this detail for a spread-elbow embodiment like that shown in FIGS. 3a-b. FIG. 10b shows this detail for another embodiment like that shown in FIGS. 9a-c.

[0062] FIGS. 11a-d provide more information about how valve structure 200 may be mounted in valve support structure or frame 100. The three leaflets of valve structure 200 are identified by reference numbers 210a, b, and c. If desired, a cuff (e.g., of fabric and/or tissue sheet material) can be integrated onto the valve assembly to promote tissue ingrowth and to help seal the valve to prevent perivalvular leakage. See, for example, FIG. 14, which shows an illustrative embodiment of such a cuff 300 secured around the outside of the annulus portion 20 of an anchoring frame 10 like that shown in FIG. 6a. As another example, FIG. 15 shows an illustrative embodiment of a cuff 300 secured around the outside of the annulus portion 20 of a short anchoring structure 10 like that shown in FIG. 7c. In each of FIGS. 14 and 15 the cuff 300 may be secured to the underlying structure (e.g., 10) with suture material 310 that passes through the cuff material and loops around adjacent portions of the frame structure 10. Although FIGS. 14 and 15 show cuff 300 extending annularly around the outside of frame structure 10, an alternative is for cuff 300 to extend annularly around the inside of the frame structure.

[0063] FIGS. 12a-b are two views of illustrative embodiments of the assembly of components 10, 100, 200 when a short anchoring frame 10 like that shown in FIGS. 7a-c is used. FIG. 12b shows the use of spread-

- 13 -

elbow projections 112. FIG. 12a shows the use of projections 112 that do not have the spread-elbow configuration. Thus elbows like 112 can point in the same direction (e.g., as in FIG. 12a) or in opposite
5 directions (e.g., as in FIG. 12b).

[0064] FIGS. 13a-c show a rotate and lock embodiment of a valve support structure 100 in accordance with the invention. In this embodiment each commissure post 110 is effectively a single member and includes a
10 projection 112. As shown in FIG. 13a, projections 112 do not extend radially outwardly perpendicular to a circumference of the annular structure, but rather extend radially out at an angle A that is not a right angle to the circumference. FIG. 13c shows details of
15 the interlocking engagement between angled projections 112 and cells 22 in structure 10. The valve support structure 100 is secured to anchoring structure 10 by using a rotate and lock feature. The valve frame 100 is inserted into the anchoring structure 10 and then
20 rotated in the direction of the angled projections 112 to engage projections 112 with portions of the perimeter of cells 22.

[0065] Recapitulating and extending the foregoing, the following are some of the various possible features
25 and highlights of the invention.

[0066] Two-stage deployment valve system. Valve frame 100 and anchoring frame 10 can be integrated into the same delivery system or can be accomplished using two separate delivery systems.

30 **[0067]** Lower profile of the integrated system. Especially lower profile if collapsible/expandable valve 100/200 and anchoring 10 systems are separate.

[0068] Anchoring/docking frame 10 is delivered and deployed first and independent of the valve 100/200.

[0069] The anchoring/docking frame 10 has anchoring features and mechanisms at the inflow edge 20, middle section 40, and the outflow edge 30 to secure it in place and prevent migration. The anchoring/docking frame 10 can also have anchoring sections at the inflow 20 only, middle section 40 only, outflow 30 only, or any combination thereof.

[0070] The anchoring frame 10 will anchor in place using native geometry (patient anatomy) and may remodel that geometry to provide an adequate landing site for the subsequently delivered valve 100/200.

[0071] The collapsed valve 100/200 is delivered second and deployed/expanded within the anchoring structure 10 upon reaching the landing site. The collapsed valve 100/200 can also be expanded just before reaching the anchoring frame 10 and then pushed in to lock.

[0072] The valve 100/200 has feature geometries (e.g., 112) to make it mate and interlock in place within the existing deployed anchoring structure 10.

[0073] The valve 100/200 has independently flexing commissure posts 110 that contribute to prolonged, durable performance by reducing stresses.

[0074] A cuff (e.g., like above-mentioned cuff 300) can be integrated onto the valve frame 100 assembly to aid in sealing in order to prevent perivalvular leaks. Alternatively or in addition, such a cuff 300 can be integrated onto the anchoring frame 10 for similar purposes as shown, for example, in FIG. 14 or 15.

[0075] The valve frame 100 remains in place via the interlocking mechanism 22/112, in addition to its

- 15 -

radial force (frame 100 can be manufactured from memory-shaped nitinol or from stainless steel and then expanded with a balloon).

[0076] The slotted commissure post design (e.g., 110 in FIGS. 1a-b) facilitates leaflet integration by sliding the edges of the leaflets 200 in the inverted U-shaped opening in each post 110 and wrapping around before securing the leaflets to the valve frame 100. Alternatively, for this or other valve frames 100 shown herein, the valve frame may be dipped over specially designed mandrels to create polymeric leaflets that are integral with the frame. In other words, the leaflet structure may be created using a forming process producing polymeric leaflets that are integral with the valve support structure.

[0077] The symmetry of expanded frame cells 22 at the lower band (inflow side) 20 of the anchoring frame 10 allows freedom in valve radius orientation because the valve frame (stent) elbows 112 can interlock with any of the expanded cells 22.

[0078] In other embodiments, if rotational alignment between the valve 100/200 and the anchoring frame 10 is desired, a suture line (nitinol wire or any other appropriate member material) pre-attached to the valve 100/200 and running into corresponding and desired cell 22 locations in the anchoring frame can be used. The suture line can be used to guide the valve 100/200 as it is being advanced; and once at the desired location, the valve 100/200 can be deployed and the holding/retaining line can be removed. Upon deployment, the suture line can be cut and removed.

[0079] A sealing cuff (e.g., like 300) can be

- 16 -

incorporated on the valve frame 100, the anchoring frame 10, or both, to prevent leakage.

[0080] Other interlocking concepts/geometries between the valve frame 100 and anchoring frame 10 are possible and can be employed. What has been presented is an example.

[0081] The contour/geometry of the interlocking cell 22 in the anchoring frame 10 can be of different geometries that would also adapt, mate, and interlock with corresponding shapes 112 on the valve frame 100.

[0082] The short anchoring frame embodiment (e.g., FIGS. 7a-c) has capabilities in anchoring using barbs 44 on the inflow end, using its outward bias radial force, and using elongated barbs 42 (straight or curved) on the outflow end. The elongated barbs 42 have a dual function (anchoring by engaging native calcified leaflets and holding those leaflets radially outwardly, away, and clear to prevent interference with new valve function). Another embodiment may have the barbs 42 connected together on the outflow end, allowing shorter sections to engage the native leaflets. The height of the short frame 10 can be short enough so it does not interfere with blood perfusion into the patient's coronary arteries.

[0083] The anchoring frame 10 can be self-expanding or balloon expandable. The valve frame 100 can also be self-expanding or balloon expandable.

[0084] The delivery system used in accordance with the invention can have both scenarios integrated in series or a desired combination of self- and balloon-expanding mechanisms.

[0085] The invention provides the ability to precisely size the valve frame 100 once the anchoring

- 17 -

frame 10 is deployed (in the case of separate systems). Once the anchoring frame 10 is in place, the opening can be sized (measured, e.g., fluoroscopically) and the appropriate valve 100/200 size can be selected to be expanded and implanted within the anchoring frame 10.

5 **[0086]** Restating at least some of the foregoing in terms that may to some extent be different from terms used at other points in this specification, apparatus for use as a prosthetic heart valve may include an
10 annular anchoring structure (e.g., 10) that is adapted for (1) delivery into a patient in a circumferentially collapsed condition, and (2) circumferential re-expansion and anchoring engagement with tissue of the patient when at an implant site in the patient. The
15 apparatus may further include an annular valve support structure (e.g., 100) that is initially separate from the anchoring structure 10 and that is adapted for (1) delivery into the patient in a circumferentially collapsed condition, and (2) circumferential re-
20 expansion and interengagement with the anchoring structure when adjacent to the anchoring structure in the patient. The apparatus may still further include a flexible leaflet structure (e.g., 200) disposed inside the valve support structure.

25 **[0087]** The above-mentioned anchoring structure 10 may include a plurality of closed-perimeter, open-center cells (e.g., 22) disposed in an array that extends annularly (circumferentially) around the anchoring structure.

30 **[0088]** The above-mentioned valve support structure 100 may include a plurality of projections (e.g., 112), each of which can extend radially

- 18 -

outwardly into a respective one of the above-mentioned cells 22.

[0089] The above-mentioned valve support structure 100 may include a plurality of
5 circumferentially spaced commissure post structures (e.g., 110). Each of the above-mentioned projections 112 may be on a respective one of the commissure post structures.

[0090] Each of the above-mentioned projections 112
10 may include first and second inclined surfaces (e.g., 113a and 113b in FIG. 4a) that meet at a radially outermost peak (e.g., 113c in FIG. 4a). The first inclined surface 113a may incline from the peak 113c radially inwardly in a direction toward an inflow end
15 of the apparatus (e.g., toward the bottom as viewed in FIG. 4a). The second inclined surface 113b may incline from the peak 113c radially inwardly in a direction toward an outflow end of the apparatus (e.g., toward the top as viewed in FIG. 4a).

20 [0091] Each of the above-mentioned projections 112 and the respective cell 22 into which that projection can extend may be sized so that the first inclined surface 113a can contact a first portion (e.g., 23a in FIG. 6b) of the perimeter of the cell that is toward
25 the inflow end of the apparatus, and also so that, at the same time, the second inclined surface 113b can contact a second portion (e.g., 23b in FIG. 6b) of the perimeter of the cell that is toward the outflow end of the apparatus. Interlocking features of this kind help
30 prevent relative movement between frames 10 and 100 after those components have interlocked. (As used in contexts like this, "contact" may mean either direct contact or contact that is transmitted through one or

- 19 -

more intervening layers of other material such as fabric, tissue, or the like.)

[0092] Each of the above-mentioned projections 112 may further include third and fourth inclined surfaces (e.g., 113d and 113e in FIG. 3a) that meet at a radially outermost peak (e.g., 113f in FIG. 3a). The third and fourth surfaces 113d and 113e and the second peak 113f may be circumferentially spaced from the first and second inclined surfaces 113a and 113b and the first peak 113c, respectively (e.g., as shown in FIG. 3a, or as shown in FIG. 5b). The third inclined surface 113d may incline from the second peak 113f radially inwardly in a direction toward the inflow end (e.g., toward the bottom in FIG. 3a), and the fourth inclined surface 113e may incline from the second peak 113f radially inwardly in a direction toward the outflow end (e.g., toward the top in FIG. 3a).

[0093] Each of the above-mentioned projections 112 and the respective cell 22 into which that projection can extend may be sized so that all four of the above-mentioned inclined surfaces 113a, 113b, 113d, and 113e can, at the same time, contact respective portions of the perimeter of the cell (see, for example, FIG. 10a where such four cell perimeter portions are identified as 25a, 25b, 25d and 25e). Two of these cell perimeter portions 25a and 25d are toward the inflow end (e.g., toward the bottom in FIG. 10a), and the other two cell perimeter portions 25b and 25e are toward the outflow end (e.g., toward the top in FIG. 10a).

[0094] In each of the above-mentioned projections 112, the first and third inclined surfaces 113a and 113d may diverge from one another toward the first and second peaks 113c and 113f (e.g.,

- 20 -

as shown in FIG. 3a). The same may be true of the second and fourth inclined surfaces 113d and 113e. This gives a projection 112 a spread elbow configuration as described elsewhere in this specification.

5 **[0095]** The above-mentioned first and third cell perimeter portions 25a and 25d may meet at a point (e.g., 27a in FIG. 10a) and may incline away from one another toward the outflow end (e.g., toward the top in
10 FIG. 10a). The above-mentioned second and fourth cell perimeter portions 25b and 25e may similarly meet at a point (e.g., 27b in FIG. 10a) and may incline away from one another toward the inflow end (e.g., toward the bottom in FIG. 10a).

15 **[0096]** The above-mentioned anchoring structure 10 may include a plurality of members (e.g., 44 in FIG. 13c) that are adapted (e.g., as a result of resilient bias) to incline radially outwardly on an inflow side of the patient's native heart valve annulus
20 at the implant site. Alternatively or in addition, the anchoring structure 10 may include a plurality of members (e.g., 42) that are adapted (e.g., as a result of resilient bias) to incline radially outwardly on an outflow side of the patient's native heart valve
25 annulus at the implant site. In such a case, the members 42 may be adapted to push radially outwardly on the patient's native heart valve leaflets at the implant site.

30 **[0097]** The above-mentioned anchoring structure 10 may be resiliently biased to circumferentially re-expand. Alternatively or in addition, the above-mentioned valve support structure 100 may be resiliently biased to circumferentially re-expand.

[0098] The above-mentioned anchoring structure 10 may include an annular annulus inflow portion (e.g., 20) adapted for interengagement with the valve support structure 100. Anchoring structure 10 may further
5 include an annular aortic outflow portion (e.g., 30) adapted for disposition in the patient's aorta downstream from the patient's native aortic valve at the implant site. Anchoring structure 10 may still further include at least one connecting strut (e.g.,
10 42) extending between and connecting the annulus inflow portion 20 and the aortic outflow portion 30.

[0099] A method of implanting a prosthetic heart valve in a patient may include implanting an annular anchoring structure (e.g., 10) in the patient by
15 delivering the anchoring structure into the patient in a circumferentially collapsed condition and then circumferentially expanding the anchoring structure while in the patient to implant the anchoring structure at an implant site in the patient. The method may
20 further include delivering an annular valve support structure (e.g., 100), which is initially separate from the anchoring structure 10, into the patient in a circumferentially collapsed condition. The method may still further include circumferentially expanding the
25 valve support structure 100 while in the patient, and interlocking the expanded valve support structure with the implanted anchoring structure 10.

[0100] A method like the above may employ inserting the valve support structure 100 into the implanted
30 anchoring structure 10 in the direction that blood will flow through the implanted valve. Alternatively, the method may employ inserting the valve support structure 100 into the implanted anchoring structure 10

- 22 -

in a direction that is opposite to the above-mentioned bloodflow direction.

[0101] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, instead of both of components 10 and 100 being elastically compressible and re-expandable, either or both of those components may be plastically compressible and re-expandable. Such plastic re-expansion may be, for example, by inflation of a balloon catheter temporarily inserted inside the component to be plastically re-expanded.

The Invention Claimed Is:

1. Apparatus for use as a prosthetic heart valve comprising:

an annular anchoring structure that is adapted for (1) delivery into a patient in a
5 circumferentially collapsed condition, and (2) circumferential re-expansion and anchoring engagement with tissue of the patient when at an implant site in the patient;

an annular valve support structure that
10 is initially separate from the anchoring structure and that is adapted for (1) delivery into the patient in a circumferentially collapsed condition, and (2) circumferential re-expansion and interengagement with the anchoring structure when adjacent to the anchoring
15 structure in the patient; and

a flexible leaflet structure disposed inside the valve support structure.

2. The apparatus defined in claim 1 wherein the anchoring structure comprises a plurality of closed-perimeter, open-center cells disposed in an array that extends annularly around the anchoring
5 structure.

3. The apparatus defined in claim 2 wherein the valve support structure comprises a plurality of projections, each of which can extend radially outwardly into a respective one of the cells.

4. The apparatus defined in claim 3 wherein the valve support structure comprises a plurality of circumferentially spaced commissure post structures,

- 24 -

and wherein each of the projections is on a respective
5 one of the commissure post structures.

5. The apparatus defined in claim 4 wherein
each of the projections comprises first and second
inclined surfaces that meet at a radially outermost
peak, the first inclined surface inclining from the
5 peak radially inwardly in a direction toward an inflow
end of the apparatus, and the second inclined surface
inclining from the peak radially inwardly in a
direction toward an outflow end of the apparatus.

6. The apparatus defined in claim 5 wherein
each of the projections and the respective cell into
which that projection can extend are sized so that the
first inclined surface can contact a first portion of
5 the perimeter of the cell that is toward the inflow end
of the apparatus, and at the same time the second
inclined surface can contact a second portion of the
perimeter of the cell that is toward the outflow end of
the apparatus.

7. The apparatus defined in claim 6 wherein
each of the projections further comprises third and
fourth inclined surfaces that meet at a radially
outermost second peak, the third and fourth inclined
5 surfaces and the second peak being circumferentially
spaced from the first and second inclined surfaces and
the peak, respectively, the third inclined surface
inclining from the second peak radially inwardly in a
direction toward the inflow end, and the fourth
10 inclined surface inclining from the second peak
radially inwardly in a direction toward the outflow
end.

- 25 -

8. The apparatus defined in claim 7 wherein each of the projections and the respective cell into which that projection can extend are further sized so that the third inclined surface can contact a third
5 portion of the perimeter of the cell that is toward the inflow end at the same time that the first inclined surface can contact the first portion, and so that, at that same time, the fourth inclined surface can contact a fourth portion of the perimeter of the cell that is
10 toward the outflow end.

9. The apparatus defined in claim 8 wherein, in each of the projections, the first and third inclined surfaces diverge from one another toward the peak and the second peak, and the second and fourth
5 inclined surfaces also diverge from one another toward the peak and the second peak.

10. The apparatus defined in claim 9 wherein the first and third portions meet at a first point and incline away from one another toward the outflow end, and wherein the second and fourth portions meet at a
5 second point and incline away from one another toward the inflow end.

11. The apparatus defined in claim 1 wherein the anchoring structure comprises a plurality of members that are resiliently biased to incline radially outwardly on an inflow side of the patient's native
5 heart valve annulus at the implant site.

12. The apparatus defined in claim 1 wherein the anchoring structure comprises a plurality of members that are resiliently biased to incline radially

- 26 -

outwardly on an outflow side of the patient's native
5 heart valve annulus at the implant site.

13. The apparatus defined in claim 12
wherein the members are adapted to push radially
outwardly on the patient's native heart valve leaflets
at the implant site.

14. The apparatus defined in claim 1 wherein
the anchoring structure is resiliently biased to
circumferentially re-expand.

15. The apparatus defined in claim 1 wherein
the valve support structure is resiliently biased to
circumferentially re-expand.

16. The apparatus defined in claim 1 wherein
the anchoring structure comprises:

an annular annulus inflow portion
adapted for inter-engagement with the valve support
5 structure;

an annular aortic outflow portion
adapted for disposition in the patient's aorta
downstream from the patient's native aortic valve at
the implant site; and

10 a least one connecting strut extending
between and connecting the annulus inflow portion and
the aortic outflow portion.

17. The apparatus defined in claim 1 wherein
the leaflet structure comprises a leaflet made of a
material selected from the group consisting of
biological tissue, metal, polymers, and mesh-reinforced
5 polymers.

- 27 -

18. The apparatus defined in claim 1 wherein the leaflet structure is created using a forming process producing polymeric leaflets that are integral with the valve support structure.

19. The apparatus defined in claim 1 further comprising:

an annular cuff structure secured to at least one of the anchoring structure and the valve support structure.

20. A method of implanting a prosthetic heart valve in a patient comprising:

implanting an annular anchoring structure in the patient by delivering the anchoring structure into the patient in a circumferentially collapsed condition and then circumferentially expanding the anchoring structure while in the patient to implant the anchoring structure at an implant site in the patient;

delivering an annular valve support structure, which is initially separate from the anchoring structure, into the patient in a circumferentially collapsed condition;

circumferentially expanding the valve support structure while in the patient; and

interlocking the expanded valve support structure with the implanted anchoring structure.

21. The method defined in claim 20 wherein the prosthetic heart valve is implanted in the patient so that blood will flow through it in a bloodflow direction, and wherein the method further comprises:

- 28 -

5 inserting the valve support structure
into the implanted anchoring structure in the bloodflow
direction.

22. The method defined in claim 20 wherein
the prosthetic heart valve is implanted in the patient
so that blood will flow through it in a bloodflow
direction, and wherein the method further comprises:

5 inserting the valve support structure
into the implanted anchoring structure opposite the
bloodflow direction.

1/26

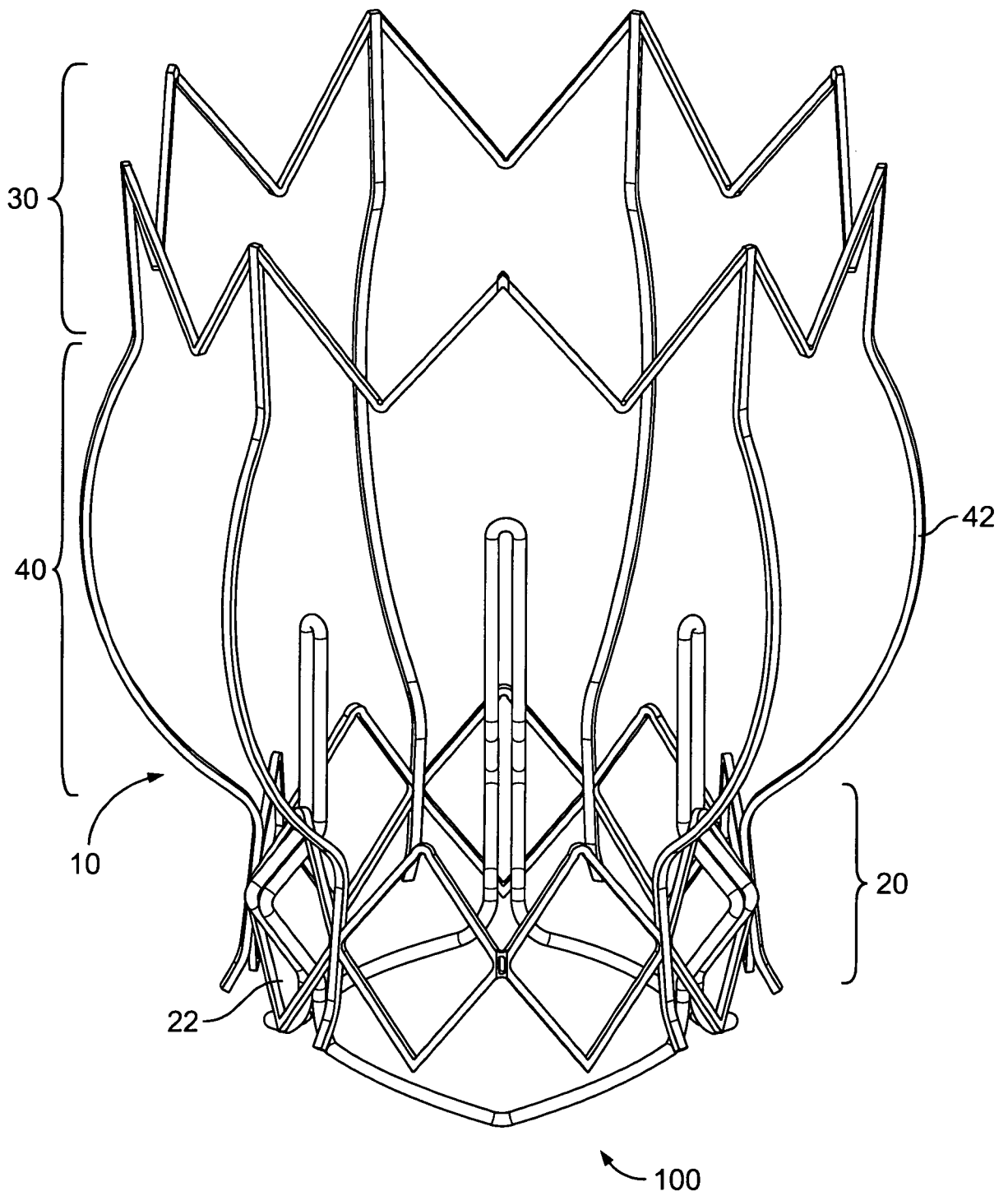


FIG. 1A

2/26

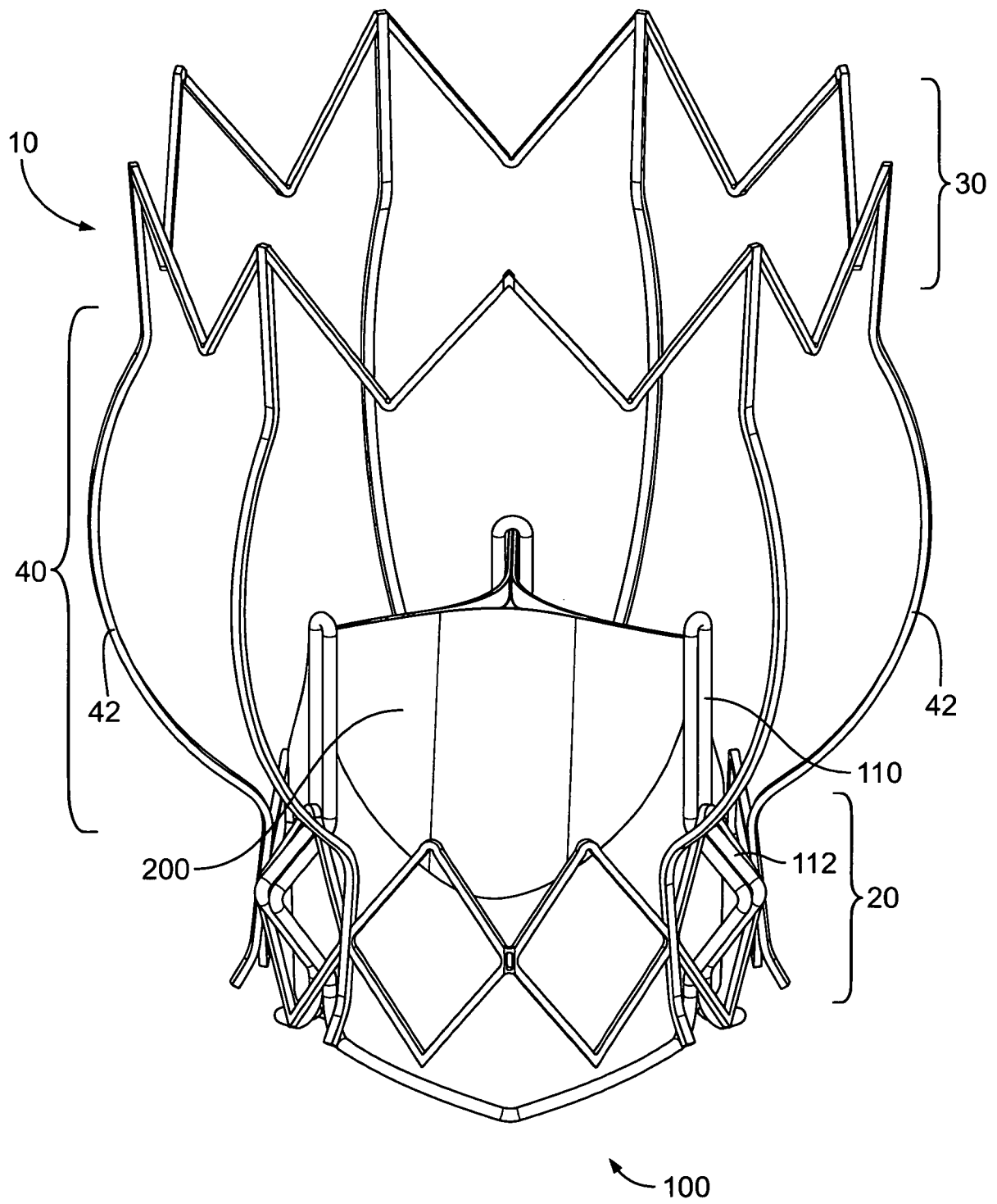


FIG. 1B

3/26

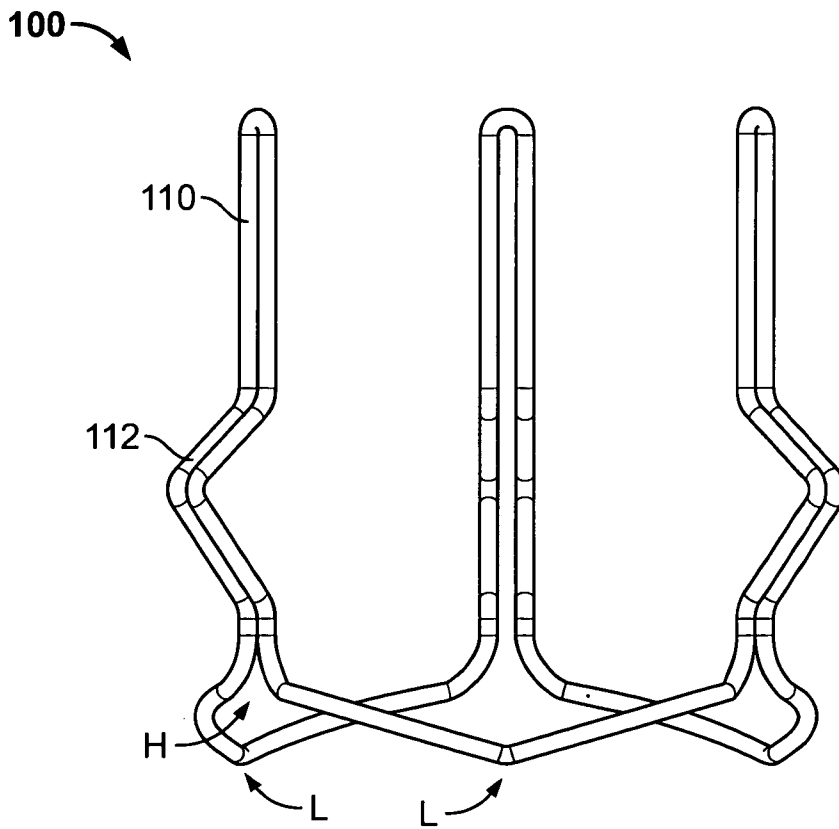


FIG. 2A

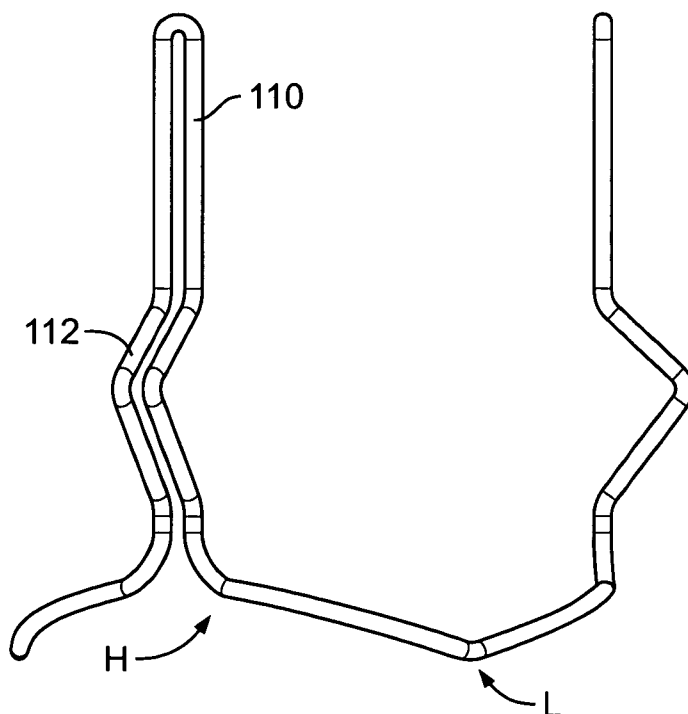


FIG. 2B

4/26

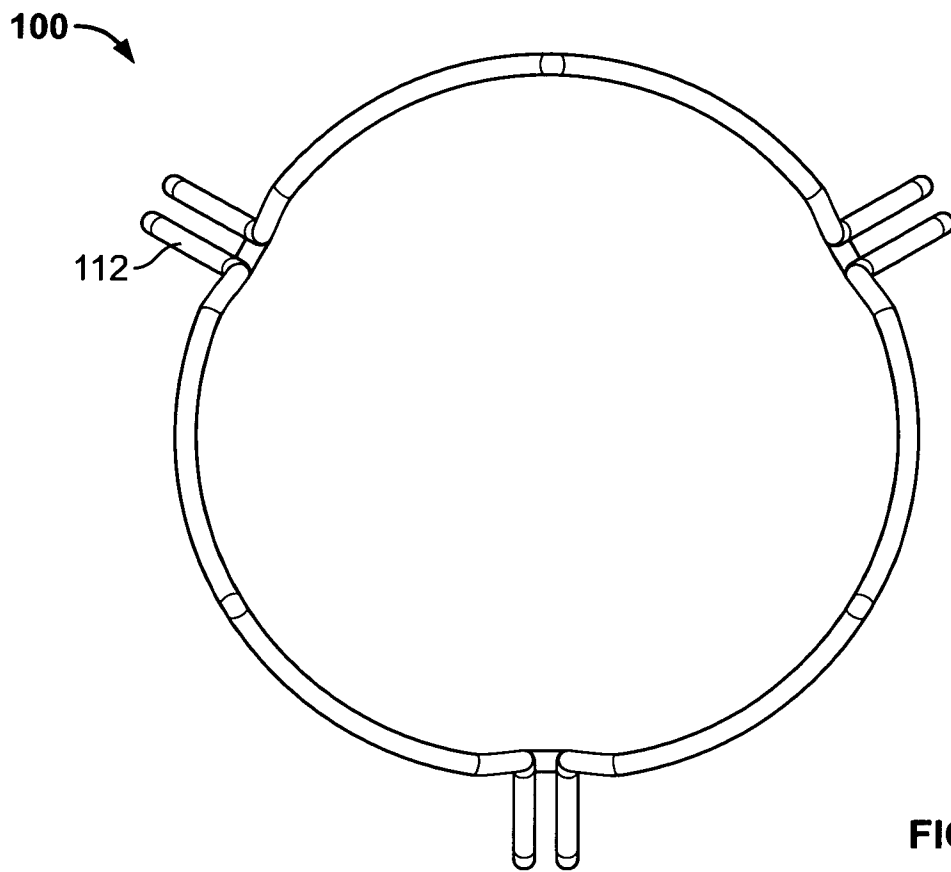


FIG. 2C

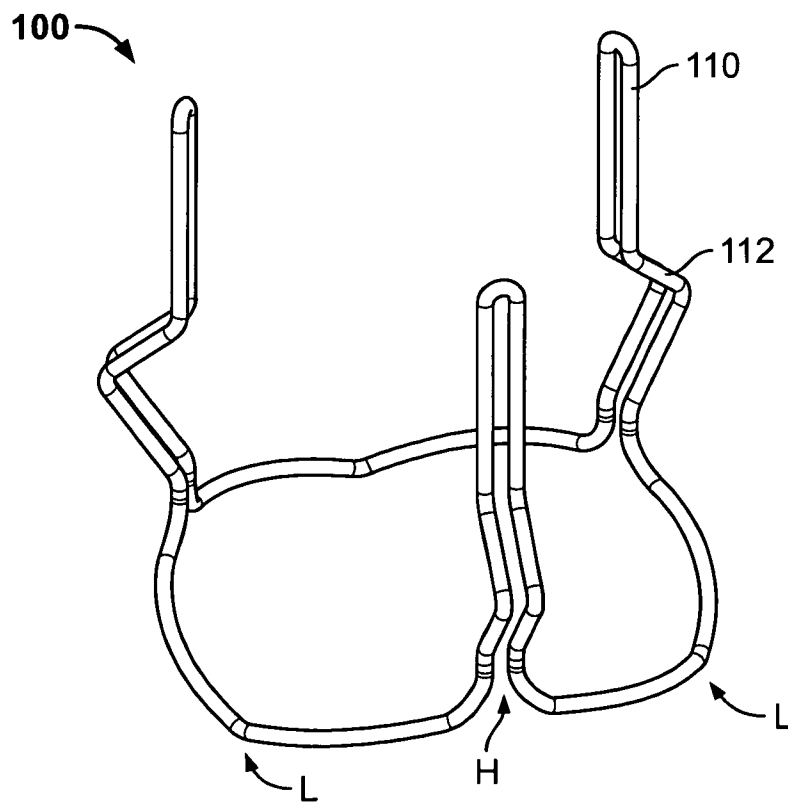


FIG. 2D

5/26

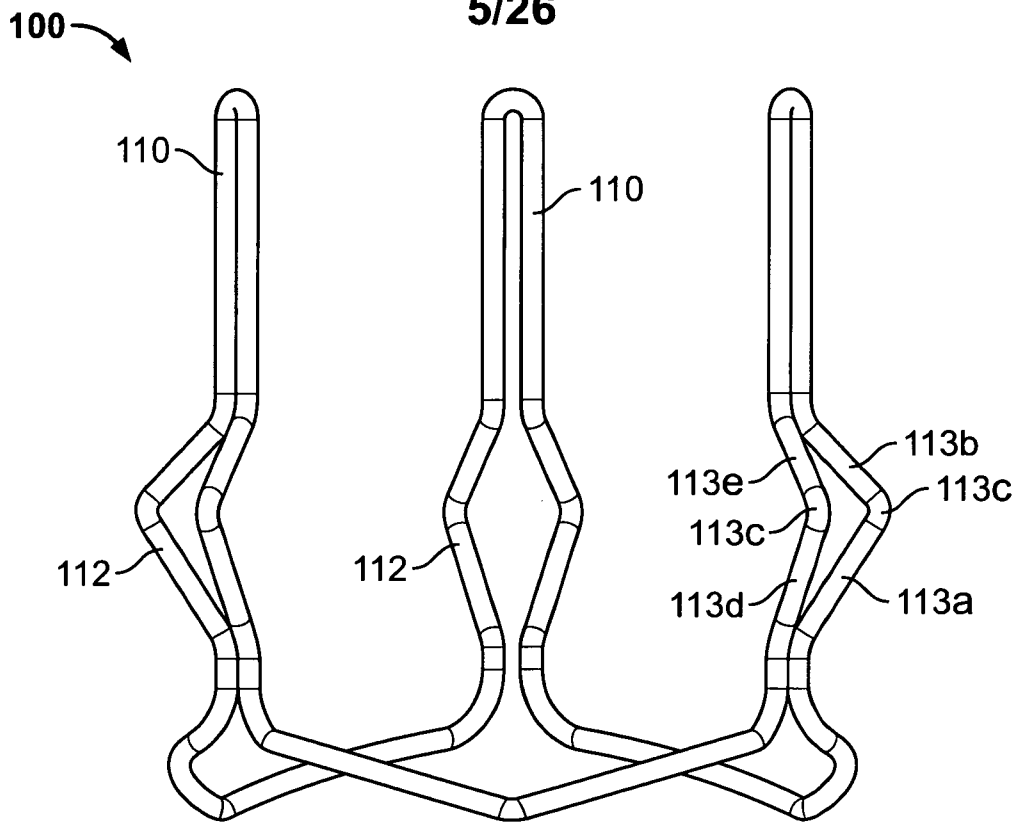


FIG. 3A

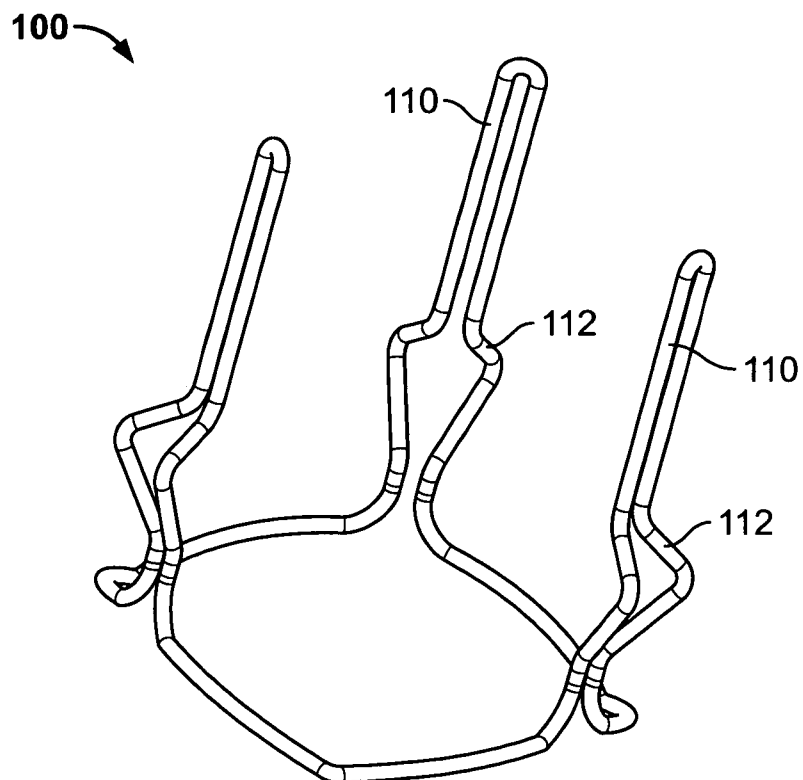


FIG. 3B

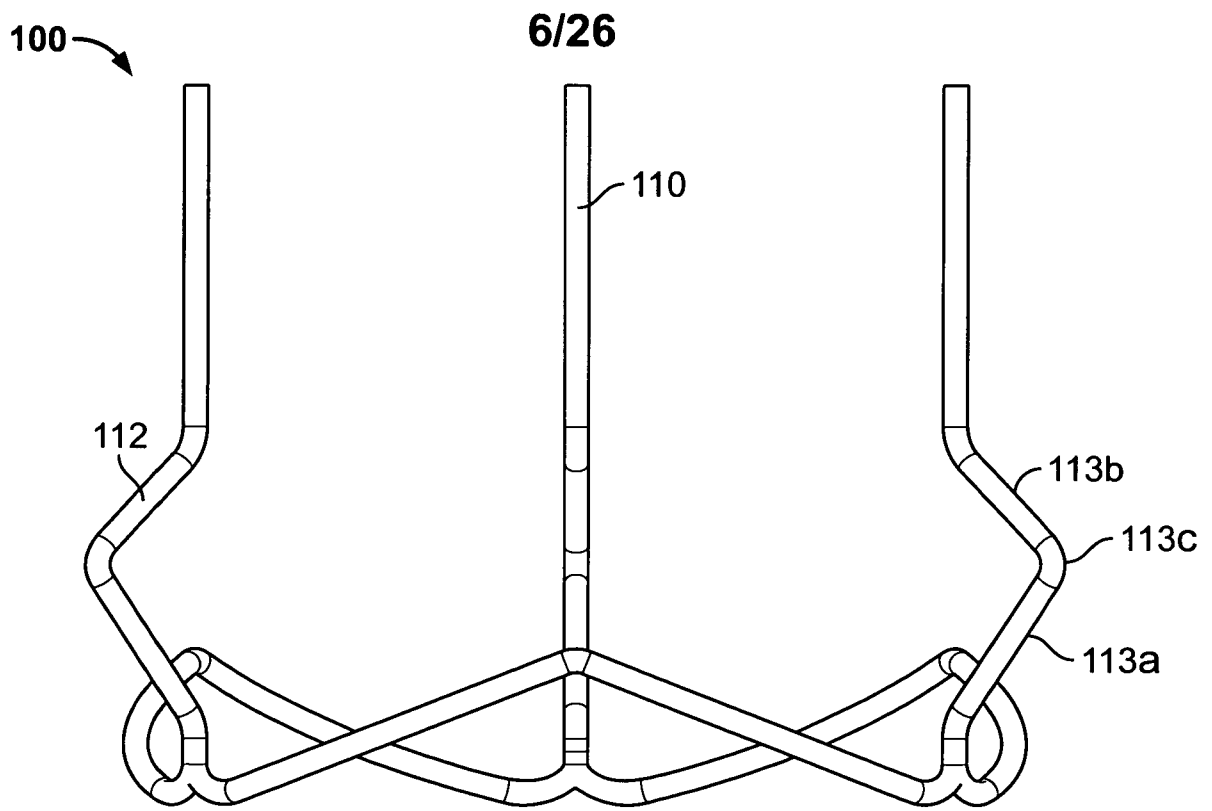


FIG. 4A

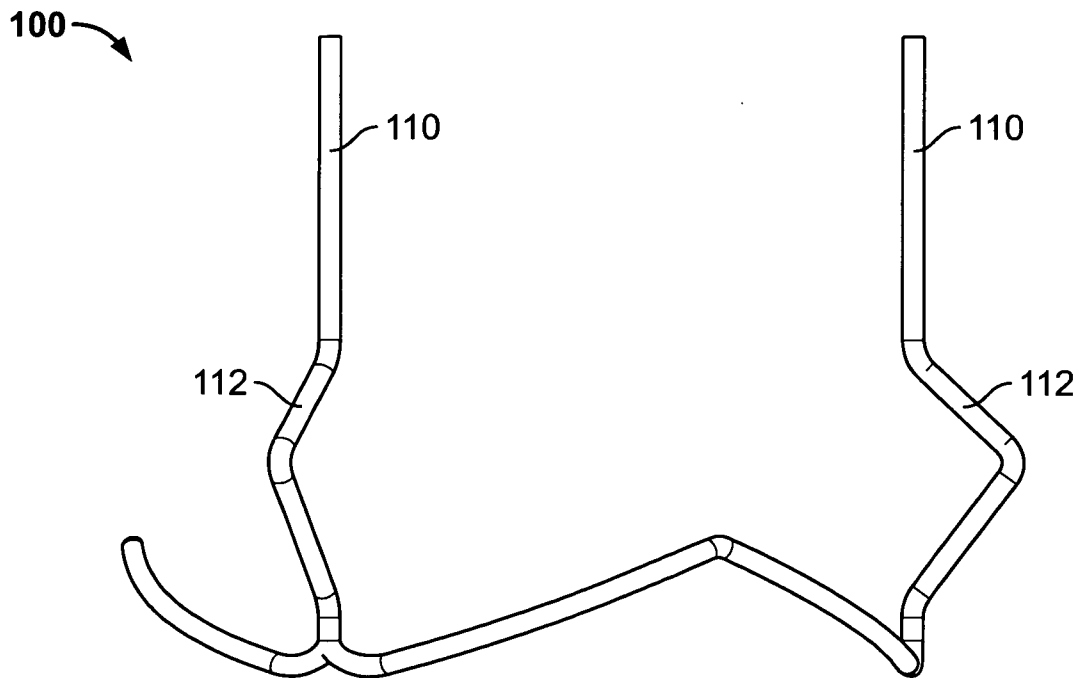


FIG. 4B

7/26

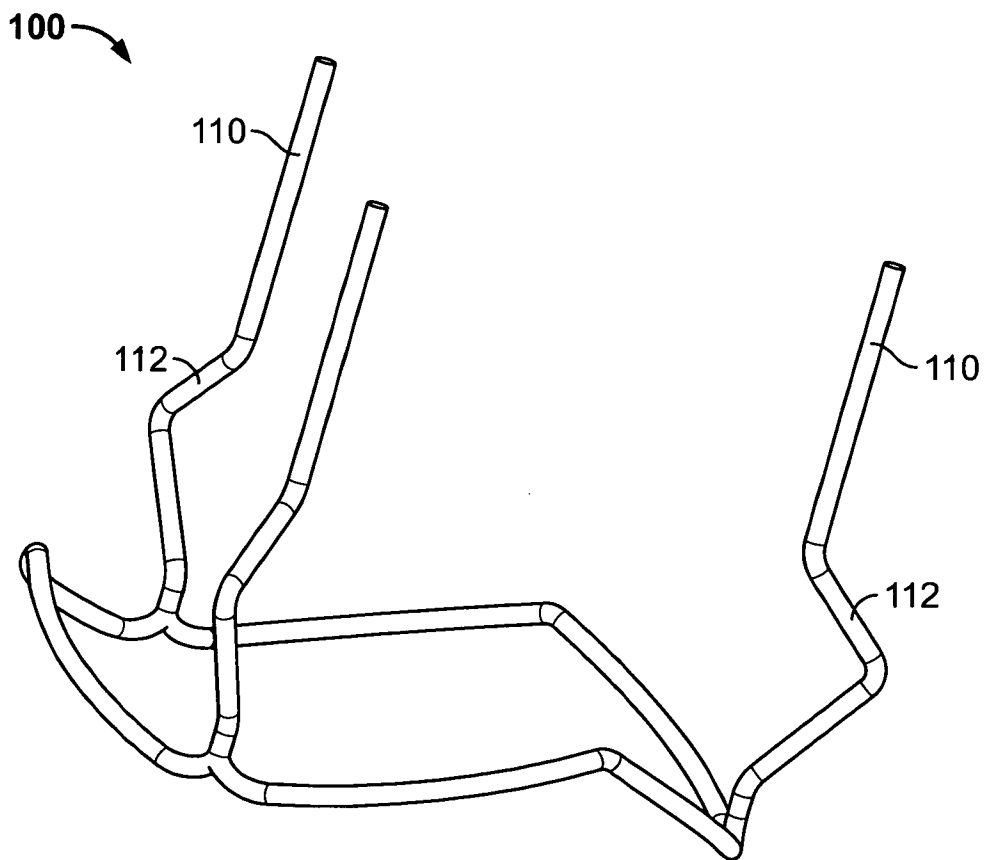


FIG. 4C

8/26

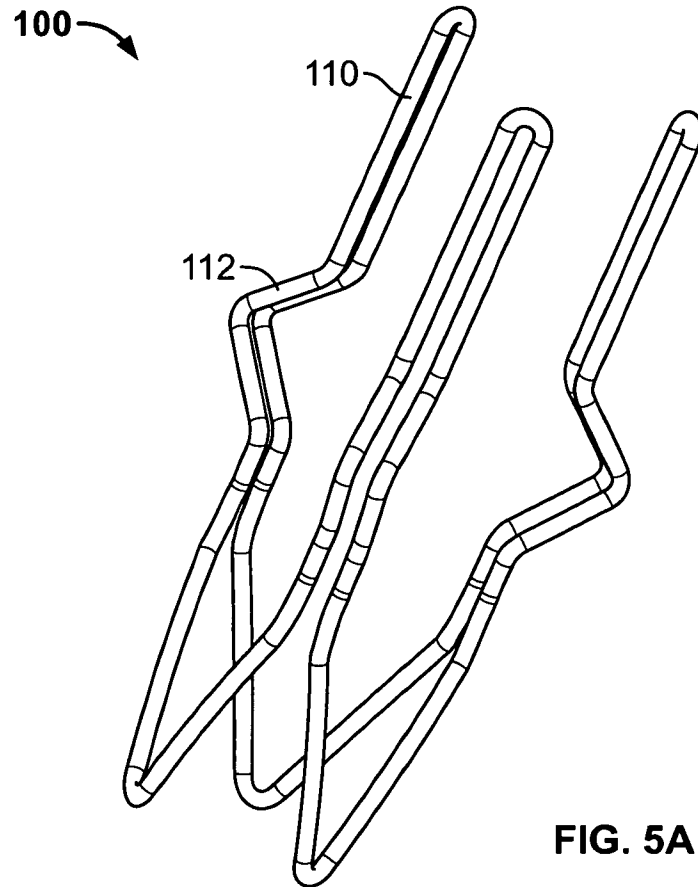


FIG. 5A

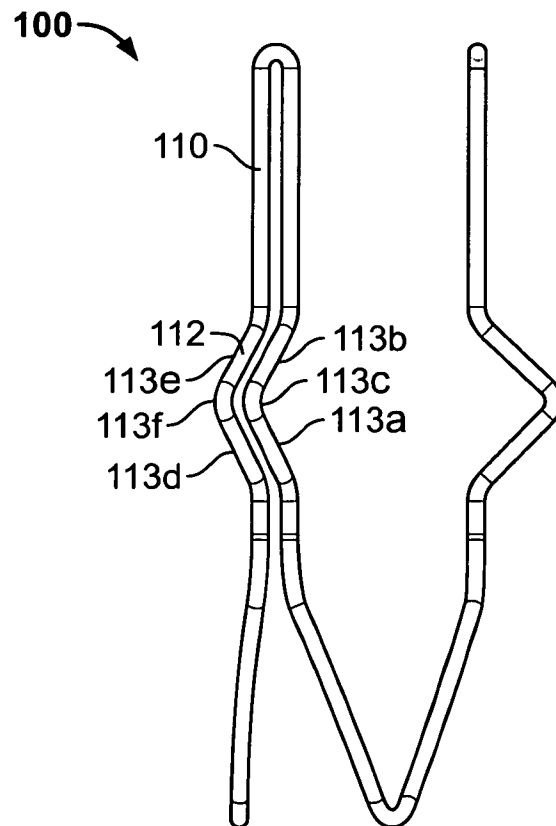


FIG. 5B

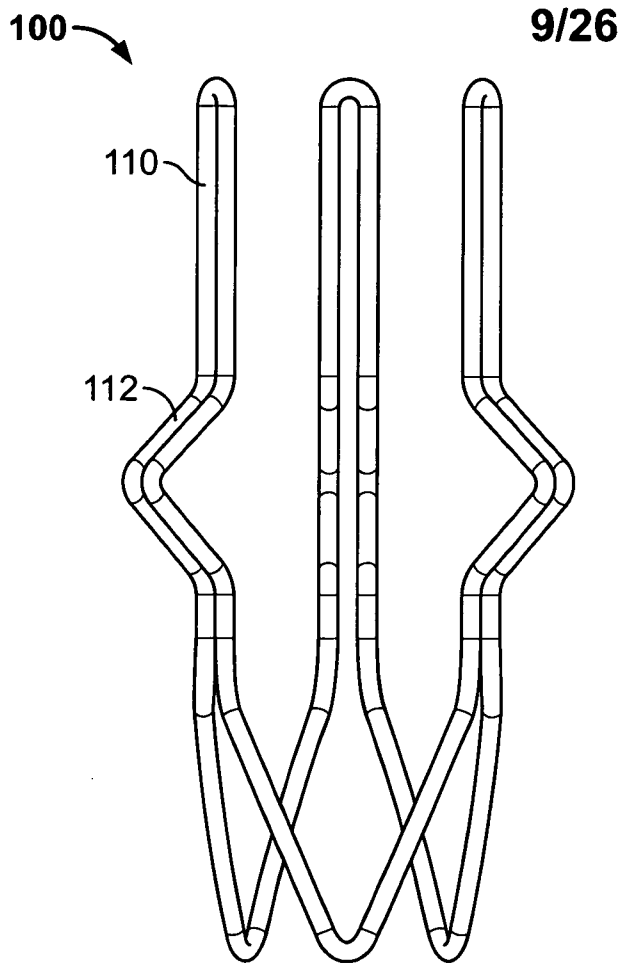


FIG. 5C

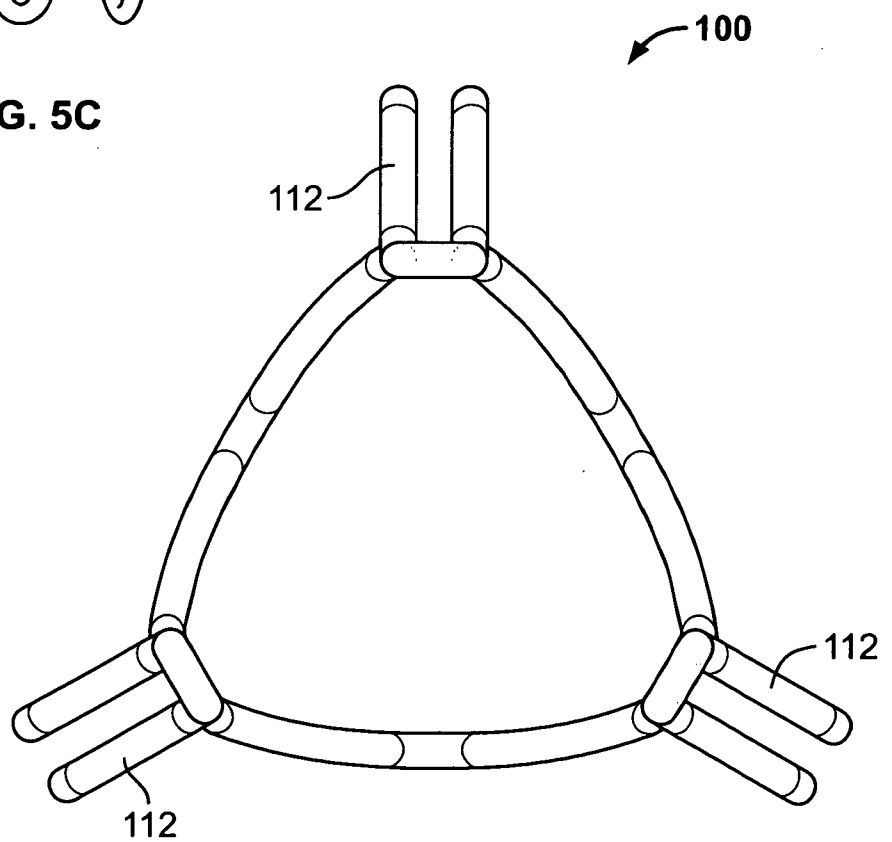


FIG. 5D

10/26

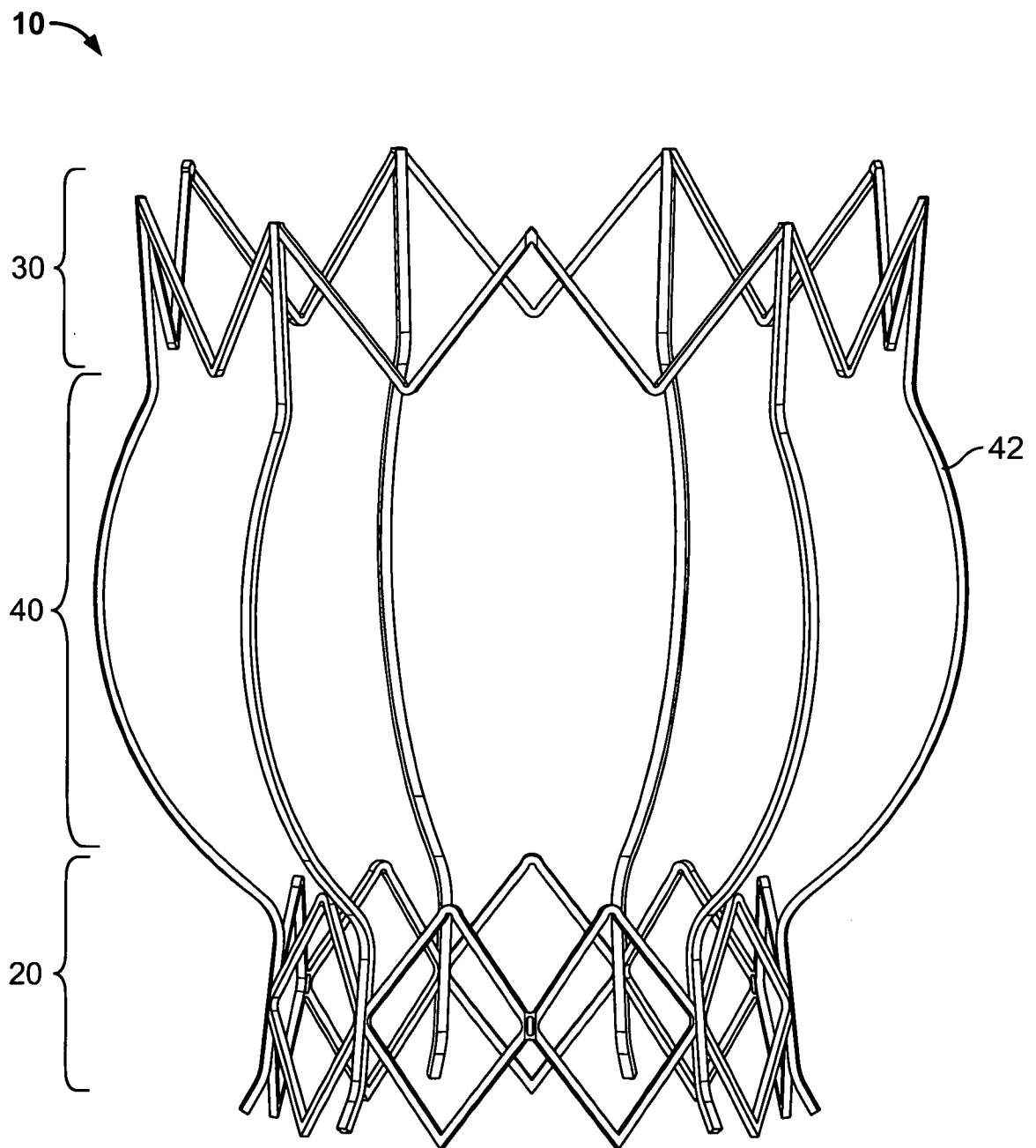


FIG. 6A

11/26

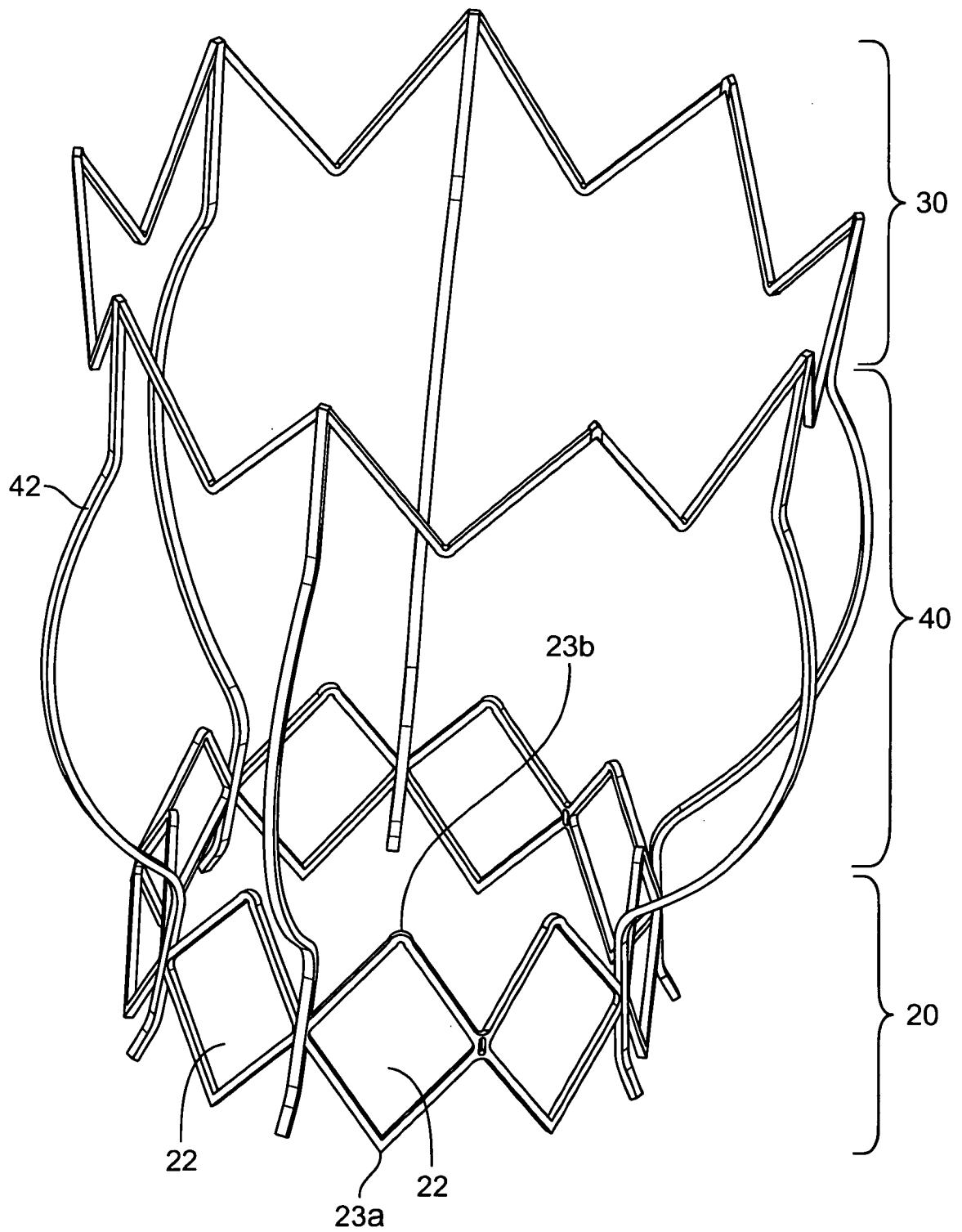


FIG. 6B

12/26

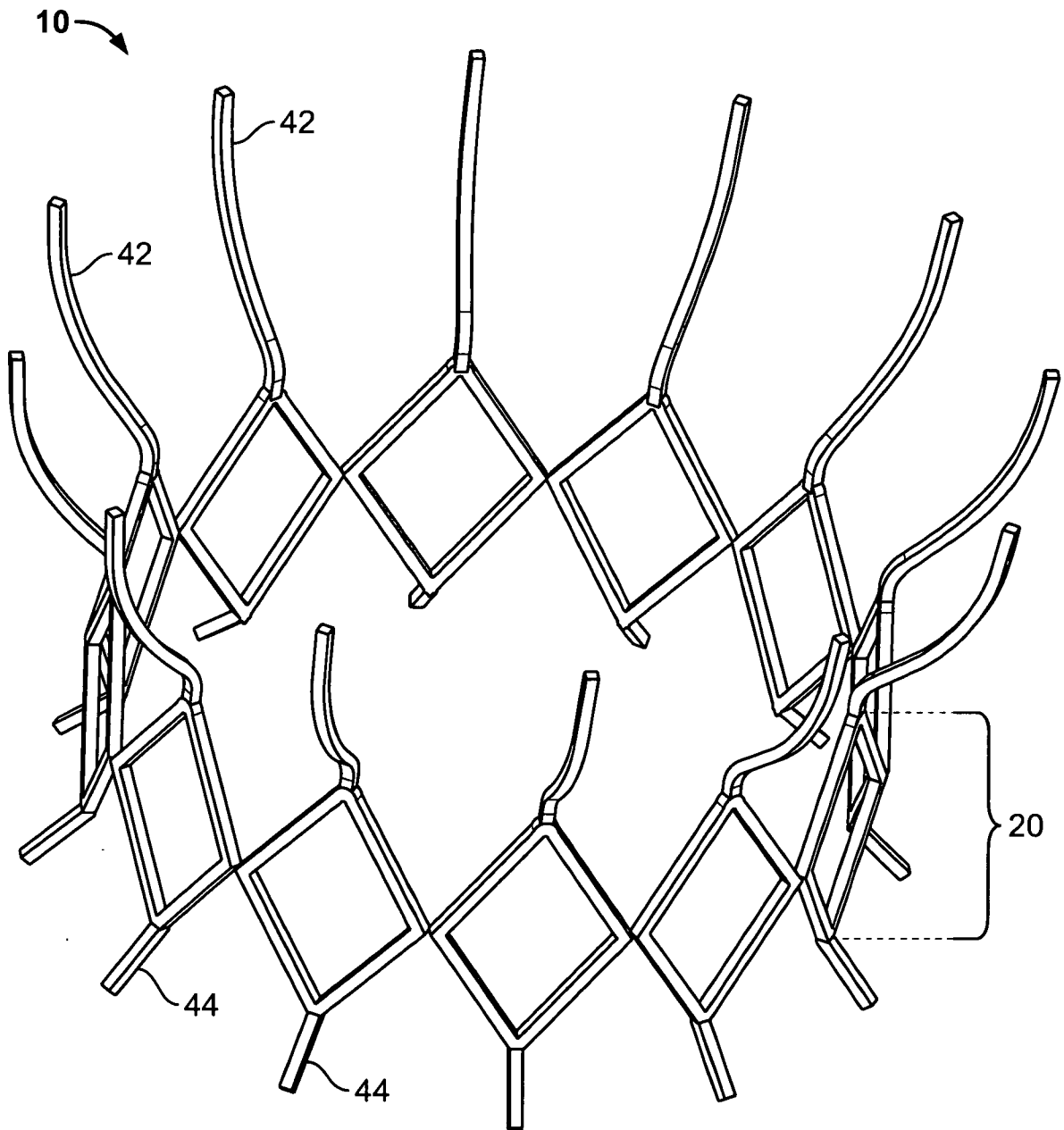


FIG. 7A

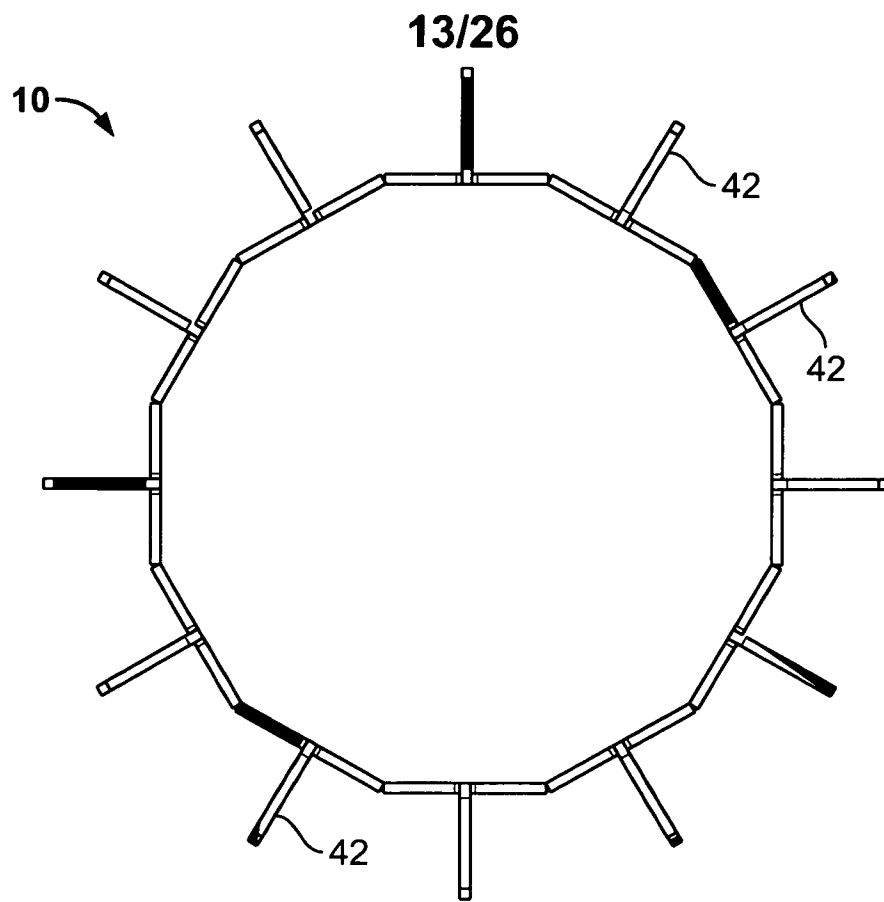


FIG. 7B

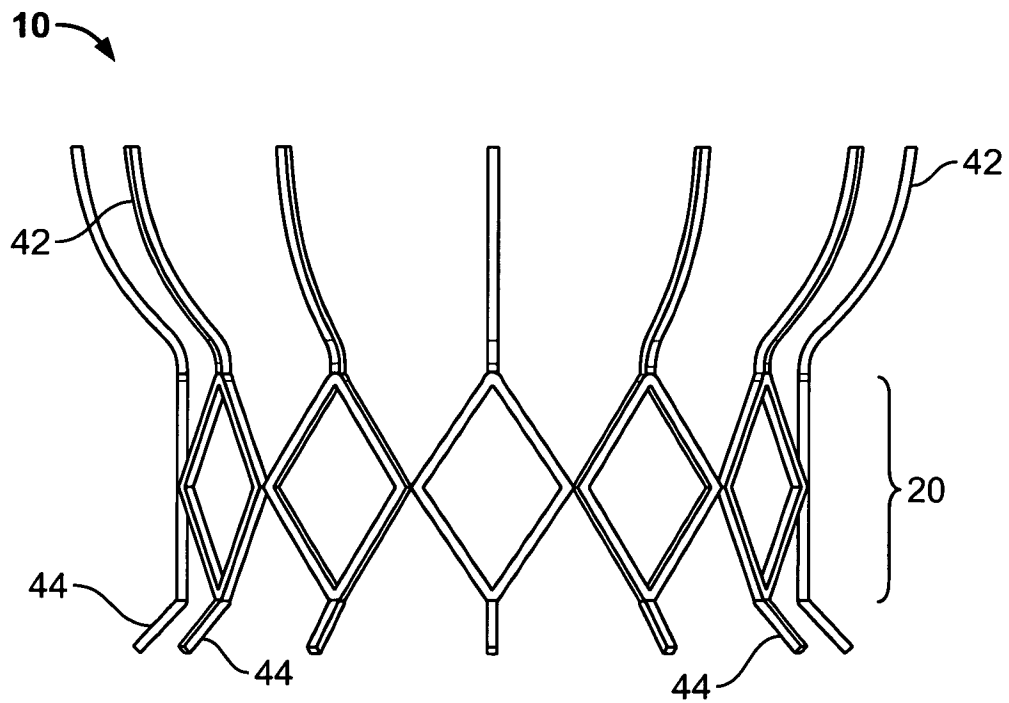


FIG. 7C

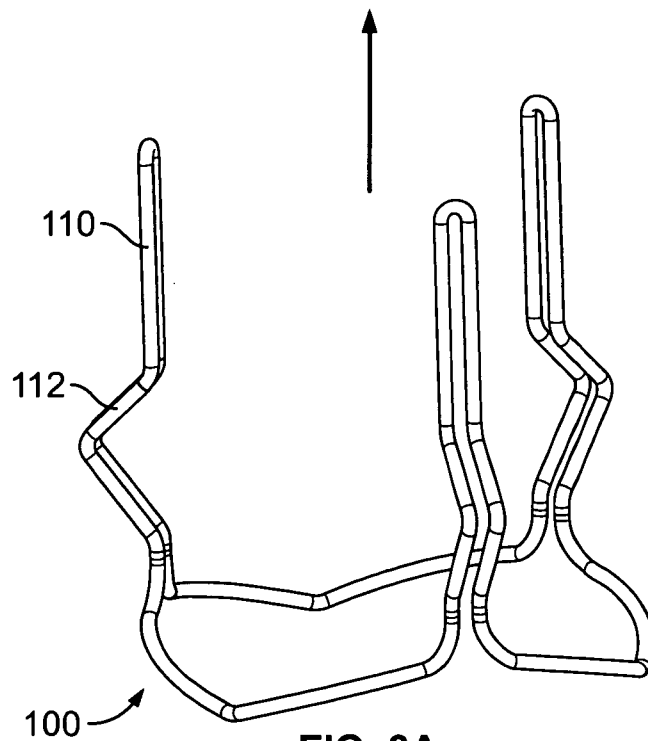
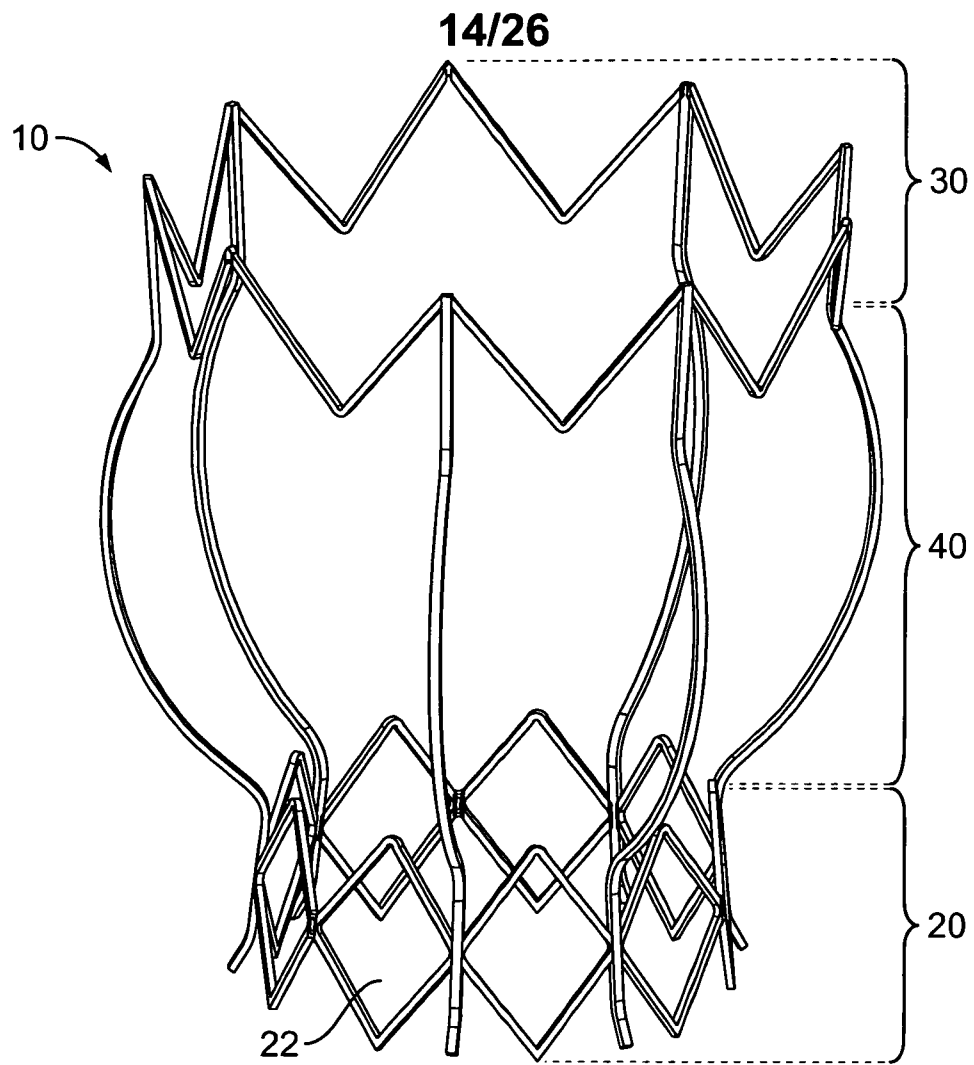
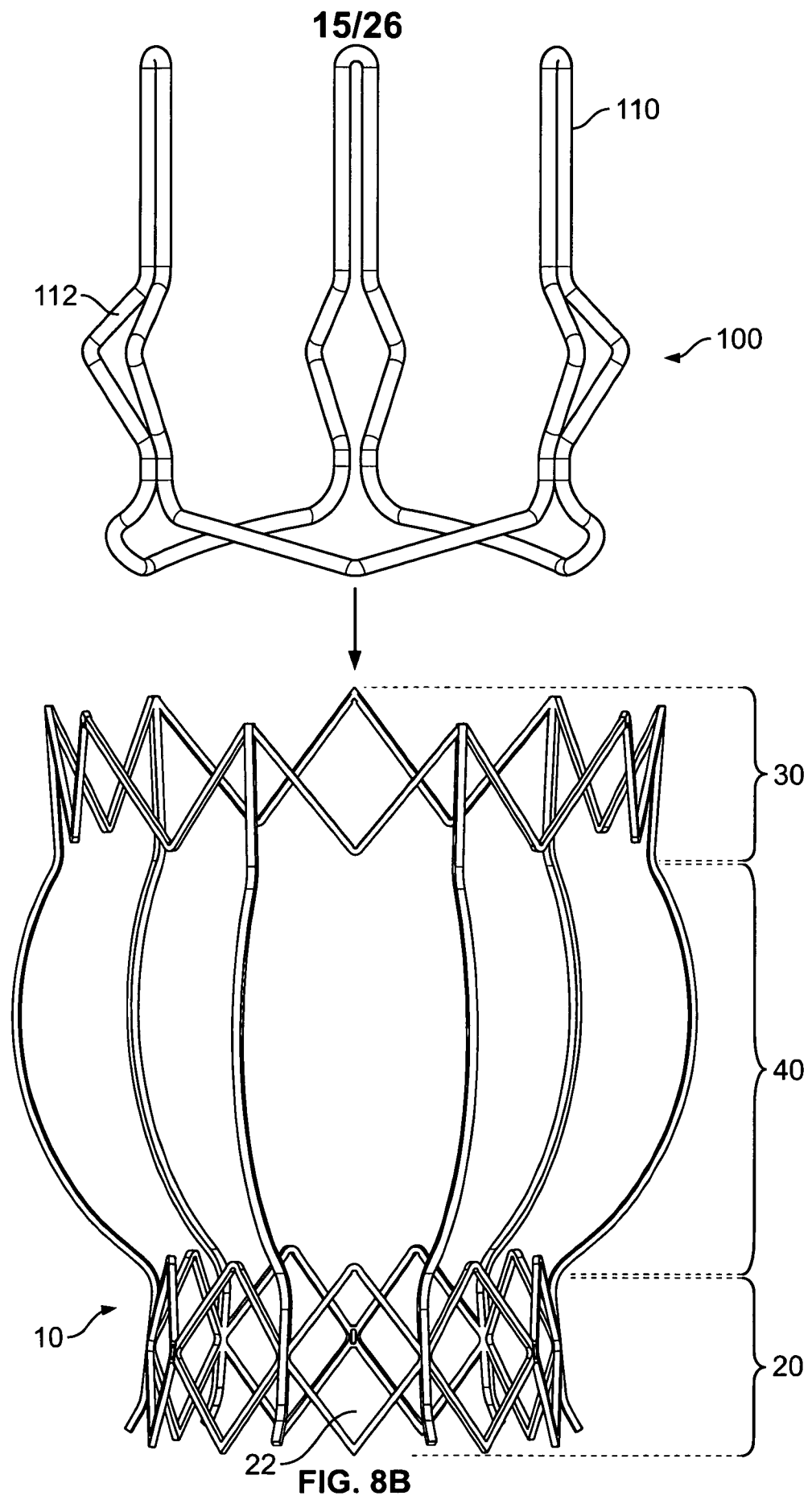


FIG. 8A



16/26

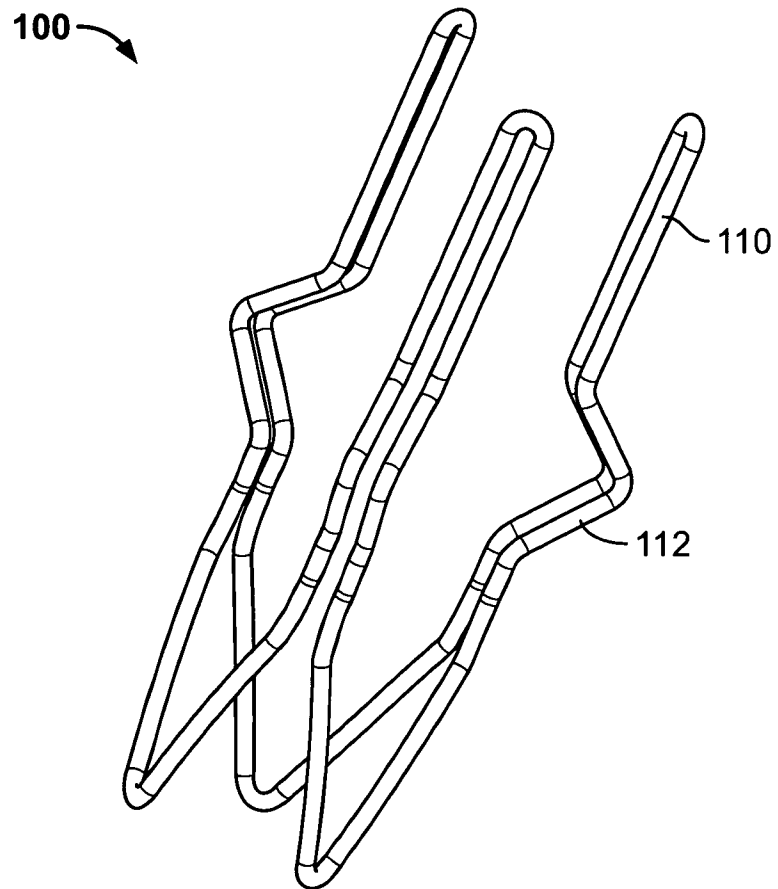


FIG. 9A

17/26

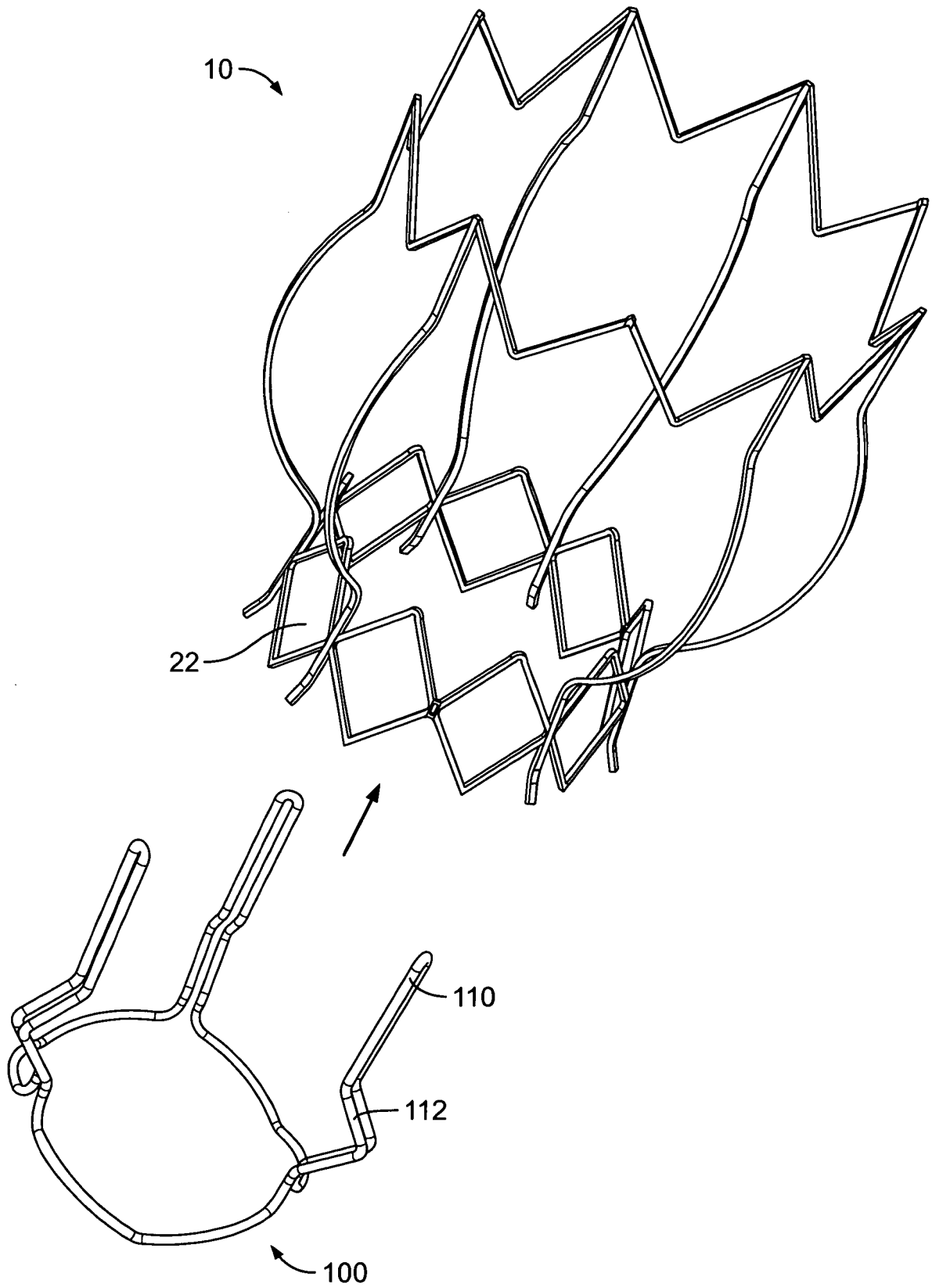


FIG. 9B

18/26

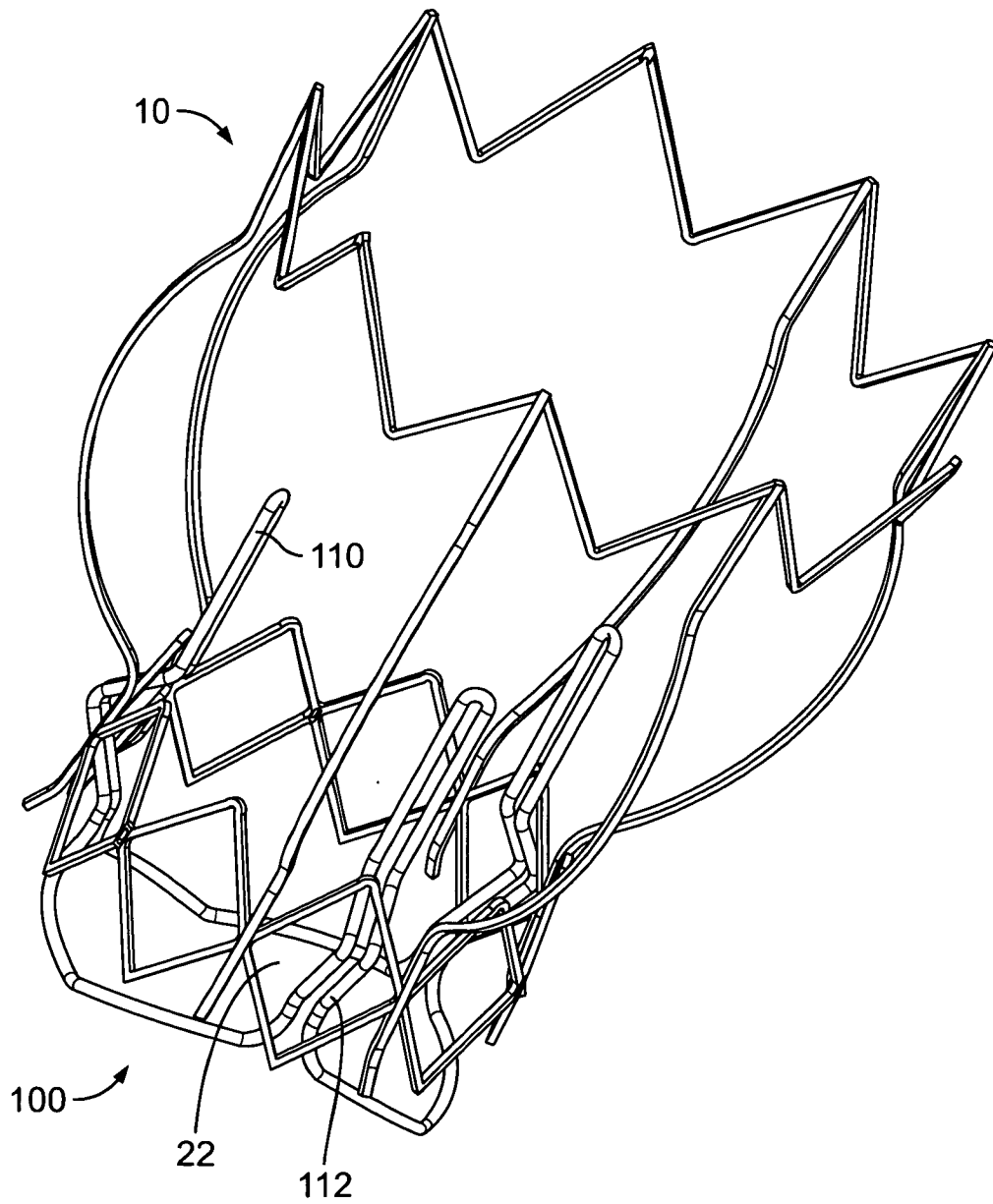


FIG. 9C

19/26

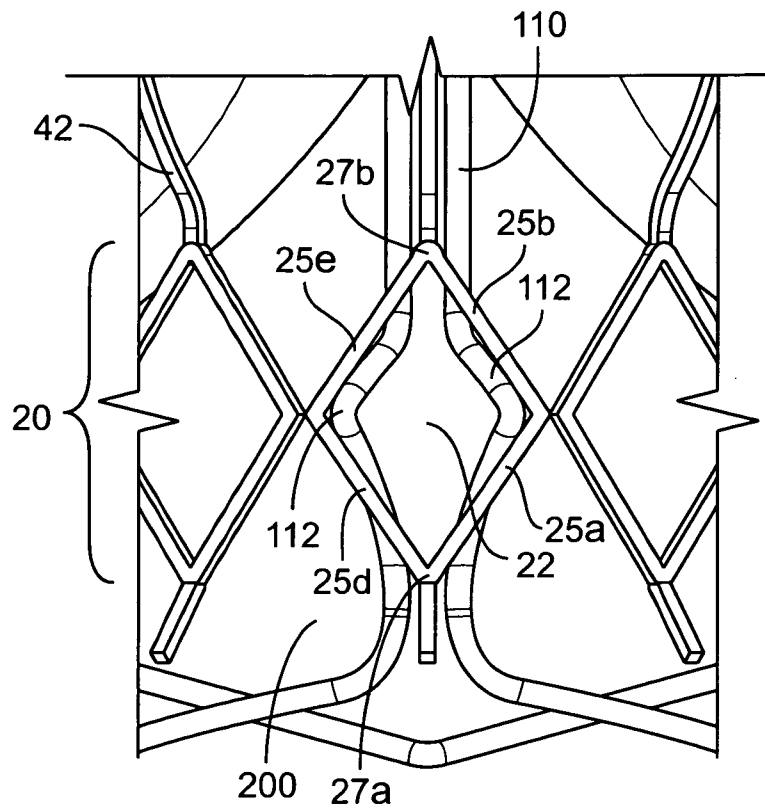


FIG. 10A

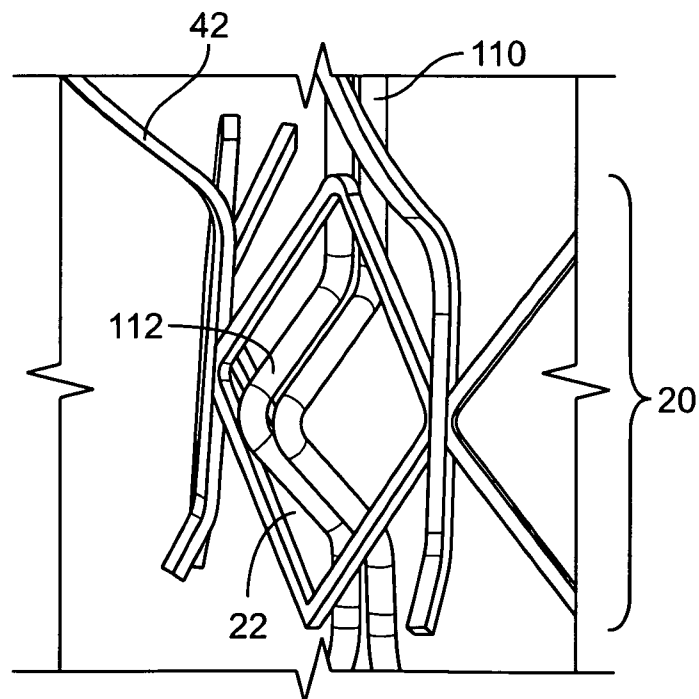


FIG. 10B

20/26

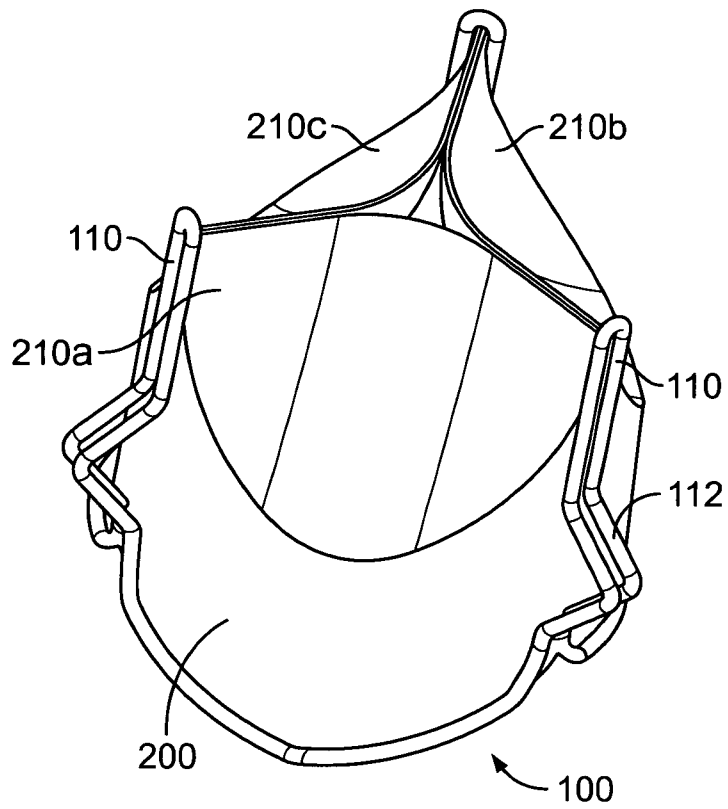


FIG. 11A

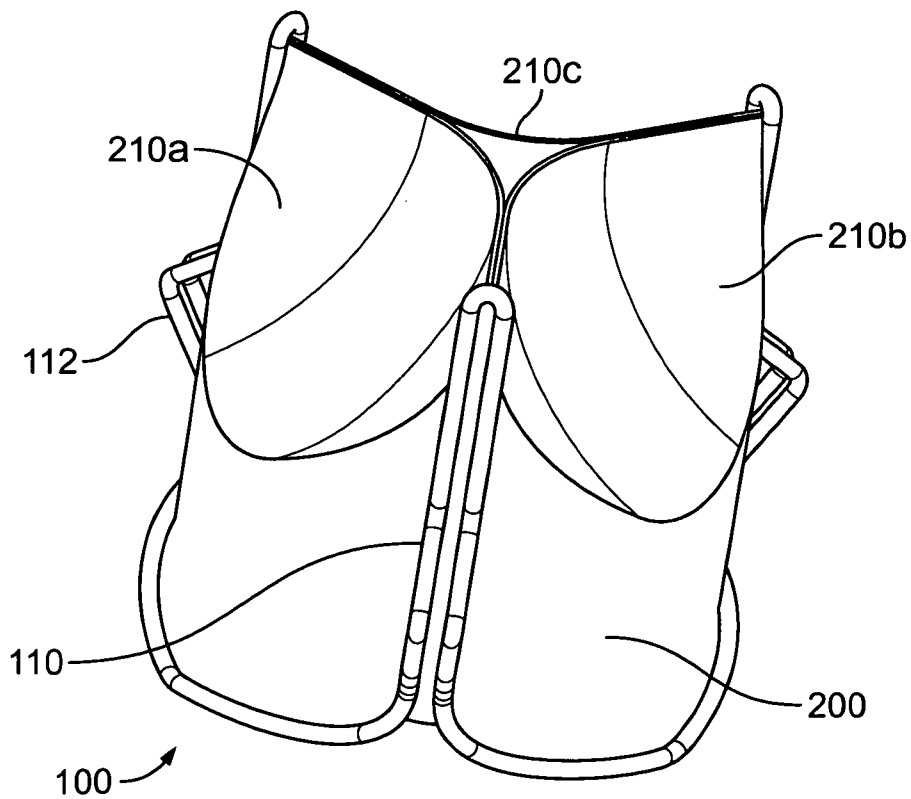


FIG. 11B

21/26

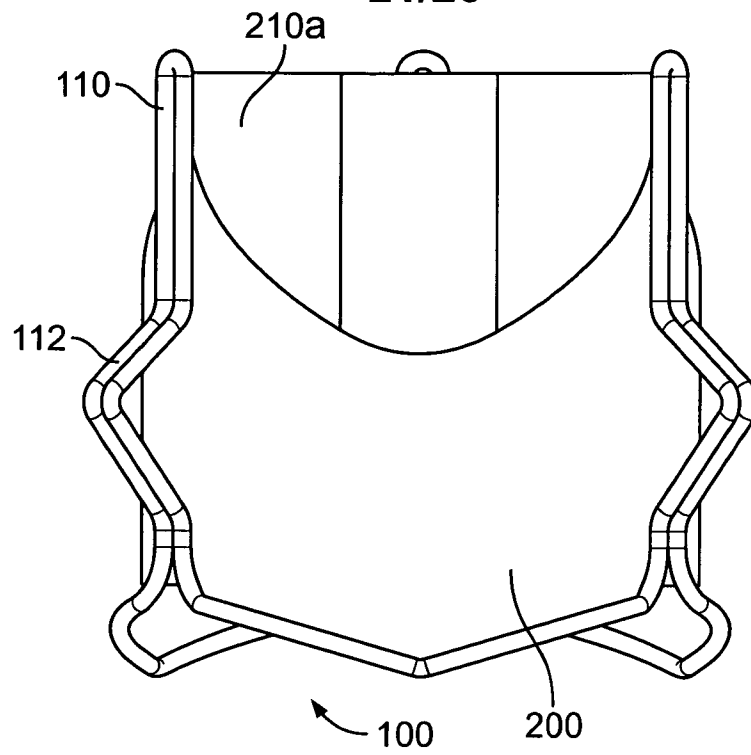


FIG. 11C

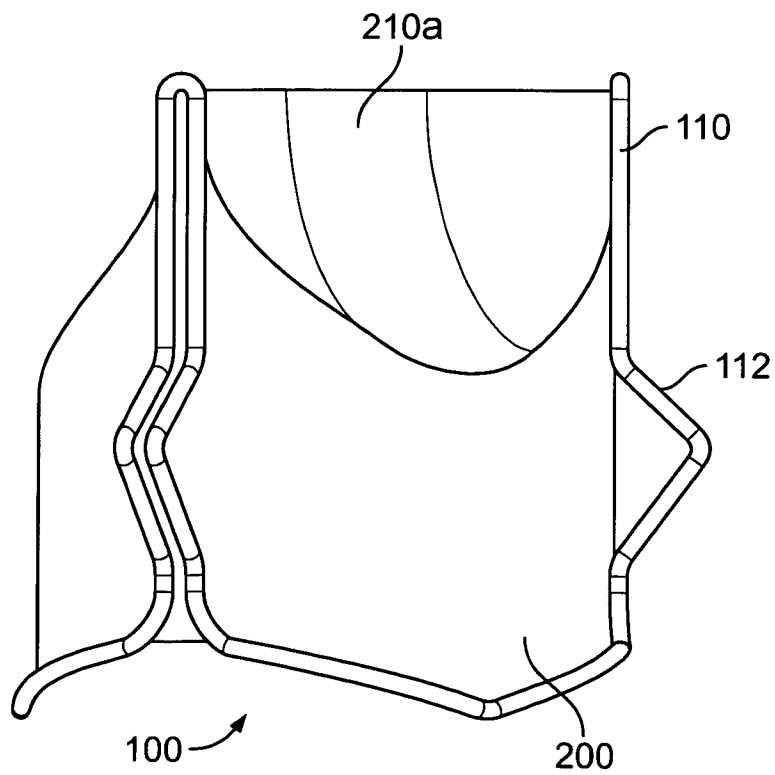


FIG. 11D

22/26

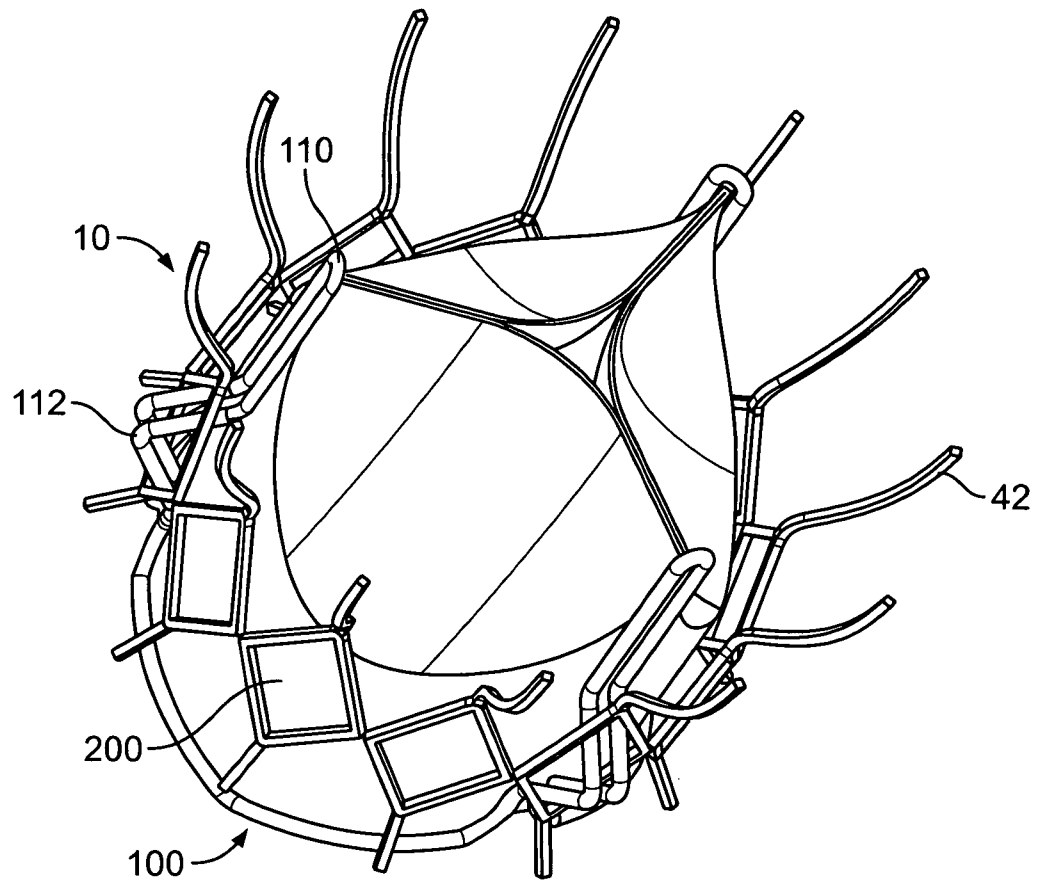


FIG. 12A

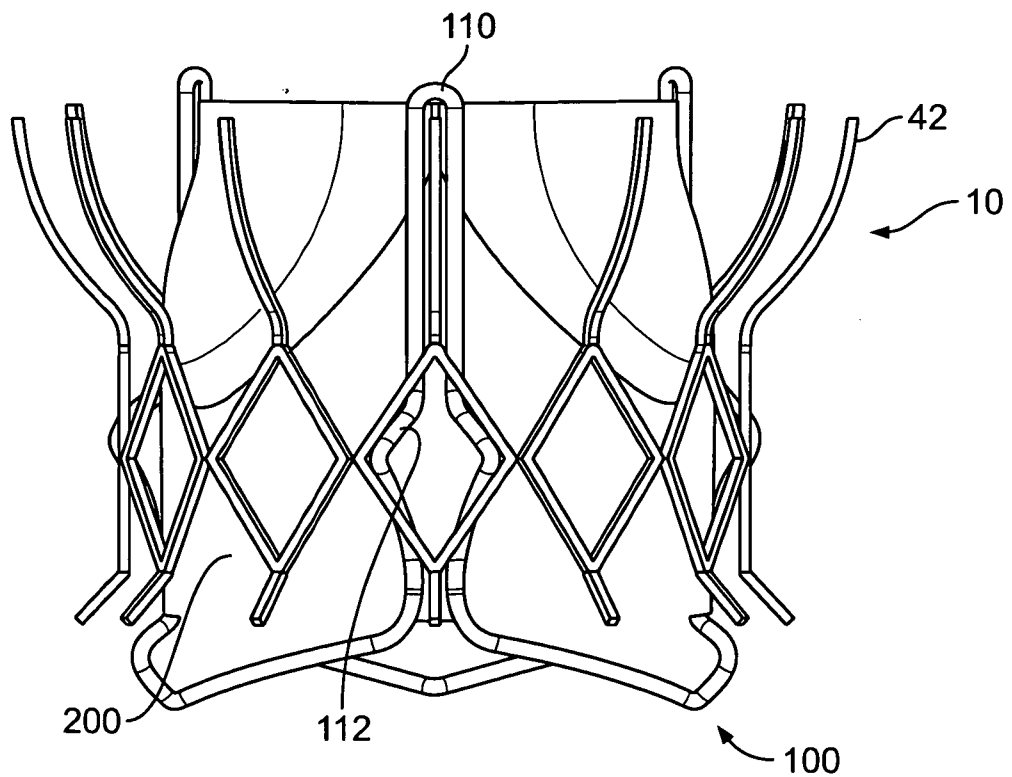


FIG. 12B

23/26

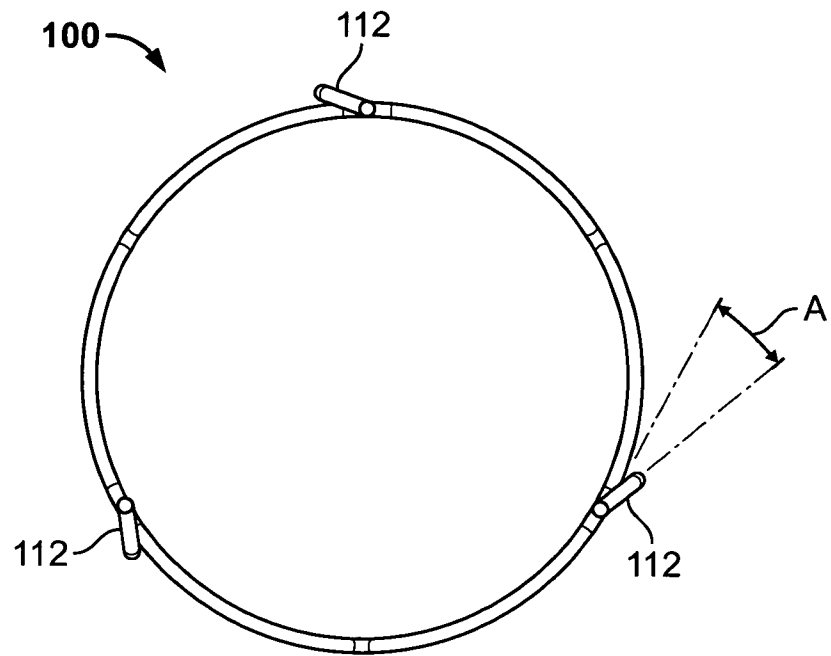


FIG. 13A

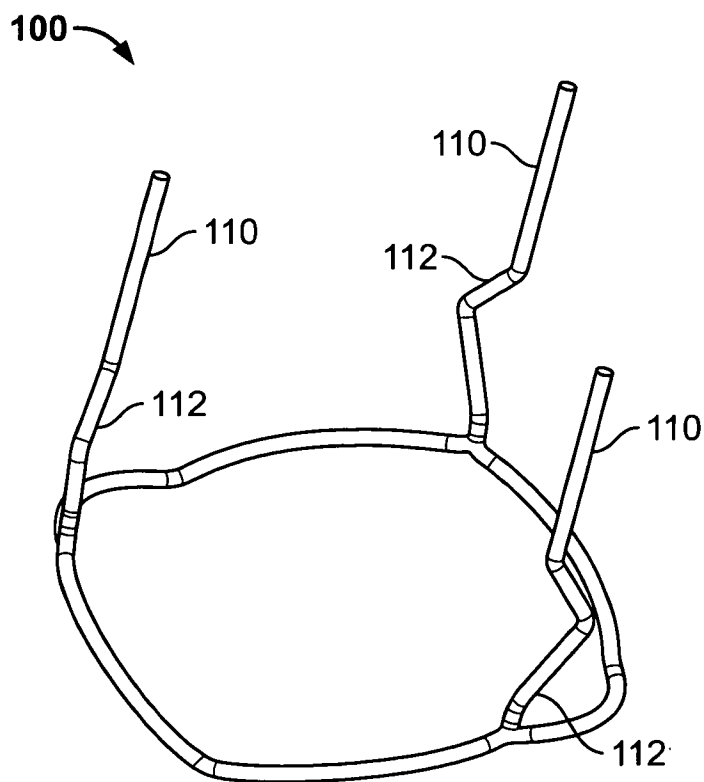


FIG. 13B

24/26

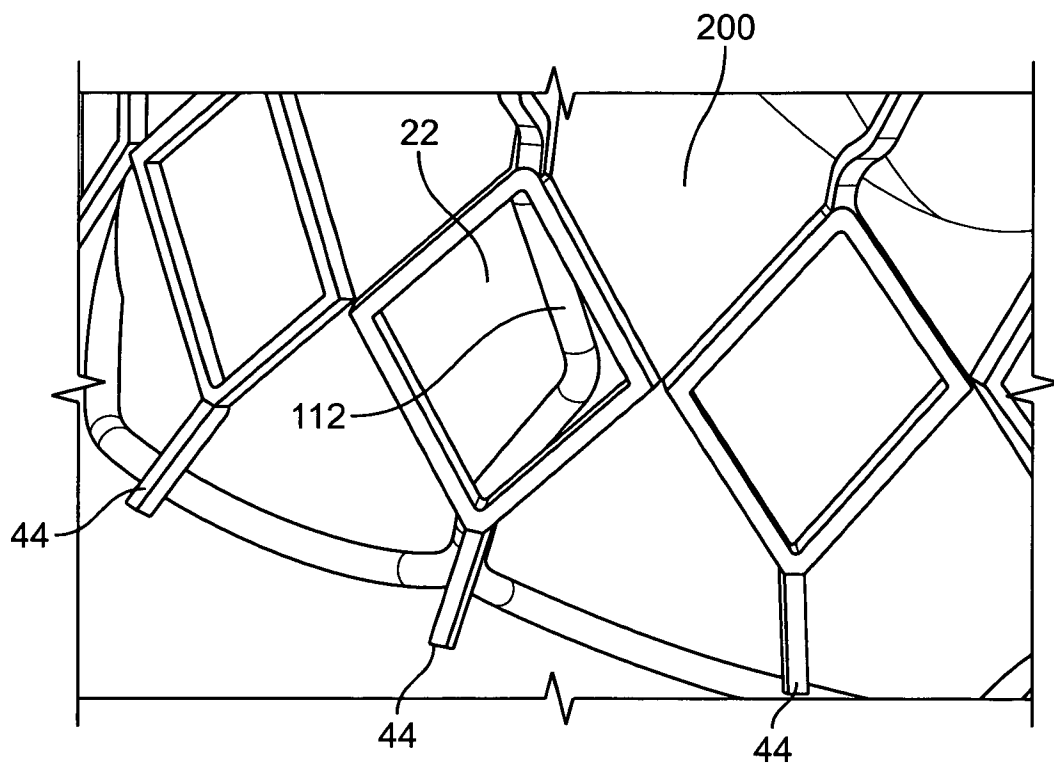


FIG. 13C

25/26

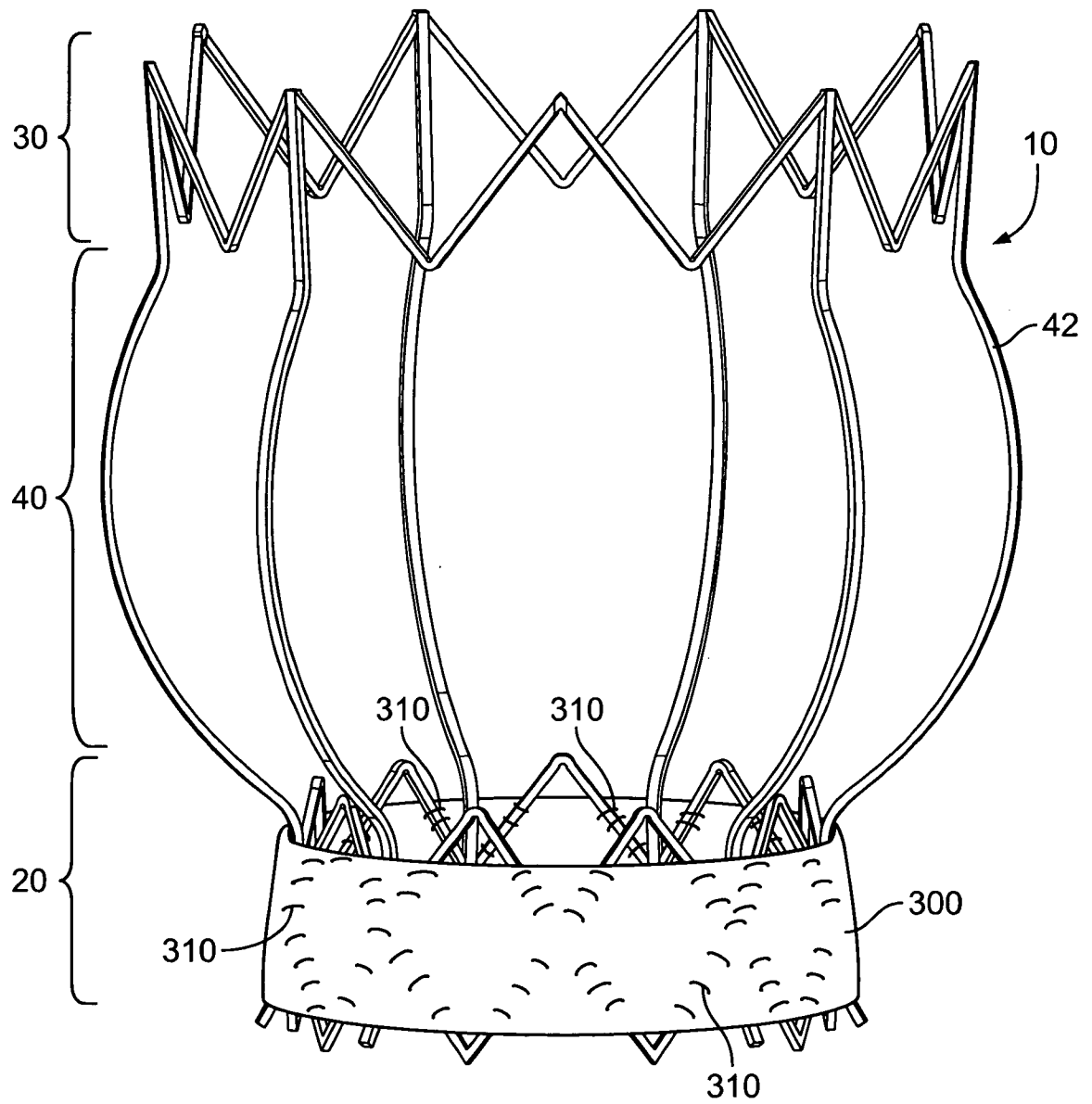


FIG. 14

26/26

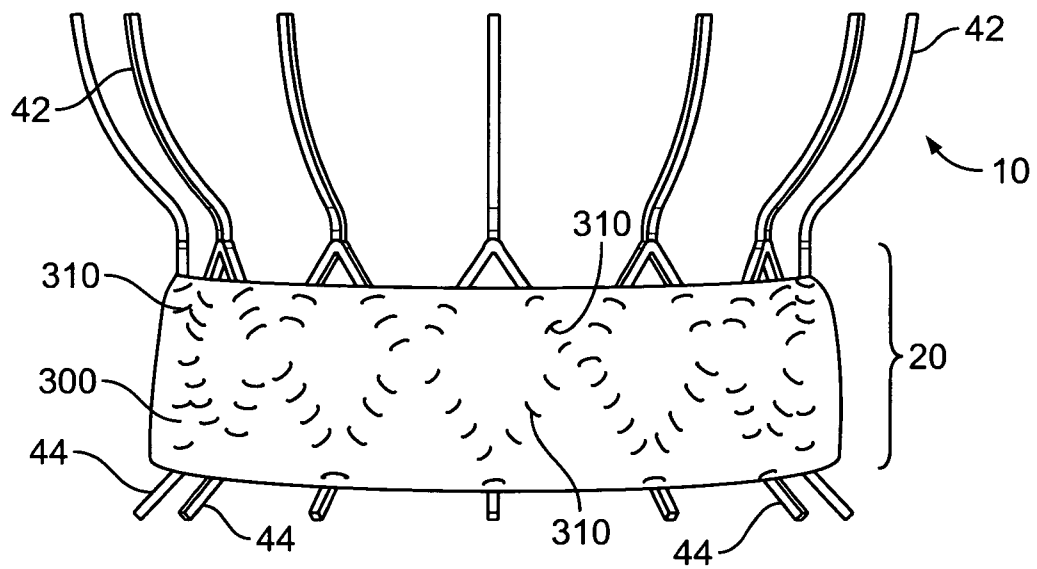


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/011177

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/127756 A (EDWARDS LIFESCIENCES CORPORATION) 30 November 2006 (2006-11-30) the whole document -----	1-4, 11, 13-15, 17-19



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

3 February 2009

Date of mailing of the international search report

11/02/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Smith, Colin

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/011177

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-22
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/011177

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006127756 A	30-11-2006	CA 2607744 A1	30-11-2006
		CN 101180010 A	14-05-2008
		EP 1883375 A2	06-02-2008
		JP 2008541863 T	27-11-2008
		US 2006287719 A1	21-12-2006