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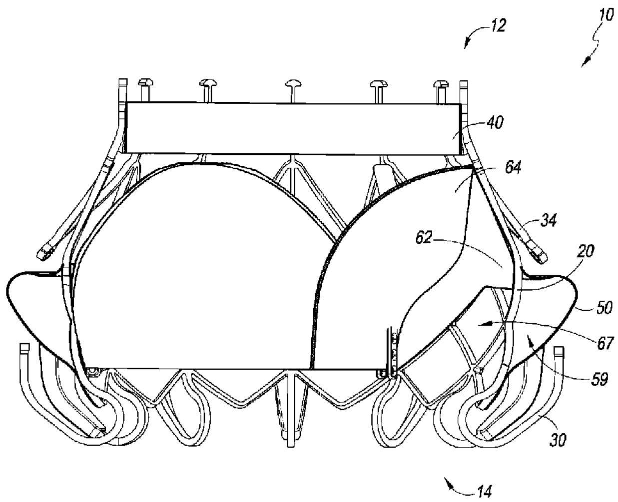

(57) Abrégé/Abstract:
A prosthesis (10) can be configured to grasp intralumenal tissue when deployed within a body cavity and prevent axial flow of fluid around an exterior of the prosthesis. The prosthesis comprises an expandable frame (20) configured to radially expand and contract for deployment within the body cavity and an annular flap (50) positioned around and secured to an exterior of the expandable frame, the annular flap having a distal edge secured at or near the distal end (14) of the frame and extending to a proximal edge secured at an intermediate location on the frame between the proximal (12) and distal (14) ends. The prosthesis also comprises a valve body positioned within an interior of the expandable frame, wherein the valve body comprises: an inner skirt (62) secured to the interior of the expandable frame (20); and a plurality of leaflets (64) configured to allow flow in a first direction and prevent flow in a second opposite direction. An opening is defined at or near the distal end of the frame between the annular flap and the valve body to provide access for fluid to flow into a space (59) between the annular flap and the valve body, and wherein fluid flow into the space causes the annular flap to move from a first configuration wherein the flap is closer to the frame to a second configuration wherein the flap is spaced further away from the frame to increase the surface area of the prosthesis and create a barrier to fluid flow exterior to the frame when deployed within the body cavity.

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

[Continued on next page]

(54) **Title**: REPLACEMENT MITRAL VALVE WITH ANNULAR FLAP

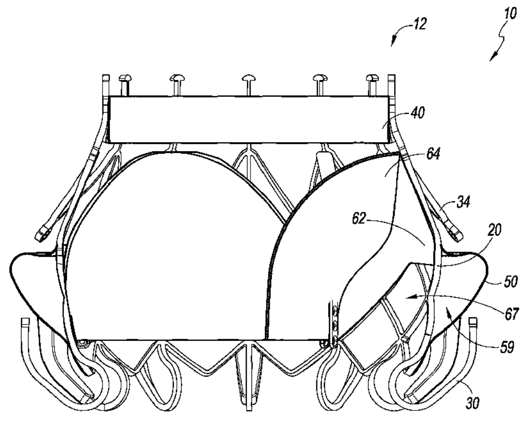

FIG. 11B

(57) **Abstract**: A prosthesis (10) can be configured to grasp intralumenal tissue when deployed within a body cavity and prevent axial flow of fluid around an exterior of the prosthesis. The prosthesis comprises an expandable frame (20) configured to radially expand and contract for deployment within the body cavity and an annular flap (50) positioned around and secured to an exterior of the expandable frame, the annular flap having a distal edge secured at or near the distal end (14) of the frame and extending to a proximal edge secured at an intermediate location on the frame between the proximal (12) and distal (14) ends. The prosthesis also comprises a valve body positioned within an interior of the expandable frame, wherein the valve body comprises: an inner skirt (62) secured to the interior of the expandable frame (20); and a plurality of leaflets (64) configured to allow flow in a first direction and prevent flow in a second opposite direction. An opening is defined at or near the distal end of the frame between the annular flap and the valve body to provide access for fluid to flow into a space (59) between the annular flap and the valve body, and wherein fluid flow into the space causes the annular flap to move from a first configuration wherein the flap is closer to the frame to a second configuration wherein the flap is spaced further away from the frame to increase the surface area of the prosthesis and create a barrier to fluid flow exterior to the frame when deployed within the body cavity.

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REPLACEMENT MITRAL VALVE WITH ANNULAR FLAP

[0001]

BACKGROUND

Field

[0002] Certain embodiments disclosed herein relate generally to prostheses for implantation within a lumen or body cavity. In particular, certain embodiments relate to expandable prostheses such as replacement heart valves, such as for the mitral valve, that are configured to atraumatically grasp intralumenal tissue.

Background

[0003] Human heart valves, which include the aortic, pulmonary, mitral and tricuspid valves, function essentially as one-way valves operating in synchronization with the pumping heart. The valves allow blood to flow downstream, but block blood from flowing upstream. Diseased heart valves exhibit impairments such as narrowing of the valve or regurgitation, which inhibit the valves' ability to control blood flow. Such impairments reduce the heart's blood-pumping efficiency and can be a debilitating and life threatening condition. For example, valve insufficiency can lead to conditions such as heart hypertrophy and dilation of the ventricle. Thus, extensive efforts have been made to develop methods and apparatuses to repair or replace impaired heart valves.

[0004] Prostheses exist to correct problems associated with impaired heart valves. For example, mechanical and tissue-based heart valve prostheses can be used to replace impaired native heart valves. More recently, substantial effort has been dedicated to developing replacement heart valves, particularly tissue-based replacement heart valves that can be delivered with less trauma to the patient than through open heart surgery. Replacement valves are being designed to be delivered through minimally invasive procedures and even percutaneous procedures. Such replacement valves often include a

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tissue-based valve body that is connected to an expandable frame that is then delivered to the native valve's annulus.

[0005] These replacement valves are often intended to at least partially block blood flow. However, a problem occurs when blood flows around the valve on the outside of the prosthesis. For example, in the context of replacement heart valves, paravalvular leakage has proven particularly challenging. An additional challenge relates to the ability of such prostheses to be secured relative to intralumenal tissue, e.g., tissue within any body lumen or cavity, in an atraumatic manner. Further challenges arise when trying to controllably deliver and secure such prostheses in a location such as at a native mitral valve.

SUMMARY OF THE INVENTION

[0006] Embodiments of the present disclosure are directed to a prosthesis, such as but not limited to a replacement heart valve. According to some embodiments, a prosthesis can be configured to be deployed within a body cavity and prevent axial flow of fluid around an exterior of the prosthesis. The prosthesis can include an expandable frame configured to radially expand and contract for deployment within the body cavity, and an annular flap positioned around an exterior of the expandable frame. Further embodiments are directed to methods of delivering a prosthesis, e.g. a replacement heart valve, and methods of using a prosthesis to create a barrier to fluid flow exterior to the prosthesis (e.g., to prevent paravalvular leakage).

[0007] In some embodiments, the prosthesis can include an expandable frame having a proximal end and a distal end and a longitudinal axis extending therethrough. In some embodiments, the frame can be designed to radially expand and contract for deployment within the body cavity. The prosthesis can include an annular flap positioned around and secured to an exterior of the frame. The annular flap may have a distal edge secured at or near the distal end of the frame and extending to a proximal edge secured at an intermediate location on the frame between the proximal and distal ends. The prosthesis can include a valve body positioned within an interior of the expandable frame. In some embodiments, the valve body can include an inner skirt secured to the interior of the expandable frame and a plurality of leaflets designed to allow flow in a first direction and prevent flow in a second opposite direction. In some embodiments, an opening is defined at or near the distal end of the frame between the annular flap and the valve body which can provide access for fluid to flow into a space between the annular flap and the valve body. In some embodiments, the fluid flow into the space can cause the annular flap to move from a first configuration wherein the flap is closer to the frame to a second configuration wherein the flap is spaced further away from the frame to increase the surface area of the prosthesis and create a barrier to fluid flow exterior to the frame when deployed within the body cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIGURE 1A is a proximal oriented, perspective view of an embodiment of a prosthesis illustrating a frame, a plurality of anchors, a band, a flap, and a valve body.

[0009] FIGURE 1B is a distal oriented, perspective view of the prosthesis of FIGURE 1A.

[0010] FIGURE 2 is a front elevation view of the prosthesis of FIGURE 1.

[0011] FIGURE 3 is a front elevation view of another embodiment of a prosthesis.

[0012] FIGURE 4 is a front elevation view of an embodiment of a frame.

[0013] FIGURE 5 is a perspective view of an embodiment of an annular flap.

[0014] FIGURE 6 is a front elevation view of the annular flap of FIGURE 5.

[0015] FIGURE 7 is a perspective view of an embodiment of a valve body.

[0016] FIGURE 8 is a front perspective view of the valve body of FIGURE 7.

[0017] FIGURE 9 is a front elevation of an embodiment of a prosthesis illustrating a frame, a plurality of anchors, a band, a flap, and a valve body.

[0018] FIGURE 10 is a front elevation another embodiment of a prosthesis.

[0019] FIGURE 11A is a partial cross-sectional view of the prosthesis of FIGURE 1 with the annular flap in a first configuration.

[0020] FIGURE 11B is a partial cross-sectional view of the prosthesis of FIGURE 11A with the annular flap in a first configuration.

[0021] FIGURE 12A is a partial cross-sectional view of the prosthesis of FIGURE 1 with the annular flap in a first configuration, the valve body being removed.

[0022] FIGURE 12B is a partial cross-sectional view of the prosthesis of FIGURE 12A with the annular flap in a first configuration.

[0023] FIGURE 13A-15 illustrate schematic representations of the prosthesis of Figure 3 positioned within a heart, with FIGURES 13A-13C illustrating the prosthesis in situ with distal anchors contacting the ventricular side of a mitral valve annulus, FIGURES 14A-14B illustrating the prosthesis in situ with distal anchors not contacting the ventricular side of the mitral valve annulus, and FIGURE 15 illustrating the prosthesis in situ with distal anchors not extending between the chordae tendineae.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0024] The embodiment of Figures 1A-4 illustrates a prosthesis **10**. The prosthesis **10** can have components, features, and/or functionality similar to those described in any of U.S. Publication Nos. 2014/0277390, 2014/0277422, and 2014/0277427.

With reference first to the embodiments of Figures 1A-4, the prosthesis **10** can include a frame **20**, anchors **30, 34**, a band **40**, an annular flap or sail **50** and a valve body **60**. The prosthesis **10** can include a proximal end **12** and a distal end **14** with openings defined at both ends **12**, **14** such that fluid can flow therethrough. In some embodiments, the proximal end **12** can be placed in the left atrium while the distal end **14** can be placed in the left ventricle such that prosthesis **10** can function as a replacement for a mitral valve. As will be discussed in greater detail below and as discussed in U.S. Publication Nos. 2014/0277390, 2014/0277422, and 2014/0277427, the prosthesis **10** can allow blood flow in a first direction from the proximal end **12** to the distal end **14** while preventing blood flow in a second direction from the distal end **14** to the proximal end **12**. For example, during diastole the valve body **60** may be open to allow blood flow from the proximal end **12** to the distal end **14**, and during systole the valve body **60** may be closed to prevent blood flow from the distal end **14** to the proximal end **12**.

[0025] With reference now to the embodiment of Figure 4, the embodiment illustrates an expandable frame **20** of the prosthesis **10** which can have a proximal end **22** and a distal end **24**. In some embodiments, such as the illustrated embodiment, the frame **20** can include an intermediate portion **26** which has a greater diameter than the diameter of the frame **20** at the proximal and/or distal ends **22, 24** when the frame **20** is in an expanded configuration. In some embodiments, such as the illustrated embodiment, the frame **20** can include an intermediate portion **26** which has a greater cross-sectional area than the cross-

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sectional area of the frame **20** at the proximal and/or distal ends **22, 24** when the frame **20** is in an expanded configuration. The frame **20** can be designed to expand radially and contract for deployment within a body cavity, such as at a heart valve location such as the mitral valve. For example, as described in greater detail in U.S. Publication Nos. 2014/0277390, 2014/0277422, and 2014/0277427, the frame **20** can include a plurality of struts which define a plurality of foreshortening cells. In some embodiments, the frame **20** can be designed to radially and contract radially from a longitudinal axis **28** extending through the frame **20**. As illustrated in the embodiments of Figures 1-4, the proximal end **22** can define a proximal opening **23** and the distal end **24** can define a distal opening **25**.

[0026] With continued reference to the embodiments of Figures 1A-4 which illustrates the prosthesis **10**, in some embodiments the prosthesis **10** can include one or more distal anchors **30**. The distal anchors **30** can be positioned along or proximate a distal end **24** of the frame **20** and can be connected to the frame **20**. The distal anchors **30** can be designed such that when the frame **20** is in an expanded configuration an end or tip **32** of each distal anchor **30** is positioned radially outward from the frame **20** and extends generally in a proximal direction. In some embodiments, the prosthesis **10** can include one or more proximal anchors **34**. The proximal anchors **34** can be positioned along or proximate a proximal end **22** of the frame **20** and can be connected to the frame **20**. The proximal anchors **34** can be designed such that when the frame **20** is in an expanded configuration an end or tip **36** of each proximal anchor **34** is positioned radially outward from the frame **20** and extends generally in a distal direction. In some embodiments, one or more anchors **30, 34** can include cushions **38**, **39** covering one or more of such anchors.

[0027] In some embodiments, the cushion **38** can be formed from two separate pieces of material such as an inner portion positioned within a covering such that the covering forms a layer surrounding the inner portion. For example, the inner portion can be wholly contained within the covering. In some embodiments, the inner portion can be formed of a foam material such that the inner portion is at least somewhat compliant and the covering can be formed of a biocompatible, fabric material. The embodiment of Figures 1A, 1B and 2 illustrates cushions **38** on alternating distal anchors **30**, the cushions **38** extending partially from an end or tip of the anchor **30** towards the connection between the anchor **30**

and the frame **20**. Use of cushions **38** on alternating distal anchors **30** can maintain a smaller form factor while in the prosthesis **10** is in a contracted state for delivery. As such, for embodiments having twelve distal anchors **30**, a total of six distal anchors **30** can have cushions **38** and a total of six distal anchors **30** may not have a cushion **38**. The cushions **38** can advantageously increase contact area of the anchors **30** on tissue. This can reduce trauma between the anchor **30** and such tissue. Moreover, this can facilitate growth of tissue in and/or around the anchor **30** in embodiments where the cushions **38** are formed of a material which encourages tissue growth. The cushions **38** on anchors **30** adjacent anchors **30** without a cushion **38** can also beneficially reduce any potential trauma caused by adjacent anchors **30** without a cushion **38**.

[0028] The embodiment of Figure 3 illustrates cushions **38**, **39** on all distal anchors **30**. As shown some of the distal anchors **30** include thicker cushions **38** than other distal anchors **30**. The cushions **38**, **39** can extend the majority or entirety of the length of the anchor **30** from an end or tip of the anchor **30** towards the connection between the anchor **30** and the frame **20**. As shown, two distal anchors **30** include thicker cushions **38** with a distal anchor **30** having a thinner cushion **39** positioned therebetween. As such, for embodiments having twelve distal anchors **30**, a total of eight distal anchors **30** can have thicker cushions **38** and a total of four distal anchors **30** can include thinner cushions **39**. The thicker cushions **38** can be formed of an inner portion and a cover layer, with the inner portion being formed from a compliant material, such as foam, and the covering can be formed of a biocompatible, fabric material. As shown, the inner portion can be positioned only around a portion of the anchor **30** whereas the covering can extend the majority or entirety of the length of the anchor **30**. The thinner cushion **39** can be a cover layer with a thinner inner portion or without an inner portion. The inner portion and/or the covering can be formed of a material which encourages tissue growth.

[0029] Other configurations of cushions **38**, **39** can also be used. For example, in some embodiments, the cushions **38**, **39** can be included on proximal anchors **34**. In some embodiments, the cushions **38**, **39** can be positioned on other portions of the frame **20** such as, but not limited to, one or more of the struts forming the frame **20**. The cushions **38**, **39** can advantageously increase contact area of the prosthesis **10** on tissue. This can reduce trauma between the frame **20** and such tissue. Moreover, this can facilitate growth of tissue in and/or around the frame **20** in embodiments where the cushions **38**, **39** are formed of a material which encourages tissue growth. In some embodiments, the covering of cushions **38**, **39** can extend from the annular flap **50** and be formed from materials similar to those of the annular flap **50**. The covering of cushions **38**, **39** can cover a majority or the entirety of the distal anchors **30** as shown in Figure 3. In some embodiments, the cushions **38**, **39** can be attached to the distal anchors **30** via circumferential stitching about a longitudinal axis of the distal anchor **30**.

[0030] With reference to the embodiments of Figures 1A-3, in some embodiments the prosthesis **10** can include a band **40** along or proximate the proximal end **22** of the frame **20**. The band **40** can include features and perform functions similar to those described in U.S. Patent Application No. 13/403,929 filed February 23, 2012, titled REPLACEMENT VALVE AND METHOD, published as U.S. Publication No. 2012/0215303.

[0031] With reference to the embodiments of Figures 1A-3, 5 and 6, the prosthesis **10** can include an annular flap **50** which can be positioned around and secured to an exterior of the frame **20**. The annular flap **50** can have a distal edge **52** secured at or proximate the distal end **24** of the frame **20** and extend to a proximal edge **54** secured at or proximate an intermediate location, such as the intermediate portion **26**, on the frame **20** between the proximal and distal ends **22, 24**. In some embodiments, the distal edge **52** of the annular flap **50** can be provided with a shape that generally corresponds to the shape of the frame **20**. This can facilitate the securement of the flap **50** to the frame **20**. For example, as illustrated in the embodiments of Figures 1A-3, 5 and 6, the distal edge **52** can include a generally triangular pattern **56** which follows the generally triangular, zig-zag or undulating pattern of the struts of frame **20** along the distal end **24** of frame **20**. Other shapes and/or patterns **56** can be used along the distal edge **52** of the annular flap **50**. In some embodiments, the distal edge **52** of the annular flap **50** can have no pattern. In some embodiments the distal edge **52** does not follow the pattern of the struts of the frame **20** and/or can have a different pattern from that of the struts.

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[0032] In some embodiments, such as the embodiments of Figures 1A-3, 5 and 6, the annular flap **50** can have a flange **58**. The flange **58** can extend generally radially outward in a direction generally orthogonal to the longitudinal axis **28** extending through the frame **20**. In some embodiments, the flange **58** can also project proximally and/or distally. The flange **58** can be used to further prevent or inhibit backflow of fluids around the prosthesis **10**. In some embodiments, the flange **58** can be formed from a first layer of resilient material, such as polyethylene terephthalate (PET) or any other biocompatible material, which extends radially outward from the frame **10**. In some embodiments, a second layer of resilient material, such as PET or any other biocompatible material, can extend from the first layer in a distal direction towards a distal end **24** of the frame **20**. In some embodiments, the first and second layers can be connected together using a suitable mechanism such as adhesives or sutures. In some embodiments, the annular flap **50** can be formed from a single layer of resilient material. In some embodiments, the first and/or second layers can be formed from a deformable material. In some embodiments, the first and/or second layers can be formed from a material which is wholly or substantially fluid impermeable. The annular flap **50** can also include other structures, such as wires formed from resilient materials such as nitinol, to allow at least portions of the annular flap **50** to retain a particular shape. These structures may be positioned on an inner surface of the annular flap **50**.

[0033] In some embodiments, the flange **58** can be formed when the annular flap **50** is in an expanded configuration. When the flap is in an expanded configuration, such as illustrated in the embodiment of Figure 6, the radius of the annular flap **50** can decrease distal of the flange **58**. As will be described in further detail below, the annular flap **50** can have a first, collapsed or deflated configuration in which the flap **50** is closer to the frame **20** to a second, expanded or inflated configuration in which the flap **50** is spaced further away from the frame **20**. The expanded configuration can increase the surface area of the prosthesis **10** and create a barrier to fluid flow exterior to the frame **20** when deployed within a body cavity. The transition from the first configuration to the second configuration, and from the second configuration to the first configuration, can be triggered by blood flow into and out of the interior region of the flap **50**, as described further below.

[0034] With reference to the embodiments of Figures 1A-3 and 7-10, the prosthesis **10** can include a valve body **60** positioned within an interior of the frame **20**. In some embodiments, the valve body **60** can include an inner skirt **62** secured to the interior of the frame **20**. The valve body **60** can include a plurality of leaflets **64** which can be designed to allow flow in a first direction, such as a proximal to distal direction, while preventing flow in a second direction, such as a distal to proximal direction. In some embodiments, the leaflets **64** have a curved, proximal edge which is fixed to the inner skirt **62** and a distal edge which freely moves. In such embodiments, movement of the distal edges towards and away from each other can allow the valve body **60** to open and close depending on the direction of flow. Accordingly, the valve body **60** can function as a one-way valve such as a mitral valve. In some embodiments, the leaflets **64** are secured to the inner skirt **62**. The leaflets **64** and the inner skirt **62** can be manufactured from the same material or from different materials. For example, the inner skirt **62** can be manufactured from a more rigid material than the leaflets **64**. In some embodiments, the distal end **66** of the inner skirt **62** can be secured at or proximate the distal end **24** of the frame **20**. In some embodiments, such as is illustrated in the embodiments of Figures 9 and 10, the distal end **66** of the inner skirt **62** can be positioned slightly proximal of the distal end **24** of the frame **20**. This can allow facilitate blood flow around the outside of the inner skirt **62** and into the annular flap **50**. The inner skirt **62** can include one or more openings or cutouts **67** positioned along a distal end **66** of the inner skirt **62**. This can further facilitate blood flow around the outside of the inner skirt **62**. In some embodiments, the valve body **60** can include arms **68** to further secure the valve body **60** to the frame **20**.

[0035] Reference is now made to the embodiments of Figures 11A-B and 12A-B which illustrate two configurations of the annular flap. It should be noted that the embodiment of Figures 12A-B is similar to the embodiment of Figure 11A-B with the valve body **60** removed. As shown in the embodiments of Figures 11A and 12A, in a first configuration the annular flap **50** is positioned closer to the frame **20**. In the event that fluid flows in a second direction, such as a distal to proximal direction, at least a portion of the fluid can enter into an opening between the frame **20** and the annular flap **50**, such as opening or cutout **67** formed along the distal end **66** of the inner skirt **62**, and collect within a space **59**

such that the annular flap **50** takes on the second configuration as shown in the embodiments of Figures 11B and 12B. As shown in the embodiments of Figure 1B, the frame **20** can be positioned within the space **59** between the annular flap **50** and the valve body **60**. This effect can be enhanced if the valve body **60** is designed to prevent fluid flow in the second direction (e.g., distal to proximal), such that a substantial portion of fluid is forced around and into the annular flap **50**. The annular flap **50** can revert back to the first configuration when fluid flows in a first direction, such as a proximal to distal direction, such that fluid is expelled from within the space **59**. In some embodiments, the space **59** can be formed between the inner skirt **62** and the flap **50**. For example, both the inner skirt **62** and the flap **50** can be connected to the frame **20** along this region, such as along a proximal edge **54** of the flap **50**, such that the inner skirt **62** and flap **50** serve as a barrier to flow of fluid outward from space **59**.

[0036] Reference is now made to Figure 13A-15 which illustrate schematic representations of an embodiment of a replacement heart valve **10** positioned within a native mitral valve of a heart **100**. A portion of the native mitral valve is shown schematically and represents typical anatomy, including a left atrium **102** positioned above an annulus **106** and a left ventricle **104** positioned below the annulus **106**. The left atrium **102** and left ventricle **104** communicate with one another through a mitral annulus **106**. Also shown schematically in Figures 13A-15 is a native mitral leaflet **108** having chordae tendineae **110** that connect a downstream end of the mitral leaflet **108** to the papillary muscle of the left ventricle **104**. The portion of the replacement heart valve **10** disposed upstream of the annulus **106** (toward the left atrium) can be referred to as being positioned supra-annularly. The portion generally within the annulus **106** is referred to as positioned intra-annularly. The portion downstream of the annulus **106** is referred to as being positioned sub-annularly (toward the left ventricle). In the illustrated embodiment, only a part of the foreshortening portion is positioned intra-annularly or sub-annularly, and the rest of the replacement heart valve **10** is supra-annular.

[0037] As shown in the situations illustrated in Figures 13A-14, the replacement heart valve **10** can be disposed so that the mitral annulus **106** is between the distal anchors **30** and the proximal anchors **34**. In some situations, the prosthesis **10** can be positioned such that ends or tips **32** of the distal anchors **30** contact the annulus **106** as shown, for example, in Figures 13A-13C. In some situations, the prosthesis **10** can be positioned such that ends or tips **32** of the distal anchors **30** do not contact the annulus **106** as shown, for example, in Figures 14A-14B. In some situations, the prosthesis **10** can be positioned such that the distal anchors **30** do not extend around the leaflet **108** as shown in Figure 15. While Figures 13A-15 are described separately below, it should be understood that one or more of the situations illustrated in Figures 13A-15 may be present when the prosthesis **10** is positioned at the implantation location, such as a native mitral valve. For example, in some situations the prosthesis **10** may be positioned such that some distal anchors **30** may contact the annulus **106** while other distal anchors **30** may not.

[0038] With reference first to the situations illustrated in Figures 13A-14B, the replacement heart valve **10** can be positioned so that the ends or tips **32** of the distal anchors **30** are on a ventricular side of the mitral annulus **106** and the ends or tips of **36** the proximal anchors **34** are on an atrial side of the mitral annulus **106**. The distal anchors **30** can be positioned such that the ends or tips **32** of the distal anchors **30** are on a ventricular side of the native leaflets beyond a location where chordae tendineae **110** connect to free ends of the native leaflets. The distal anchors **30** may extend between at least some of the chordae tendineae **110** and, in some situations such as those shown in Figures 13A-13C, can contact or engage a ventricular side of the annulus **106**. It is also contemplated that in some situations, such as those shown in Figure 14A and 14B, the distal anchors **30** may not contact the annulus **106**, though the distal anchors **30** may still contact the native leaflet **108**. In some situations, the distal anchors **30** can contact tissue of the left ventricle **104** beyond the annulus **106** and/or a ventricular side of the leaflets.

[0039] During delivery, the distal anchors **30** (along with the frame **20**) can be moved toward the ventricular side of the annulus **106** with the distal anchors **30** extending between at least some of the chordae tendineae **110** to provide tension on the chordae tendineae **110**. The degree of tension provided on the chordae tendineae **110** can differ. For example, little to no tension may be present in the chordae tendineae **110** as shown in Figure 13C where the leaflet **108** is shorter than or similar in size to the distal anchors **30**. A greater degree of tension may be present in the chordae tendineae **110** as shown in Figures 13A and

13B where the leaflet **108** is longer than the distal anchors **30** and, as such, takes on a compacted form and is pulled proximally. An even greater degree of tension may be present in the chordae tendineae **110** as shown in Figures 14A and 14B where the leaflets **108** are even longer relative to the distal anchors **30**. As shown in Figures 14A and 14B, the leaflet **108** is sufficiently long such that the distal anchors **30** do not contact the annulus **106**.

[0040] The proximal anchors **34** can be positioned such that the ends or tips **36** of the proximal anchors **34** are adjacent the atrial side of the annulus **106** and/or tissue of the left atrium **102** beyond the annulus **106**. In some situations, some or all of the proximal anchors **34** may only occasionally contact or engage atrial side of the annulus **106** and/or tissue of the left atrium **102** beyond the annulus **106**. For example, as shown in Figures 13A and 13B, the proximal anchors **34** may be spaced from the atrial side of the annulus **106** and/or tissue of the left atrium **102** beyond the annulus **106**. The proximal anchors **34** could provide axial stability for the prosthesis **10**. In some situations such as those shown in Figures 13A and 14A, some or all of the proximal anchors **34** may not contact the annular flap **50**. This may occur when the annular flap **50** is in a collapsed configuration although it may also occur when the annular flap **50** is in an expanded configuration. In some situations such as those shown in Figures 13B, 13C and 14B, some or all of the proximal anchors **34** may contact the annular flap **50**. This may occur when the annular flap **50** is in an expanded configuration although it may also occur when the annular flap **50** is in a collapsed configuration. It is also contemplated that some or all of the proximal anchors **34** may contact the atrial side of the annulus **106** and/or tissue of the left atrium **102** beyond the annulus **106**

[0041] With continued reference to the situations illustrated in Figures 13A-14B, the annular flap **50** can be positioned such that a proximal portion **51** of the annular flap **50** is positioned along or adjacent an atrial side of the annulus **106.** The proximal portion **51** can be positioned between the atrial side of the annulus **106** and the proximal anchors **34**. The proximal portion **51** can extend radially outward such that the annular flap **50** is positioned along or adjacent tissue of the left atrium **102** beyond the annulus **106**. The annular flap **50** can create a seal over the atrial side of the annulus **106** when the flap **50** is in the expanded state.

[0042] The flap **50** can transition from the collapsed state to the expanded state during systole when pressure in the left ventricle **104** increases. This increased pressure within the left ventricle **104** can cause blood within the left ventricle **104** to be directed to areas of lower pressure, such as the aorta (not shown) and the left atrium **102**. As noted above, during systole the valve body **60** may be closed to prevent blood from flowing back into the left atrium **102**. A substantial portion of blood can forced around the frame **20** and valve body **60** and into the annular flap **50** such that the flap **50** can expand. Sealing along an atrial side of the annulus **106** can be particularly effective. The left atrium **102** can be at a lower pressure in comparison to the pressure of the space **59** between the annular flap **50** and the valve body **50**, which is closer to the pressure of the left ventricle **104**. The existence of such a pressure differential between the left atrium **102** and the space **59** during systole can allow the flap **50** to apply a greater force to surrounding tissue within the left atrium **102**. During diastole, where blood flows from the left atrium **102** towards the left ventricle **104**, the flap **50** can transition from the expanded state back to the collapsed state.

[0043] In some situations such as those shown in Figure 13A and 14A, the annular flap **50** may not contact the wall of the heart **100**. This may occur when the annular flap **50** is in a collapsed configuration although it may also occur when the annular flap **50** is in an expanded configuration. In some situations such as those shown in Figure 13B, 13C and 14B, the annular flap **50** may contact the wall of the heart **100**. This may occur when the annular flap **50** is in an expanded configuration although it may also occur when the annular flap **50** is in a collapsed configuration. As shown in Figure 13A-14B, the annular flap **50** can also assist in filling gaps which exist between the leaflet **108** and the frame **20** (portions of which are illustrated in dashed lines).

[0044] In some situations such as that shown in Figure 15, the leaflet **108** may not be captured between the frame **20** (portions of which are shown in dashed lines) and the distal anchors **30**. As shown, the anchor **30** may be positioned along an atrial surface of the leaflet **108**. The anchor **30** may also be positioned along an inner surface of the annulus **106**. It is also contemplated that the anchor **30** may exert a force against the leaflet **108** such that the leaflet **108** is pushed radially outward, relative to the longitudinal axis **28**, towards a wall of the heart **100**. In such situations, the flap **50** can create a seal intra-annularly and/or along an atrial side of the leaflet **108**. In alternative situations (not shown), the flap **50** can create a seal along a ventricular side of the annulus **106**. For example, the replacement heart valve **10** may be disposed in the mitral annulus such that a portion of the annular flap **50** is positioned on the ventricular side of the native annulus **106**.

[0045] As noted above, although the in vivo situations of Figure 13A-15 have been described separately, it should be understood that one or more of these situations may be present when a prosthesis is positioned at the implantation location, such as a native mitral valve. For example, one or more of the distal anchors **30** may not capture the leaflet **108** whereas the remaining anchors **30** may capture the leaflet **108**. As another example, when the prosthesis **10** is positioned within the native mitral valve, the annular flap **50** can contact the wall of the heart **100** along one or more portions of an outermost circumference of the proximal portion **51** and may not contact the wall of the heart **100** along other portions of the outermost circumference of the proximal portion **51**. For example, the annular flap **50** may contact the wall of the heart **100** along an approximately 180 degree portion of the outermost circumference of the proximal portion **51** and may not contact the wall of the heart **100** along the remaining, approximately 180 degree portion of the outermost circumference of the proximal portion **51**.

[0046] Replacement heart valves can be delivered to a patient's heart mitral valve annulus in various ways, such as by open surgery, minimally-invasive surgery, and percutaneous or transcatheter delivery through the patient's vasculature. In some embodiments, the replacement heart valve can be delivered transapically or transfemorally.

[0047] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while a number of variations of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

[0048]

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WHAT IS CLAIMED IS:

1. A prosthesis for placement within a body cavity, the prosthesis configured to inhibit or reduce paravalvular leakage, the prosthesis comprising:

an expandable frame comprising a proximal end and a distal end and a longitudinal axis extending therethrough, the frame configured to radially expand and contract for deployment within the body cavity;

an annular flap positioned around and secured to an exterior of the expandable frame, the annular flap having a distal edge secured at or near the distal end of the frame and extending to a proximal edge secured at an intermediate location on the frame between the proximal and distal ends; and

a valve body positioned within an interior of the expandable frame, wherein the valve body comprises:

an inner skirt secured to the interior of the expandable frame; and

a plurality of leaflets configured to allow flow in a first direction and prevent flow in a second opposite direction;

wherein an opening is defined at or near the distal end of the frame between the annular flap and the valve body to provide access for fluid to flow into a space between the annular flap and the valve body, and wherein fluid flow into the space causes the annular flap to move from a first configuration wherein the flap is closer to the frame to a second configuration wherein the flap is spaced further away from the frame to increase a surface area of the prosthesis and create a barrier to fluid flow exterior to the frame when deployed within the body cavity.

2. The prosthesis of Claim 1, further comprising a plurality of distal anchors each connected to the expandable frame so that when the expandable frame is in an expanded configuration an end of each distal anchor is positioned radially outward from the expandable frame and extends generally proximally.

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3. The prosthesis of Claim 2, wherein at least some of the plurality of distal anchors comprise a cushion.

4. The prosthesis of any one of claims 1 to 3, further comprising a plurality of proximal anchors each connected to the expandable frame so that when the expandable frame is in an expanded configuration an end of each proximal anchor is positioned radially outward from the expandable frame and extends generally distally.

5. The prosthesis of any one of claims 1 to 4, further comprising a band at or near the proximal end of the expandable frame.

6. The prosthesis of any one of claims 1 to 5, wherein the expandable frame comprises a plurality of struts defining a plurality of foreshortening cells.

7. The prosthesis of Claim 6, wherein the distal edge of the annular flap is attached to undulating struts at the distal end of the expandable frame.

8. The prosthesis of any one of claims 1 to 7, wherein the intermediate location of the expandable frame has a greater cross-sectional dimension than the proximal end and the distal end of the frame when the expandable frame is in an expanded configuration.

9. The prosthesis of any one of claims 1 to 8, wherein the plurality of leaflets are configured to allow flow from the proximal end to the distal end of the expandable frame and prevent flow from the distal end to the proximal end.

10. The prosthesis of any one of claims 1 to 9, wherein the annular flap comprises a first layer of resilient material extending radially outward away from the expandable frame and a second layer of resilient material extending distally toward the distal end of the expandable frame.

11. The prosthesis of any one of claims 1 to 10, wherein at least a portion of the expandable frame is positioned within the space between the annular flap and the valve body.

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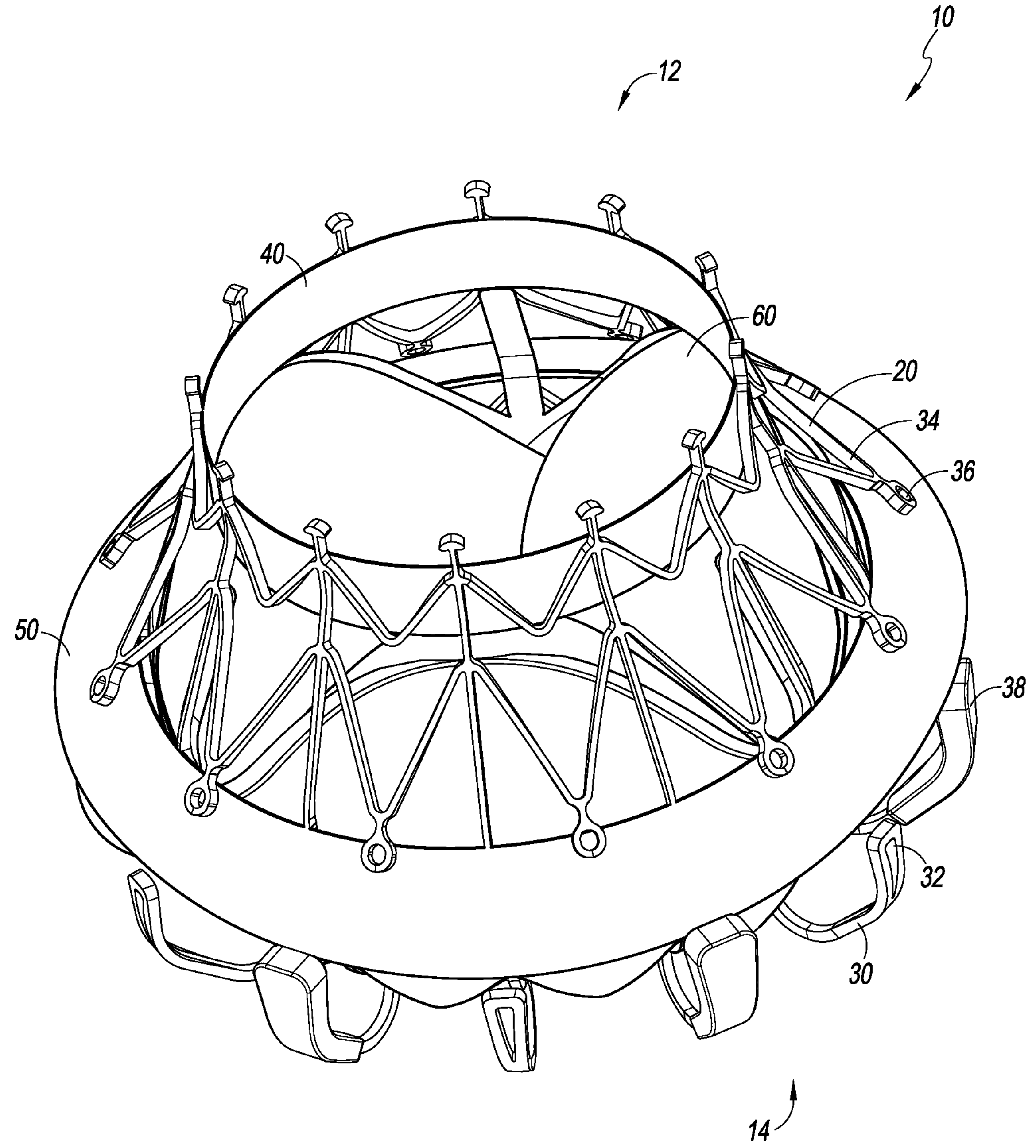


FIG. 1A

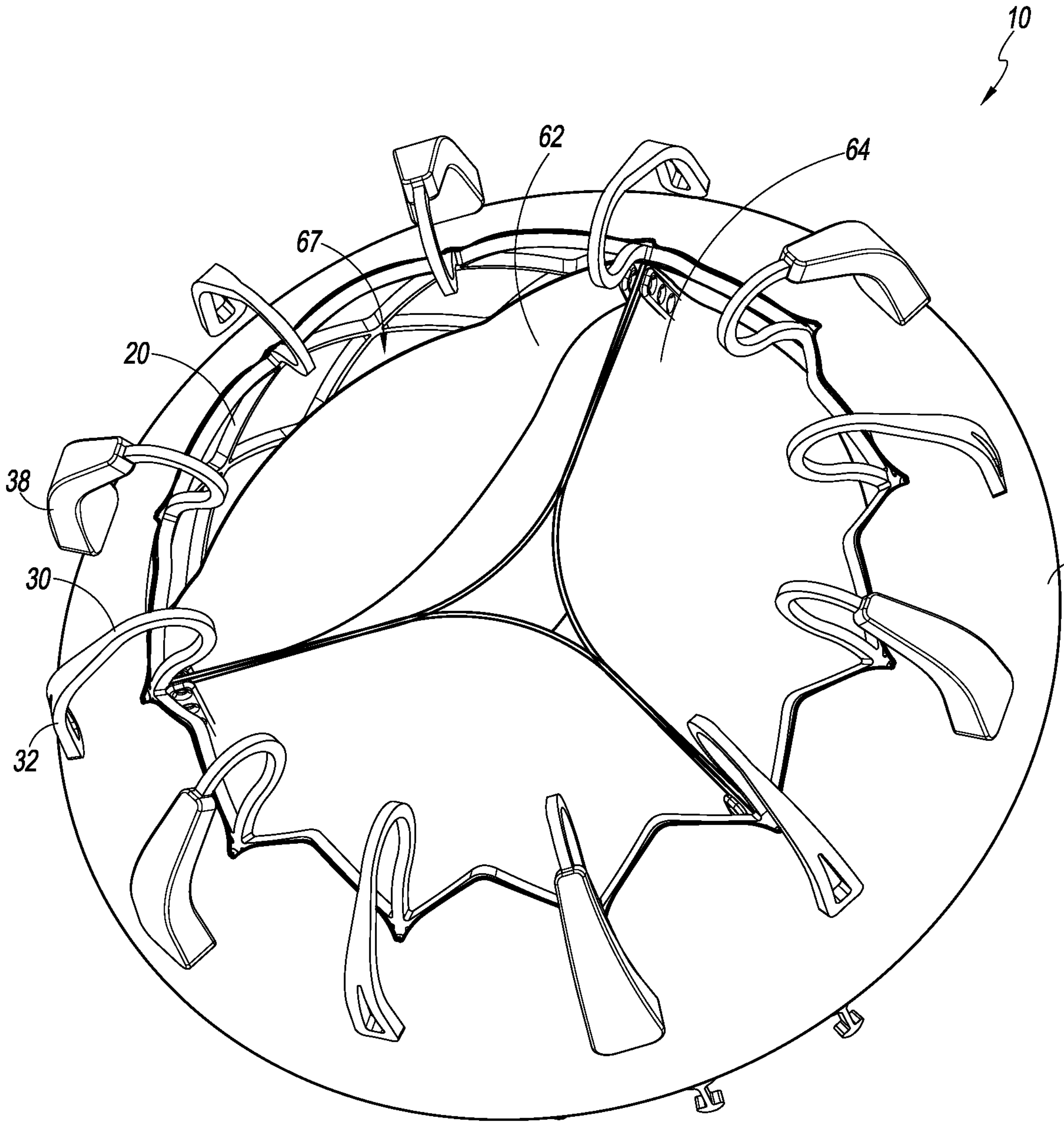


FIG. 1B

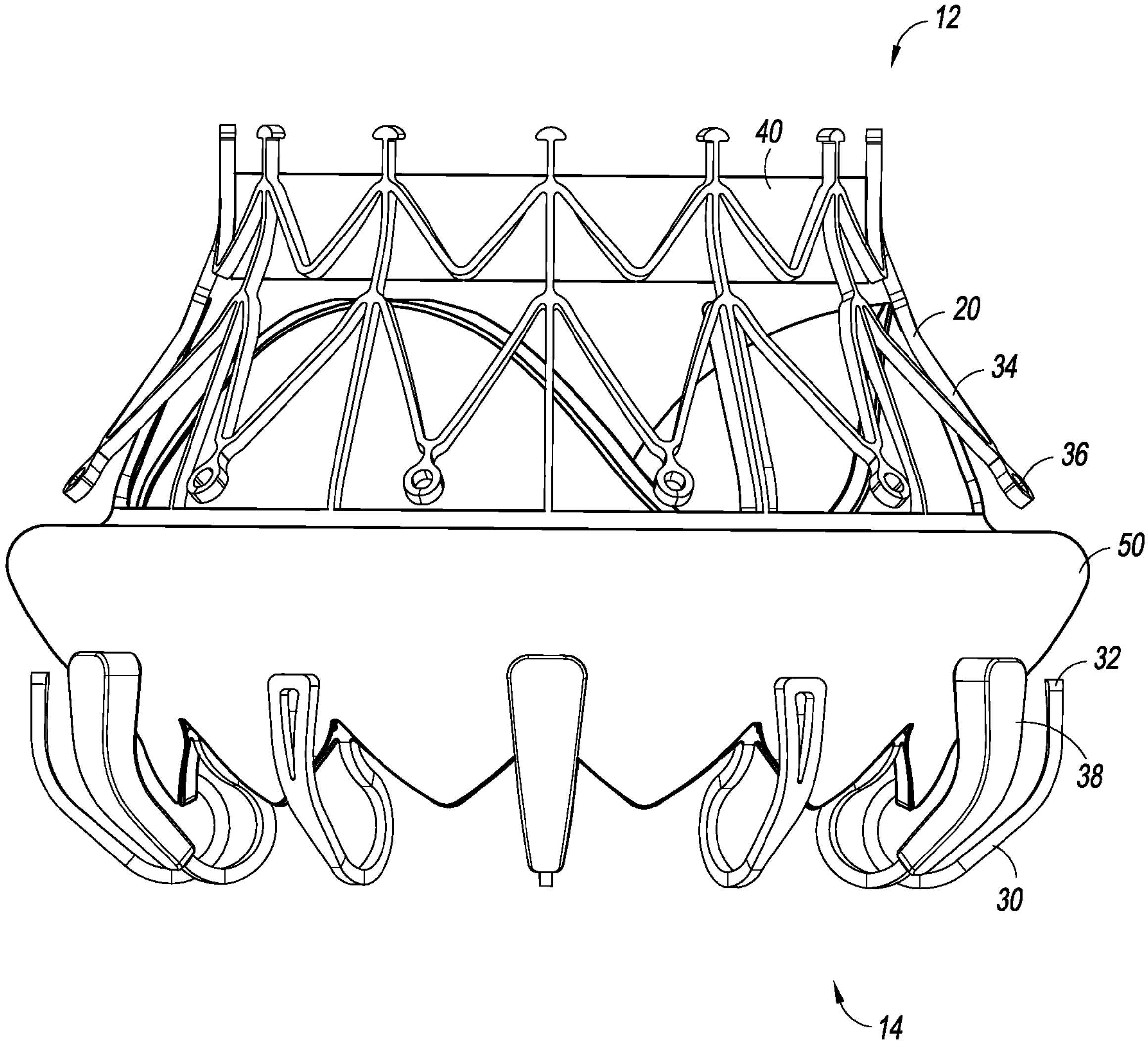


FIG. 2

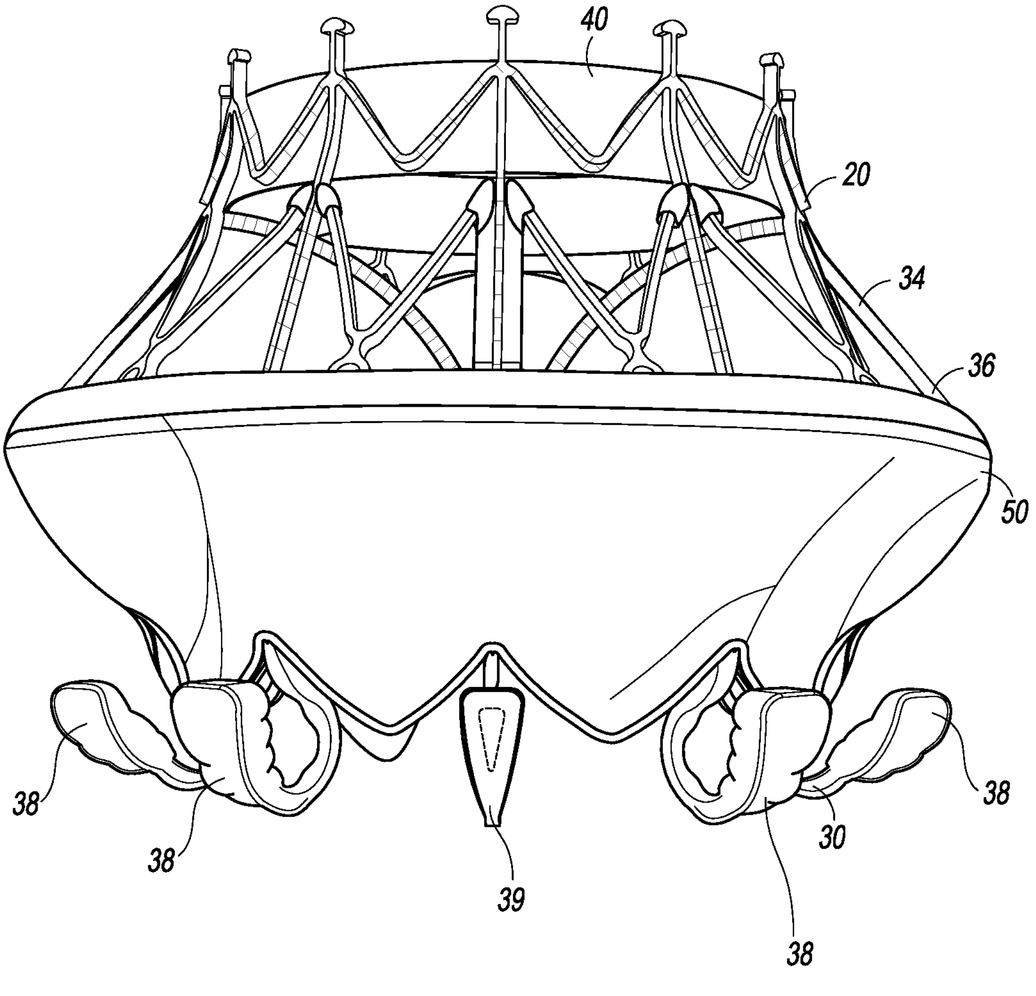


FIG. 3

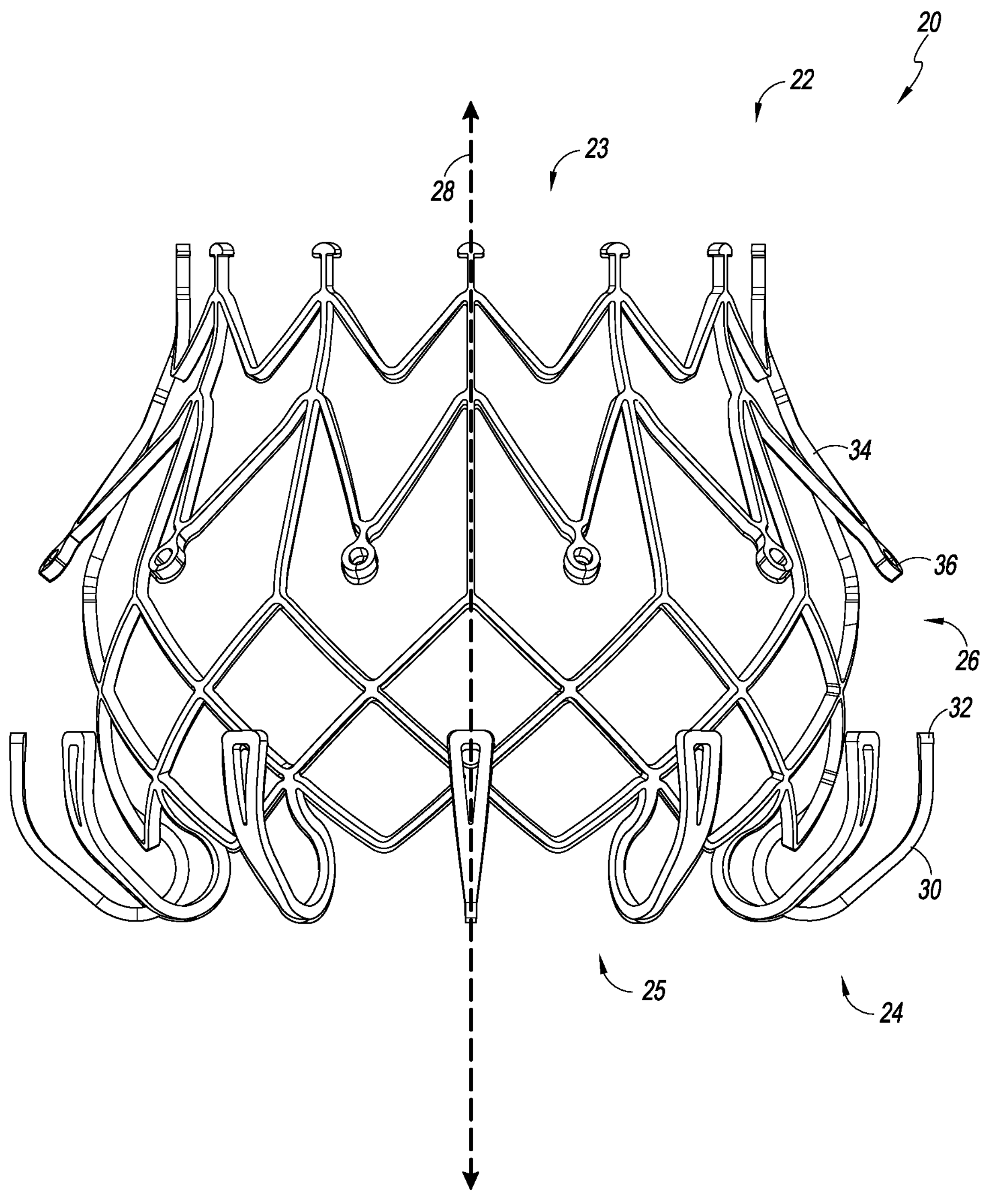


FIG. 4

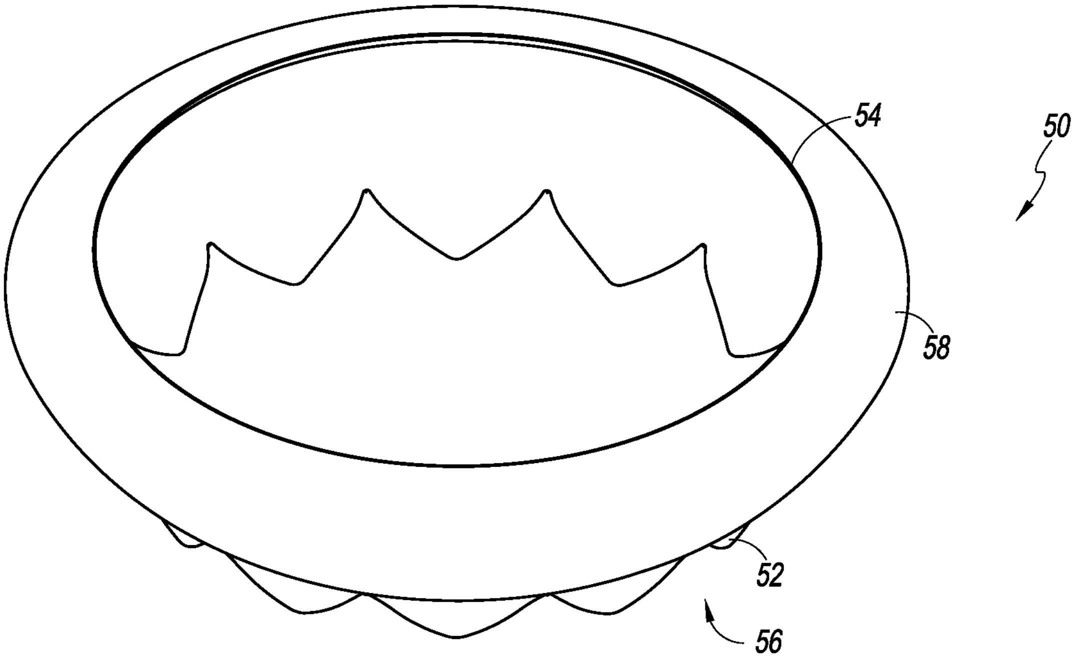


FIG. 5

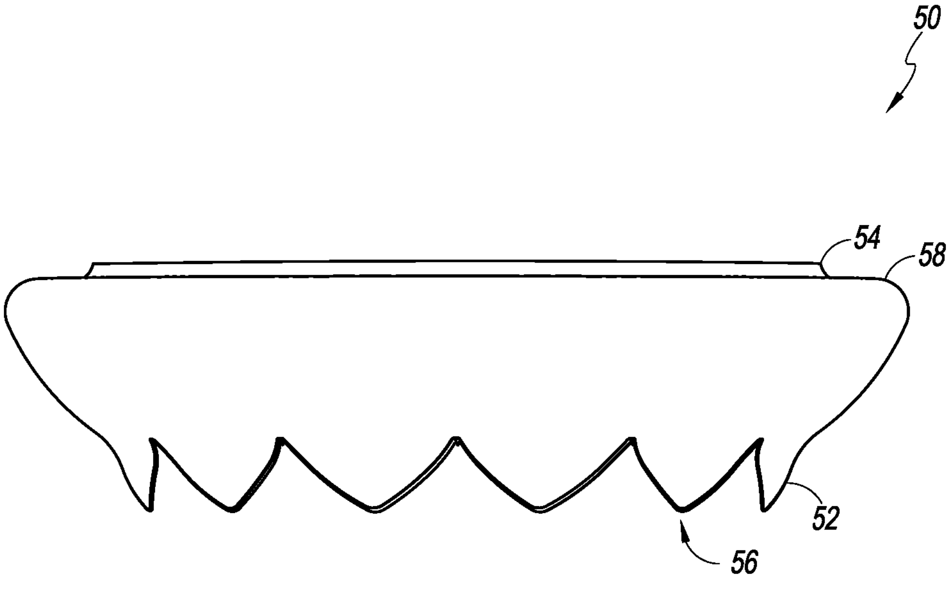


FIG. 6

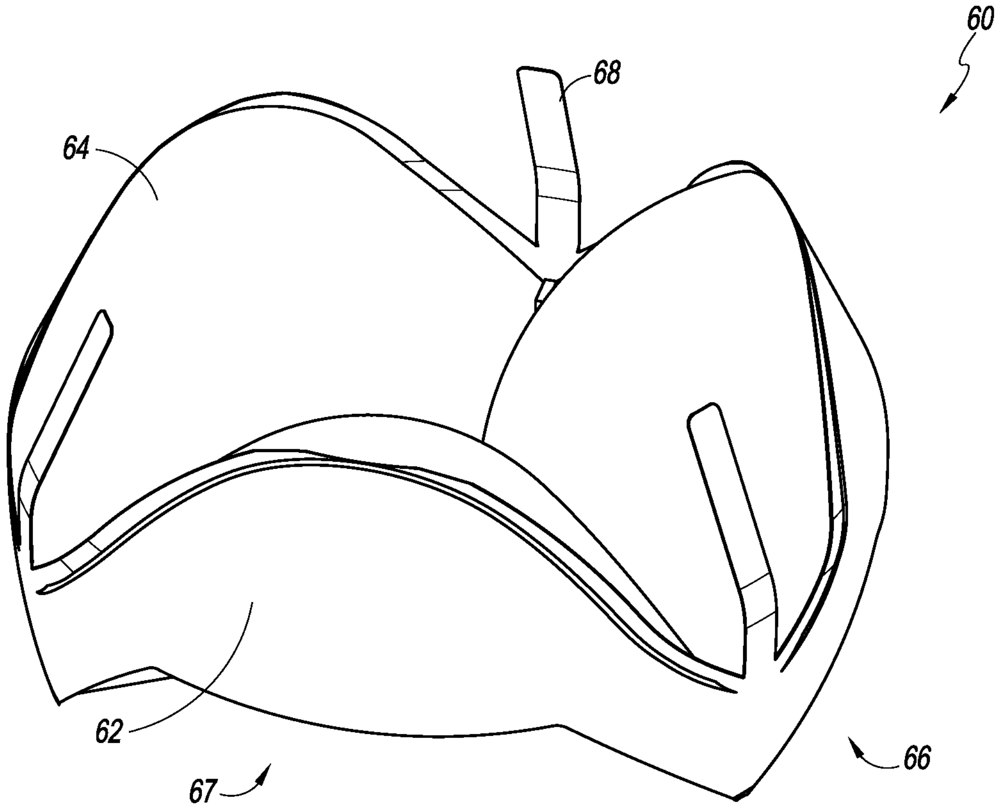


FIG. 7

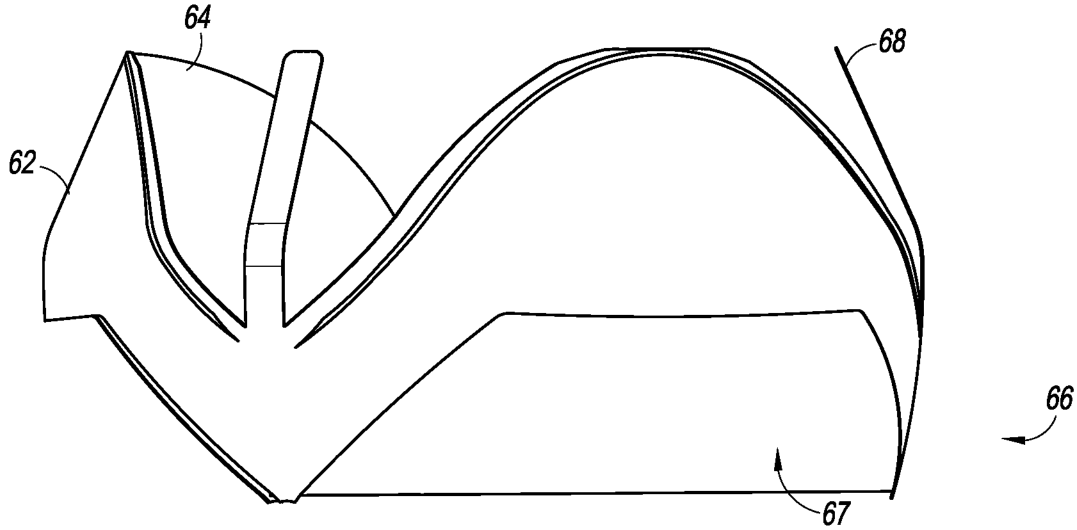


FIG. 8

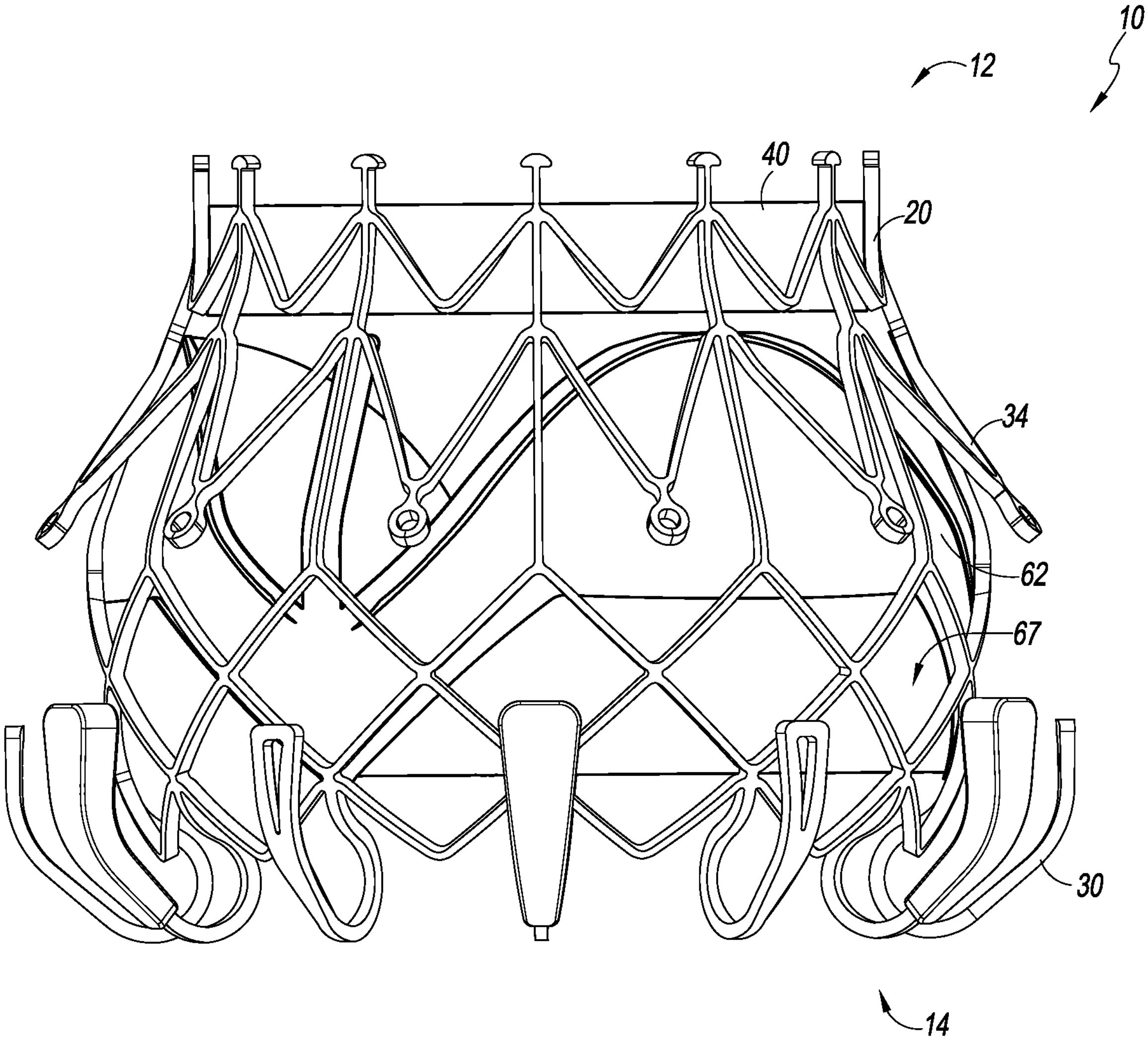


FIG. 9

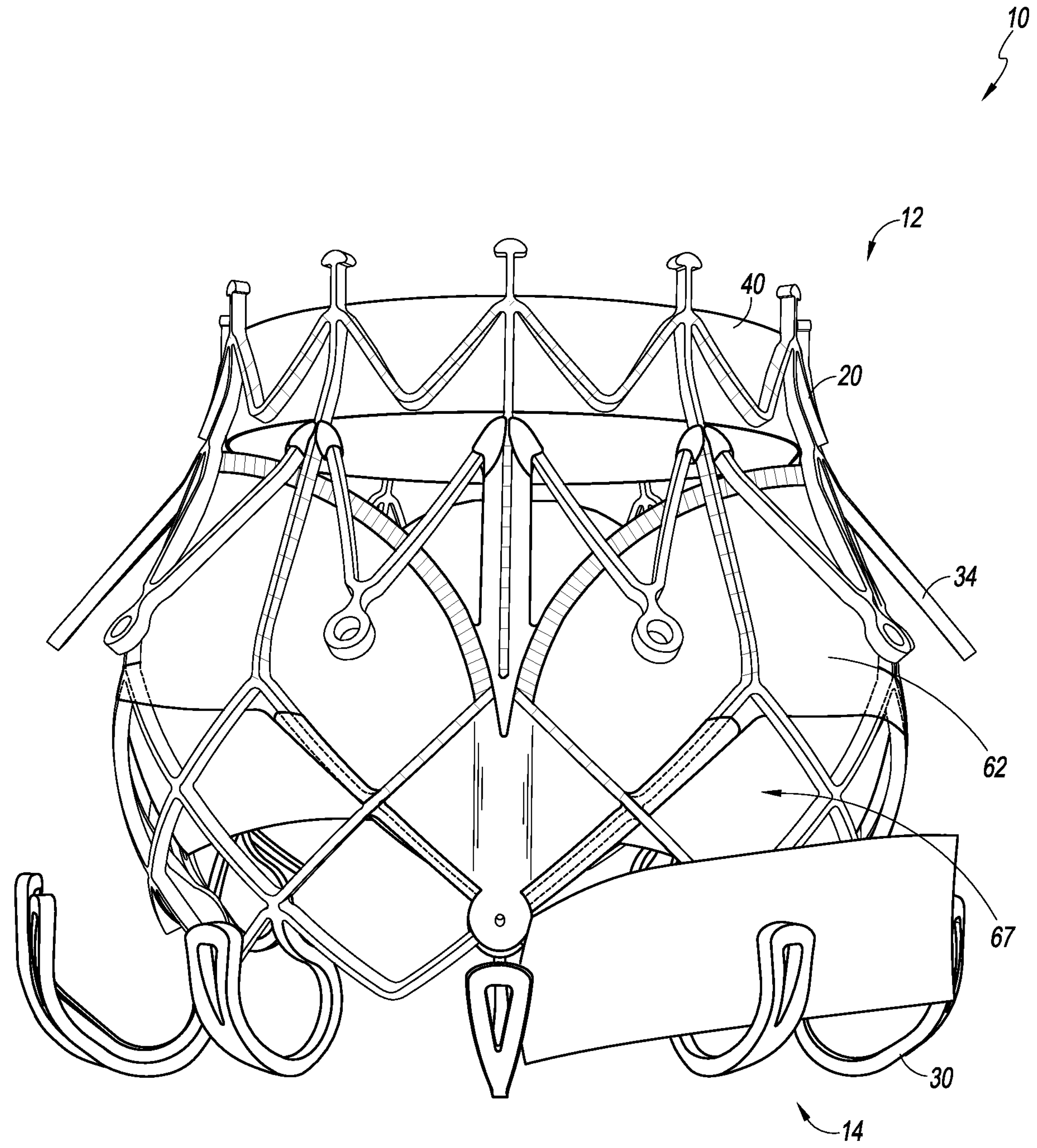


FIG. 10

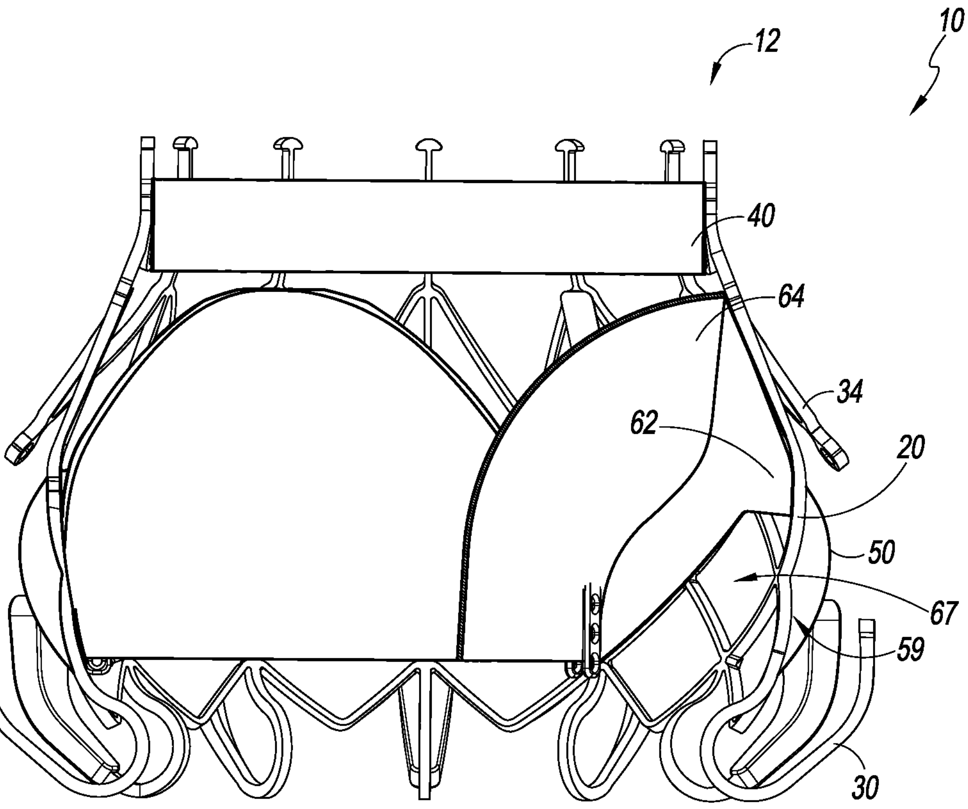


FIG. 11A

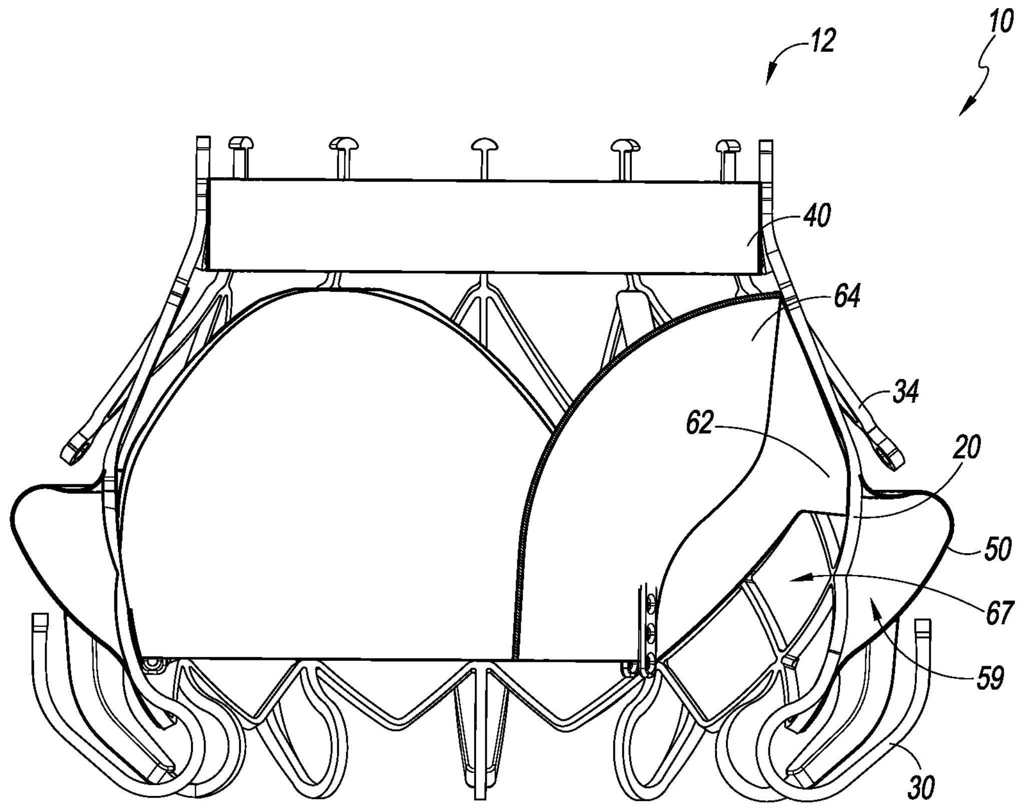


FIG. 11B

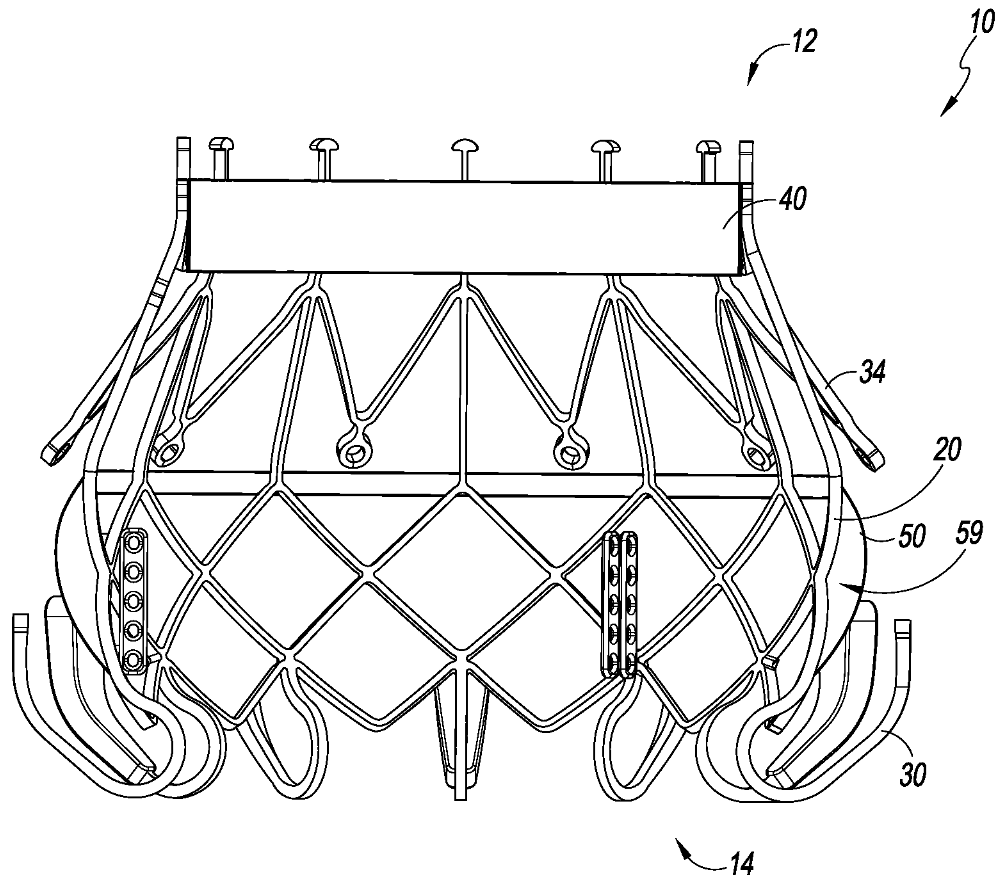


FIG. 12A

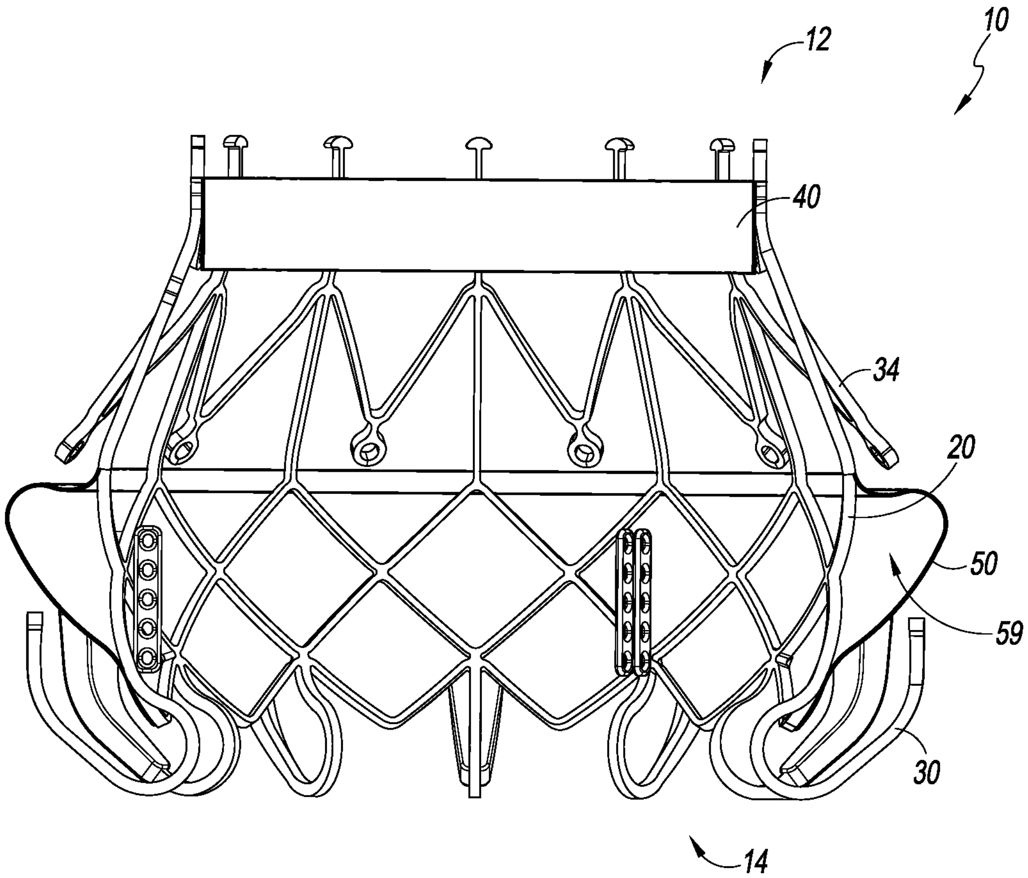


FIG. 12B

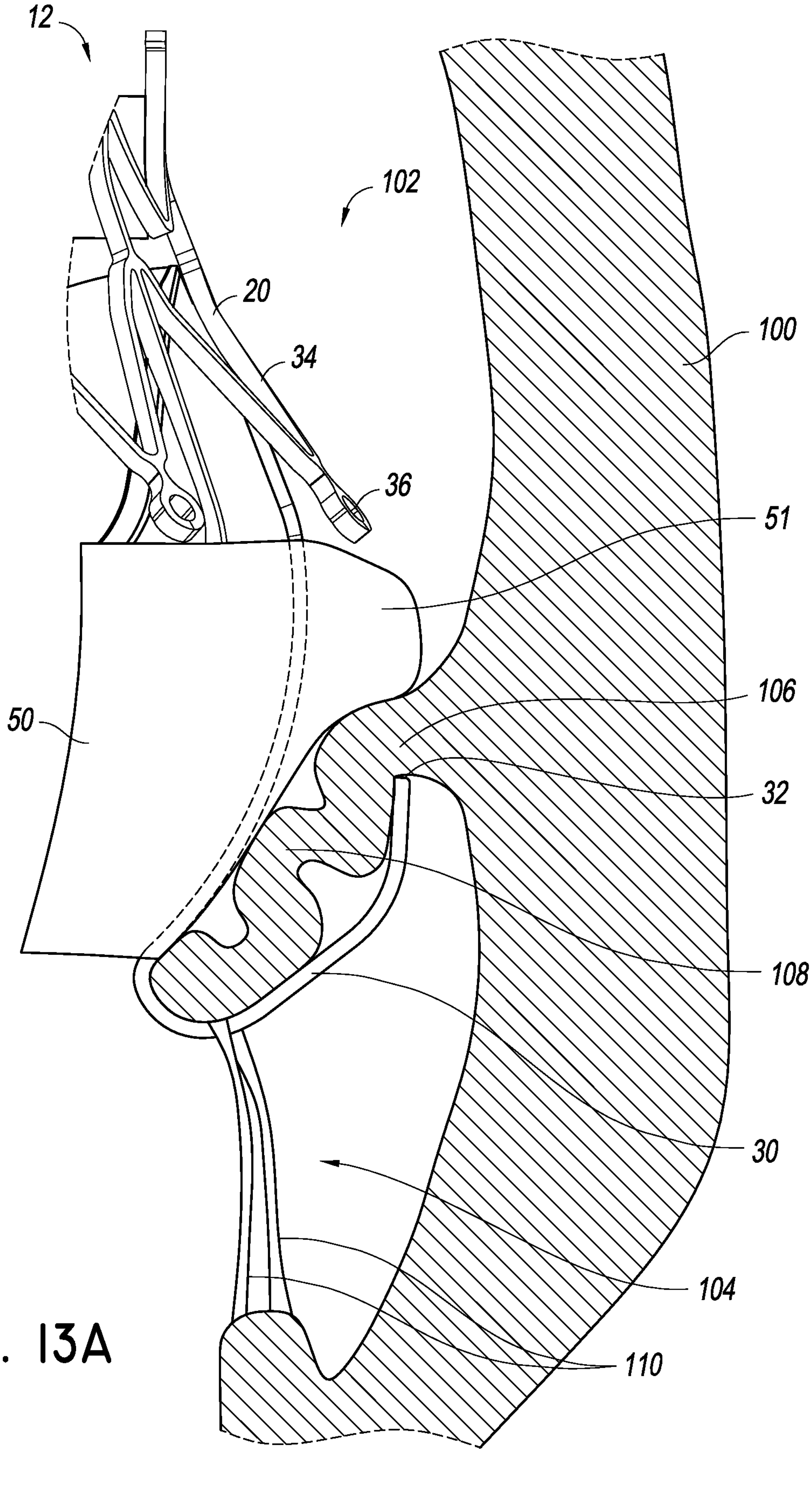


FIG. 13A

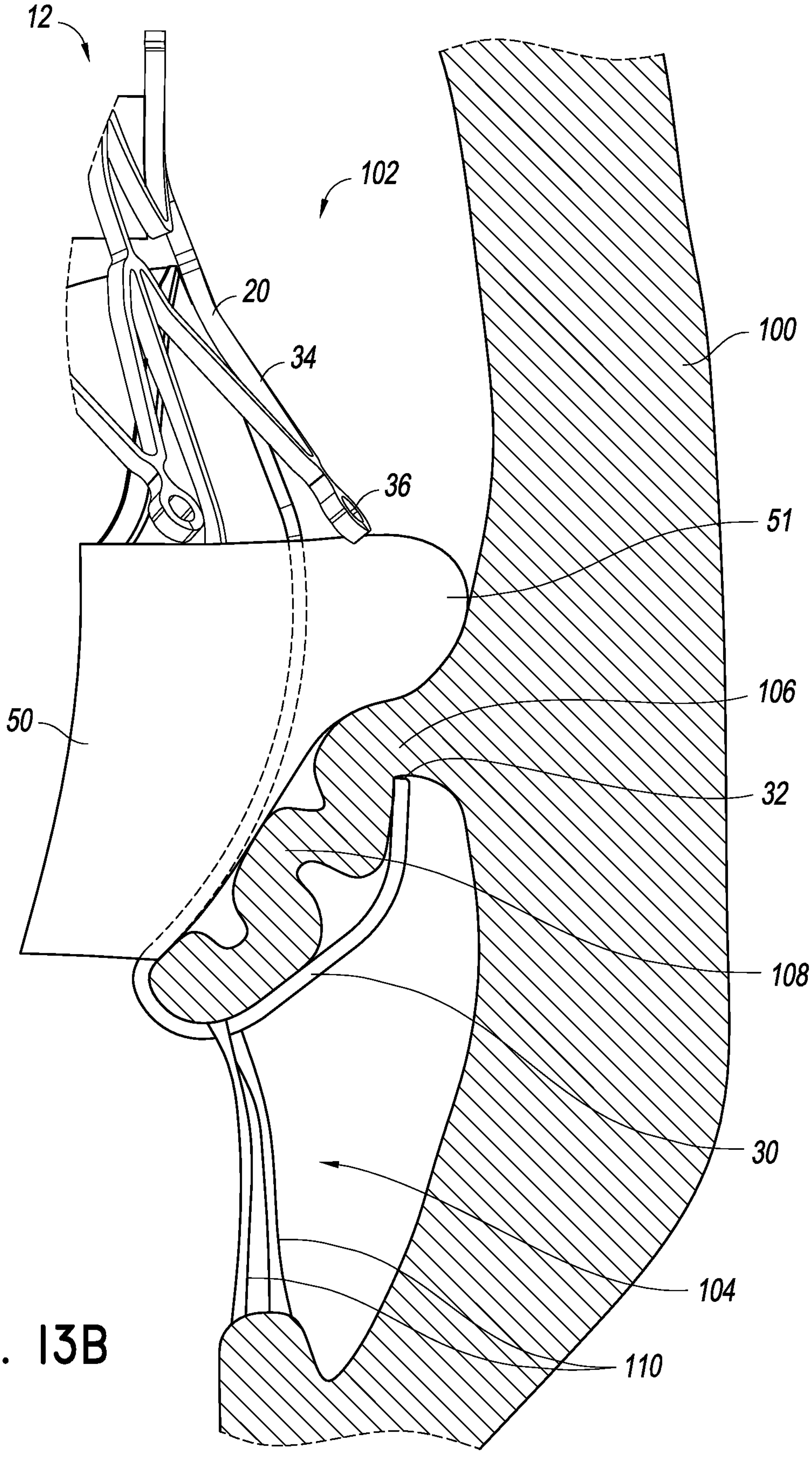


FIG. 13B

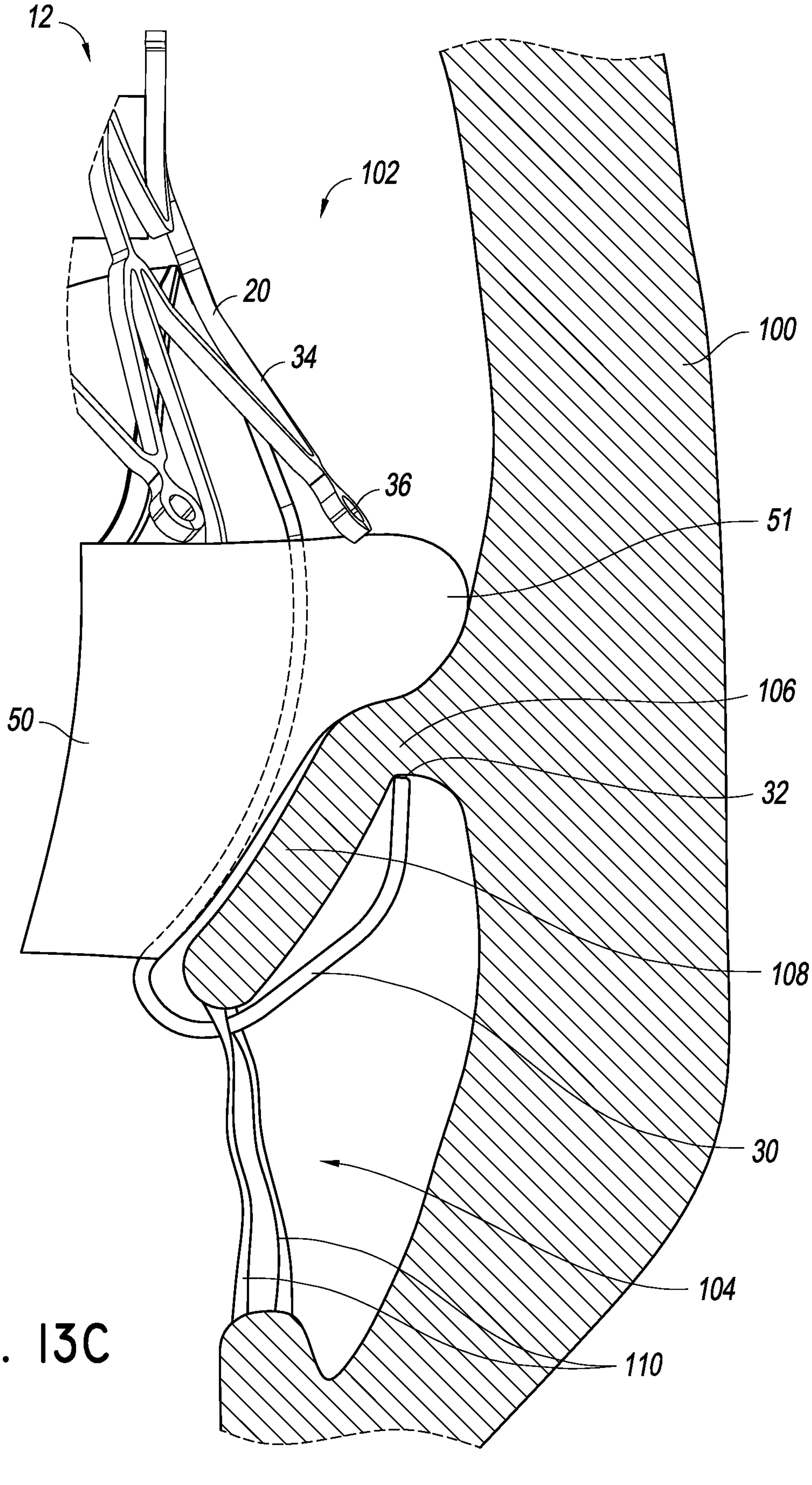


FIG. 13C

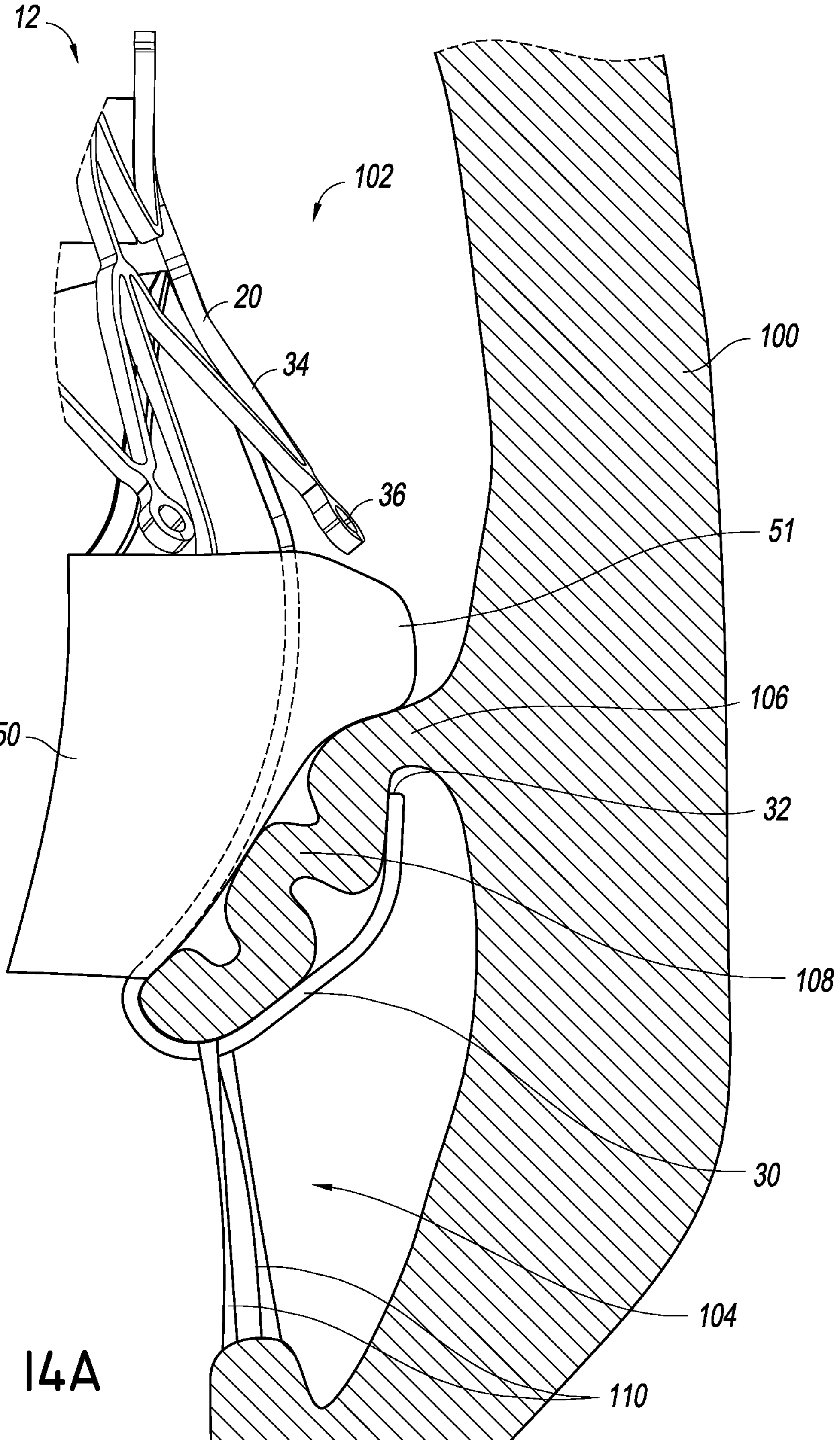


FIG. 14A

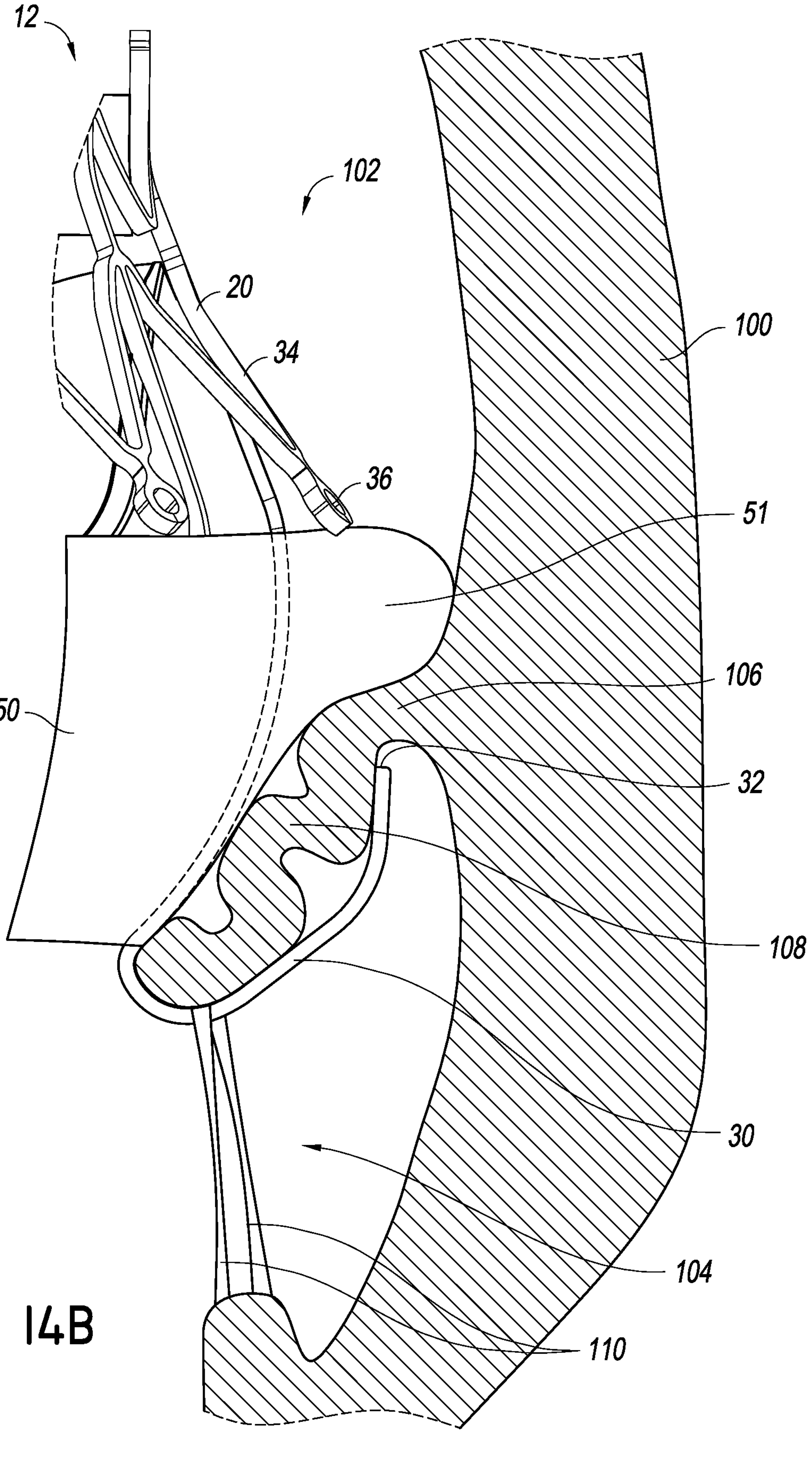


FIG. 14B

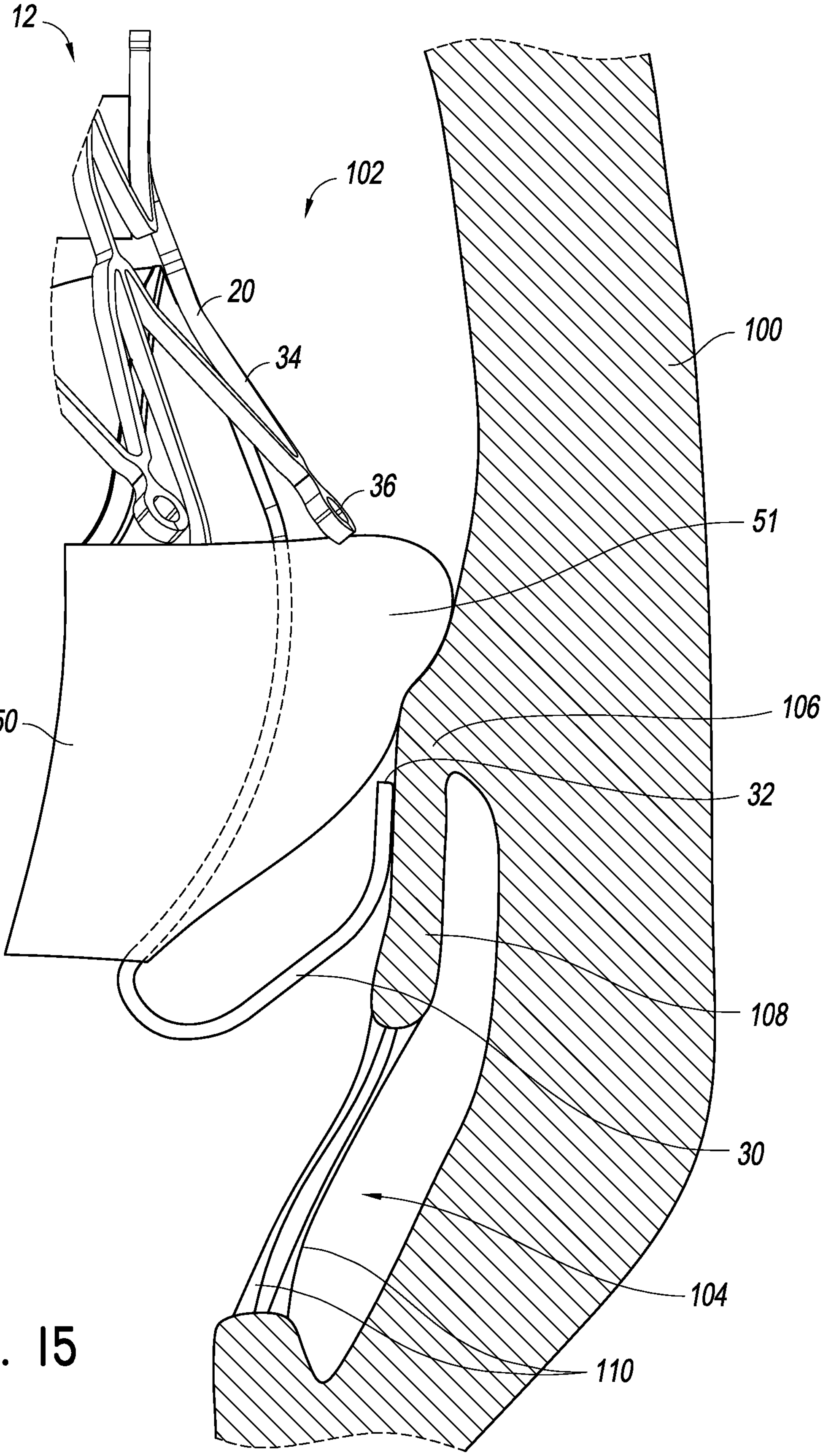
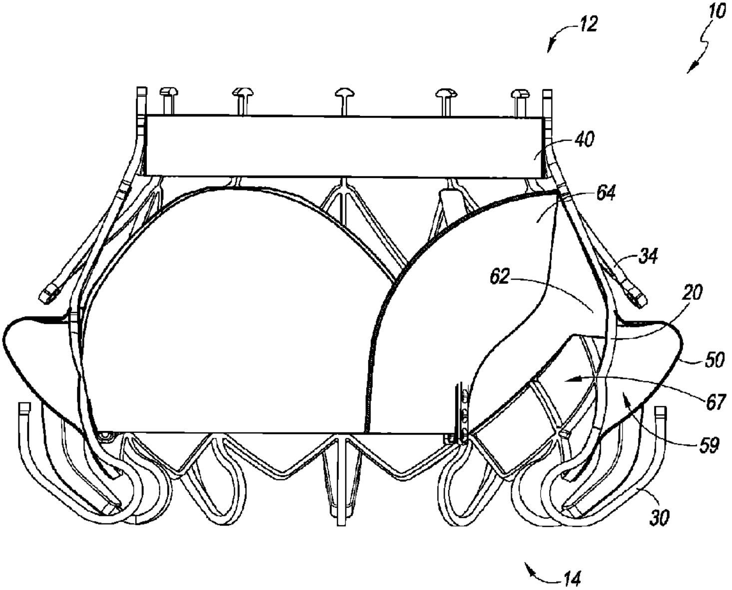


FIG. 15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