(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 November 2007 (01.11.2007)

PCT

(10) International Publication Number
WO 2007/123952 A2

(51) International Patent Classification:
A61B 17/08 (2006.01)

(21) International Application Number:
PCT/US2007/009488

(22) International Filing Date: 18 April 2007 (18.04.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/792,605 18 April 2006 (18.04.2006) US

(71) Applicant *(for all designated States except US)*: **HOSPITAL FOR SICK CHILDREN** [CA/CA]; 555 University Avenue, Suite 5286, Toronto, Ontario M5G 1X8 (CA).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CALDARONE, Christopher Anthony** [US/CA]; 96 Highland Avenue, Toronto, Ontario M4W 2A6 (CA). **VAN ARSDELL, Glen Scott** [US/CA]; 77 Gerard Street West, Apartment 2501, Toronto, Ontario M5G 2A1 (CA).

(74) Agent: **JAGTIANI, Ajay**; 10363-A Democracy Lane, Fairfax, Virginia 22030 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

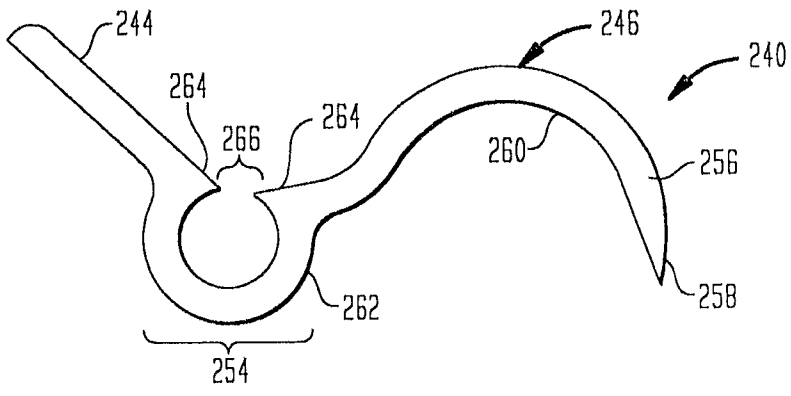
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SUTURELESS HEART VALVE



(57) Abstract: The present invention provides a sutureless heart valve (100) having plurality of prongs (140) for securing the heart valve (100) to vascular tissue (111). An insertion device (108) drives the prongs (140) into the vascular tissue (111).

WO 2007/123952 A2

SUTURELESS HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the priority of U.S. Provisional No. 60/792,605, entitled "Sutureless Heart Valve," filed April 18, 2006, the entire disclosure and contents of which is hereby incorporated by reference.

BACKGROUND

Field of the Invention

[0002] The present invention relates generally to heart valves and more particularly to systems for implanting a heart valve.

Related Art

[0003] An operational heart valve is necessary to maintaining a sufficient circulation of blood throughout the body. However, due to complications and diseases, heart valves may experience malfunctions which decrease the operational ability of the heart valve. One type of malfunction is valve stenosis, an obstruction or stiffening of the valve which increases the work on the heart to pump blood. Another type of malfunction is valve incompetence which causes valve regurgitation, *i.e.* an inefficient flow of blood allowing backflow. Both of these types of problems may be surgically repaired or may involve removing the valve and implanting a mechanical prosthetic or a bioprosthetic.

[0004] Conventionally, heart valves have been attached to the vascular tissue using sutures. Sutures require a sewing ring, commonly made of a textile material consisting of synthetic fibers, that surrounds the circumference of the heart valve. Due to the relative size of the sewing ring, the sewing ring may occupy a portion of the valve area and thereby reduce the effective orifice area which results in obstruction to operational blood flow. The use of sutures is also requires a time consuming and invasive surgical procedure that may last 30 minutes or more. While sutures are being placed, the heart is stopped and the patient is supported with the aid of a heart/lung machine. Also with sutures, it is not convenient or easy to re-position or adjust the heart valve once the sutures are made. Thus, conventional techniques of implanting a heart valve have been limited due to the need for sutures and a sewing ring to secure the heart valve.

SUMMARY

[0005] According to a first broad aspect of the present invention, there is provided an apparatus for securing a medical device to vascular tissue comprising: a ring having a plurality of rotatable prongs, each prong having at least one hook for engaging the vascular tissue; and a pusher for driving the rotation of the plurality of prongs from a relaxed state to an engaged state when the pusher is moved in an axial direction and for driving the rotation of the ring from an unlocked to locked position when the pusher is rotated about the axis of the pusher, wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state.

[0006] According to a second broad aspect of the invention, there is provided an apparatus for securing a medical device to vascular tissue comprising: a ring; and a plurality of prongs rotatably engaging the ring, each prong having at least one hook for engaging the vascular tissue, wherein the plurality of prongs include means for engaging a pusher that allow the plurality of prongs to be driven by the pusher from a relaxed state to an engaged state when the pusher is moved in an axial direction, wherein the ring includes means for engaging the pusher that allow the ring to be driven by the pusher from an unlocked to locked position when the pusher is rotated about the axis of the pusher, and wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state.

[0007] According to a third broad aspect of the invention, there is provided an apparatus for a prosthetic heart valve comprising: a ring that circumferentially surrounds one or more valves having a plurality of pivot bars; and a plurality of rotatable prongs rotatably engaging each of the plurality of pivot bars, wherein each of the plurality of rotatable prongs rotate about the plurality of pivot bars to engage vasualar tissue and wherein the ring rotates independently of the plurality of rotatable prongs and in a direction that is orthogonal to the direction of the rotation of the rotatable prongs.

[0008] According to a fourth broad aspect of the invention, there is provided an apparatus for securing a medical device to vascular tissue comprising: first means for driving the rotation of a plurality of prongs from a relaxed state to an engaged state when the first driving means is moved in an axial direction; and second means for driving the rotation of a ring from an unlocked to locked position when the second driving means is rotated about the axis of the second driving means, wherein when the ring is in a locked position, the plurality of

prongs are locked in the engaged state, and wherein each of the plurality of prongs rotatably engage the ring.

[0009] According to a fifth broad aspect of the invention, there is provided a method for securing a medical device to vascular tissue comprising the steps of: rotating a plurality of prongs from a relaxed state to an engaged state by moving a pusher an axial direction; and rotating a ring from an unlocked to locked position when the pusher is rotated about the axis of the second driving means, wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state, and wherein each of the plurality of prongs rotatably engage the ring.

[0010] According to a sixth broad aspect of the invention, there is provided a prosthetic heart valve system comprising: an annulus ring comprising: at least one valve leaflet mounted within the annual ring; a plurality openings each bisected by a pivot bar; a plurality of bumps; and a plurality of rotatable prongs, each prong having dual hooks for engaging the vascular tissue and a loop that connects the dual hooks, wherein the number of the plurality of openings is the same as the number of the plurality of bumps and plurality of rotatable prongs; and a removable insertion device comprising: a cam having a lesser shaft and greater shaft; and a pusher having a plurality of feet, wherein the pusher drives the rotation of the plurality of prongs from a relaxed state to an engaged state when the pusher is moved in an axial direction along the lesser shaft and for driving the rotation of the annulus ring from an unlocked to locked position when the pusher is rotated about the axis of the pusher on the greater shaft, wherein when the annulus ring is in a locked position, each of the plurality of prongs is snapped over each corresponding bump of the plurality of bumps to lock the plurality of prongs in the engaged state when the pusher is removed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The invention will be described in conjunction with the accompanying drawings, in which:

[0012] FIG. 1A is a cross-sectional side view of a heart valve with a cam constructed in accordance with an embodiment of the present invention;

[0013] FIG. 1B is a top view of the heart valve of FIG. 1A;

[0014] FIG. 1C is a cross-sectional side view of an implanted heart valve constructed in accordance with an embodiment of the present invention;

[0015] FIG. 1D is a top view of the heart valve with the pusher in the extended position;

[0016] FIG. 1E is a top view of the heart valve with the prongs in the relaxed state in accordance with an embodiment of the present invention;

[0017] FIG. 1F is a top view of the heart valve with the prongs in the engaged state in accordance with an embodiment of the present invention;

[0018] FIG. 1G is a partial side view of the ring of the heart valve without the prong in accordance with an embodiment of the present invention;

[0019] FIG. 2A is a side view of a prong constructed in accordance with an embodiment of the present invention;

[0020] FIG. 2B is a top view of the prong of FIG. 2A;

[0021] FIG. 2C is a bottom view of the prong of FIG. 2A;

[0022] FIG. 2D is a perspective view of the prong of FIG. 2A; and

[0023] FIG. 3A1 is a cross-sectional side view of a heart valve and insertion device where the prongs are in an relaxed state and undeployed in accordance with an embodiment of the present invention;

[0024] FIG. 3A2 is a partial top view of FIG. 3A1;

[0025] FIG. 3B1 is a cross-sectional side view of a heart valve and insertion device where the prongs are driven by pusher so as to be deployed into an engaged state in accordance with an embodiment of the present invention;

[0026] FIG. 3B2 is a partial top view of FIG. 3B1;

[0027] FIG. 3C1 is a cross-sectional side view of a heart valve and insertion device where the prongs are driven by pusher and deployed into an engaged state in accordance with an embodiment of the present invention;

[0028] FIG. 3C2 is a partial top view of FIG. 3C1;

[0029] FIG. 3D1 is a cross-sectional side view of a heart valve and insertion device where the pusher begins to drive the ring in accordance with an embodiment of the present invention;

[0030] FIG. 3D2 is a partial top view of FIG. 3D1;

[0031] FIG. 3E1 is a cross-sectional side view of a heart valve and insertion device where the pusher completes the driving of the ring in accordance with an embodiment of the present invention;

[0032] FIG. 3E2 is a partial top view of FIG. 3E1;

[0033] FIG. 3F1 is a cross-sectional side view of a heart valve and insertion device where the pusher is removed in accordance with an embodiment of the present invention; and

[0034] FIG. 3F2 is a partial top view of FIG. 3F1.

DETAILED DESCRIPTION

[0035] It is advantageous to define several terms before describing the invention. It should be appreciated that the following definitions are used throughout this application.

Definitions

[0036] Where the definition of terms departs from the commonly used meaning of the term, applicant intends to utilize the definitions provided below, unless specifically indicated.

[0037] For the purposes of the present invention, the term "engaged state" refers to the position of the prongs when at least a portion of the prongs engage the vascular tissue.

[0038] For the purposes of the present invention, the term "relaxed state" refers to the position of the prongs when not engaged with the vascular tissue.

[0039] For the purposes of the present invention, the term "unlocked position" refers to the relationship between the ring and the prongs such that the prongs are able to rotate between the relaxed and the engaged state.

[0040] For the purposes of the present invention, the term "locked position" refers to the relationship between the ring and the prongs such that the ring biases the prongs in the engaged state.

[0041] For the purposes of the present invention, the term "proximal" refers to the point nearest to the point of reference. The point of reference is a ventricle. "Distal" refers to the opposite of proximal, *i.e.*, furthest from the point of reference.

[0042] For the purposes of the present invention, the term "semi-flexible" refers to a part that may be flexed by exerting force on a portion of the part, but that returns substantially to its non-flexed shape once the force is no longer exerted on the portion of the part.

[0043] For the purposes of the present invention, the term "shape memory alloy" or "shape memory material" refers to the conventional meaning of the terms "shape memory alloy" or "shape memory material" *i.e.* an alloy or material that, after being deformed, can recover its original shape when the alloy or material is heated.

Description

[0044] The present invention is generally directed to securing a medical device without the use of sutures. An exemplary medical device that is secured using embodiments of the present invention is a sutureless prosthetic heart valve. In embodiments of the present invention, a conventional sewing ring is replaced by a rotatable ring having a plurality of rotatable prongs for engaging the vascular tissue. The rotatable prongs are rotatably mounted on the rotatable ring. The rotatable prongs are capable of securing the ring to the surrounding vascular tissues without requiring sutures. More specifically, embodiments of the present invention may engage the ring to an annulus, *i.e.* fibrous tissue surrounding the base of the heart valve. The ring is secured by using an insertion device to drive the rotation of the prongs into an engaged state and to drive the rotation of the ring to a locked position. The insertion device is moved in an axial direction to drive the rotation of the prongs and rotated about its axis to drive the rotation of the ring. Each of the prongs is rotated simultaneously using the insertion device. The rotation of the ring is orthogonal to the rotation of the prongs and independent from the rotation. Once the prongs are engaged and locked with respect to the ring, the insertion device may be removed from the patient.

[0045] In embodiments of the present invention, each prong has at least one hook for engaging the vascular tissue. A dual hook prong may be used in embodiments of the present invention, where each hook is connected by a loop at the closed end. The hooks pierce the vascular tissue and during the rotation of the prongs, the vascular tissue is pulled towards the rotatable ring thereby securing the rotatable ring in place and creating a seal between the rotatable ring and the annulus. The seal may prevent leakage of blood between the ring and annulus and may reduce the potential for thrombus formations. When the prong is rotated the insertion device applies a force to the closed end or loop to thereby drive the rotation. The prongs are retractable and may be repeatably moved between the relaxed and engaged state as necessary.

[0046] In embodiments of the present invention, the insertion device may include a pusher that is capable of moving in an axial direction and rotating about its axis. The pusher may surround a cam upon which the pusher slides. The cam and pusher may be used together during surgery and removed once the prongs are securely positioned.

[0047] Heart valves using installed using the method of the present invention may be attached in approximately one minute. This reduces the time necessary to stop the heart during surgery. Stopping the heart, while necessary, may damage the heart. Consequently, shortening the period for which the heart is stopped may decrease the potential harm to the patient during surgery.

[0048] Embodiments of the present invention relate to a fixation mechanism and methods for securing heart valves. It should be understood to those skilled in the art that the present invention may be used with any type of heart valve including such as but not limited to single leaflet disk, bileaflet disks, ball and cage, bioprosthetic, *etc.*

[0049] Embodiments of the present invention may be used in combination with prosthetic heart valves designed to replace the aortic heart valve. Such embodiments may also be used to replace other heart valves such as the mitral valve, pulmonic valve, or tricuspid valve.

[0050] In a normal heart there are several valves that regulate the flow of blood. Depleted blood travels from the superior vena cava and inferior vena cava into the right atrium. Once the right ventricle relaxes, blood in the right atrium pours through the tricuspid valve. Next the right ventricle propels blood through the pulmonary valve and into the lungs through the pulmonary arteries. Blood absorbs oxygen from the lungs and releases carbon dioxide and

returns to heart through the pulmonary veins and into the left atrium. Once the left ventricle relaxes, blood in left atrium pours through the mitral valve. The contraction of the left ventricle propels blood through the aortic valve into the aorta and out to the rest of the body.

[0051] When fitting a prosthetic heart valve using embodiments of the present invention, the natural valve cusps are cut away, after which the natural valve annulus remains behind at the location of the original valve. The natural valve annulus is a fibrous thickening on the inside of the blood vessel to which the native valve leaflets are attached. The annulus is also a suitable location for attaching a prosthetic heart valve.

[0052] Conventional heart valve replacements are attached using a circumferential sewing ring and sutures. Embodiments of the present invention eliminate the sewing ring thereby creating a larger effective orifice area as compared to valve prostheses with conventional sewing rings. In embodiments of the present invention, the ring has a smaller thickness than the width of the sewing ring of conventional devices. For conventional devices, the presence of a sewing ring diminishes the effective orifice diameter and in those devices increases the flow resistance. Embodiments of the present invention may decrease the flow resistance due to the smaller thickness of the ring which increases the valve area. For example, in small aortic roots, the small differences in effective orifice diameter have important physiologic implications and to properly fit conventional devices with a sewing ring the surgeon may have to perform a dangerous enlargement procedure. The necessity of enlargement procedures may be reduced using embodiments of the present invention.

[0053] To overcome the problems with sutures, many prior devices have also employed various "sutureless" designs. In some sutureless designs malleable hooks or pins are used to fasten the heart valve to the tissue wall. Such hooks may be made of a shape memory alloy or may assume a different shape when fasten to the heart valve. Embodiments of the present invention use semi-flexible prongs that enter the tissue while the prongs are resiliently snapped into place. Such semi-flexible prongs are advantageous over other "sutureless" designs that employ malleable hooks since the malleable hooks may loose malleability over time. In addition, some prior malleable hooks may not pierce the vascular tissue as efficiently and uniformly as a semi-flexible prong of the present invention. Also hooks made from a shape memory material are not easily removable or retractable if the surgeon needs to adjust or move the heart valve during surgery.

[0054] Another disadvantage of current "sutureless" designs is that they often use solid hooks that include barbs to limit movement to one direction, *i.e.*, only into the tissue. By avoiding the use of such barbs, embodiments of the present invention are free to move in both directions, *i.e.*, into and out of the tissue. This allows a surgeon to reset or re-position the heart valve without unnecessarily damaging the tissue. This may be done during surgery to achieve the optimal position or after the surgery to address any later complications. In addition, the heart valve may be removed with minimal impact and replaced. As may be readily understood, replacement is achieved by reversing the order of the insertion steps.

[0055] Yet another disadvantage of current "sutureless" designs is that because they often use flanges or hooks that are clamped together either using a clamp or by hand, there is not an easily accessible method or mechanism for simultaneously moving the flanges in and out of the tissue. In one embodiment, the present invention provides a means to simultaneously move the prongs in and out of the tissue. In addition, the flanges of current "sutureless" designs require mechanical or manual operations on both sides of the heart valve, which may be difficult to achieve due to the limitations of the surgical environment. Also, the flanges may not be embedded into the tissue in a uniform manner. In contrast, in one embodiment, the present invention may use a mechanism that embeds the prongs into the tissue simultaneously and in a uniform manner. Another problem with clamping hooks as is done in current "sutureless" designs is that the hooks tend to slice the tissue wall, thereby weakening the fixation. In contrast the hooks of the present invention may avoid slicing the tissue wall by pulling the tissue toward the heart valve.

[0056] Yet another disadvantage of current "sutureless" designs is that such designs use screws or helical fasteners that are driven into the tissue wall. Embodiments of the present invention are advantageous over such screws since the prongs pull tissue towards the heart valve. Also the mechanisms for screws only provide for insertion of at most two screws at one time, and thus it will take many mechanical operations to achieve any level of uniformity. For example, screws inserted at the beginning of the procedure may be inserted using a different force or pressure than screws inserted at the end of the procedure. Embodiments of the present invention are advantageous over such designs since the prongs are inserted using the same mechanical action and thus achieve uniformity.

[0057] Yet another disadvantage of current "sutureless" designs is that they have an expandable frame with anchors that are inserted into a tissue wall. In such designs the

anchors may pierce or lock into the tissue wall. Furthermore, the materials that are used in these prior designs must be flexible. Furthermore, the expandable frame may have a superstructure which extends away from the annulus and occupies a large area of the heart valve and affect the blood flow there through. This superstructure is necessary to actuate the expandable frame and to maintain the locked position. In contrast the device and method of the present invention avoid may such unnecessary components or blockages.

[0058] Turning to an embodiment of the present invention, FIGS. 1A-1G illustrate various views of a heart valve insertion system 100. Heart valve insertion system 100 includes a heart valve 104 and cam 106 and pusher 108 within a ring 110 of the heart valve 104. As shown in FIGS. 1A and 1B, heart valve 104 is between vascular tissue walls 111 and ring 110 contacts annulus 113. Note that ring 110 may also contact vascular tissue walls 111. Heart valve 104 has leaflets 114 for regulating the flow of blood. Cam 110 has a base portion 116, lesser shaft 118, greater shaft 120 and handle (not shown). Between lesser shaft 118 and greater shaft 120 is a sloping shaft 122. Pusher 108 has several feet 124, ankles 126 and aprons 128 along a cylinder 130. Cylinder 130 connects each foot 124 at the end towards the handle. Feet 124 and apron 128 form a cavity 132. The upper surface 134 of ankle 126 has an angle that approximates the angle of sloping shaft 122. Each foot 124 has a toe face 136. Along distal end of ring 110 there are several bumps 138 and a corresponding number of prongs 140. Each prong 140 rotatably engages with a pivot bar 142 such that in the relaxed state loop 144 of prong 140 is in cavity 132 and hooks 146 of prong 140 are above apron 128.

[0059] In FIG. 1G shows a wall of ring 110 with the prong removed to illustrate a closed slot 148 and an exposed slot 150. Closed slot 148 is under pivot bar 142 extends under bump 138. In addition, exposed slot 150 may have a prong opening 152 near the distal end of ring 110 and exposed slot 150 has an L-shaped portion that extends under bump 138 as shown in FIG. 1G. This allows a prong rotatably engaged with pivot bar 142 to independently slide along pivot bar 142 during the rotation of ring 110, thus allowing ring 110 to rotate without changing the position of the prongs. During the rotation of ring 110, foot 124 engages wall 153 to allow pusher 108 to drive the rotation.

[0060] In FIG. 1D when pusher 108 is slidably mounted on cam 106 and slides upwardly away from base 116 such that ankles 126 contact sloping slot 122. As pusher 108 is moved onto greater shaft 120, pusher 108 expands. Each foot 124 of pusher 108 substantially fits with exposed slot 150 so pusher 108 may engage and drive the rotation ring 110. Ring 110

rotates such that bump 138 is positioned under loop 144. Pusher 108 is rotated less than approximately 10° about its axis. Cylinder 130 is expandable between feet 124 increase the diameter of pusher 108 when ankles 126 are rotatably mounted greater shaft 120. FIG. 1C illustrates a side view of an engaged state of prongs 140 after the removal of cam 106 and pusher 108.

[0061] FIG. 1E illustrates prongs 140 in a relaxed state without cam 106 and pusher 108. FIG. 1F illustrates prongs 140 in an engaged state without cam 106 and pusher 108. Loop 144 is shown has having an asymmetrical shape, where the large portion of loop 144 fits over bump 138.

[0062] As shown in FIGS. 1A-1F, there may be a plurality of prongs. The number of prongs may vary depending on the size of ring or the annulus of the patient. Embodiments of the present invention may use between 2 and 40 prongs.

[0063] On the pusher, each ankle, foot and apron may have substantially the same width. The width of the foot should be less than the width of the prong opening of the exposed slot on the ring. This allows the foot to be inserted into the exposed slot such that one side of the foot may contact and push against the ring, thereby driving the rotation.

[0064] In addition, the pusher may have slits in the cylinder to ease the expansion as the pusher is slid upwards on the greater shaft of the cam. The cylinder may have a collapsible frame or web frame that is able to expand as the diameter of the pusher increases as the pusher moves upwardly on cam. In some embodiments each foot of the pusher may be joined together near the handle and free at the other. When pusher is one the lesser shaft the feet may contact each other to complete a cylinder. However, a gap is created between each foot when the pusher is moved on the greater shaft of the cam. The feet move in unison when driving the rotation of the ring. Depending on the locked position of the ring, the rotation may be clockwise or counter-clockwise.

[0065] The pusher may be rotated by a surgeon who twists the handle or may be a motor that drives the rotation. An example may be a Robot-Assisted Coronary Artery Bypass system.

[0066] The ring may have a variety of widths to accommodate different sizes of annulus and patients. The thickness of the ring may be approximately 1 to 2 mm. The ring may have

a height sufficient to such that the operation of the prongs does not interfere with the valve leaflets.

[0067] Although the prongs shown in FIGS. 1C, 1D and 1F engage only the annulus, the prongs may also be engaged into in the surrounding vascular tissue.

[0068] In some embodiments the ring circumferentially surrounds the valve leaflets and the valve leaflets are directly mounted within the ring. In other embodiments the leaflets are in a separate housing that may be snapped or fitted into the ring once the ring is secured to the annulus. The ring may circumferentially surround the separate housing. Various sealing gaskets may be positioned between the separate housing and ring to further seal the valve opening. The separate housing may also be threaded for fastening to the ring. The separate housing is releasably placed within the ring.

[0069] FIGS. 2A-2D illustrates prongs 240 used in embodiments of the present invention. Prong 240 has hooks 246, pivot regions 254 and loop 244. Loop 244 is shown has having a symmetrical shape. Each hook 246 has hook arms 256, each have a tip 258. Tip 258 has a sharp point to pierce through tissue. The inner edge 260 of hook 246 is blunted. A blunted inner edge 260 allows prongs 240 to pull tissue towards the ring and prevents slicing which may weaken the attachment. In pivot region 254, there are hoops 262 and flex stoppers 264 separated by a gap 266. Pivot region 254 is flexible and can rotatably engage a pivot bar on the ring. Insertion devices act upon the loop 244 when rotating prong 240 and pushes on loop 244. During such mechanical interactions, hoops 262 flex until flex stoppers 264 touch thereby narrowing gap 266 and creating a spring tension in prong 240. Once insertion device is removed the mechanical tension on loop 244 is released and each prong 240 returns to its original shape. Loop 244 is continuous and connects both pivot regions 254 and hooks 256.

[0070] Each region of prong may have a different thickness. Hooks may have a thickness from approximately 0.1 cm towards pivot region and tampers to a point at the tip. Pivot region and loop may have a substantially uniform thickness of approximately 0.1 cm. The overall length of each prong may be approximately 1 cm.

[0071] The materials used to construct the ring and prongs of the present invention may be of any biocompatible material, such as polymers, metals, advanced ceramics, natural materials, pyrolytic carbon, composites and coatings. Material for the prongs should be a stiff material that is not formed from a shape memory material. Overall the material may be

semi-flexible to that prongs may flex at pivot region, but the hooks should be stiff to pierce and compress the tissue. Such materials make the prong semi-flexible. A fixed shape material refers to materials that do not change when inserted as compared to shape memory materials that do change shape. Also, the prongs have a substantially smooth surface and do have any barbs or similar deformations that would limit movement in direction. The smooth surface provides a prong that can freely rotate between the relaxed and engaged states. Materials for cam and pusher may be suitable plastic and metal materials for medical insertion devices.

[0072] Although FIGS. 2A-2D show dual hook prong, the prong may have additional hooks. Also, some prongs may have one hook with a half loop.

[0073] Embodiments of the present invention will now be described in operation. In general to operate the heart valve fixation system the surgeon performs two movements, a pull of the pusher in a direction away from the heart and a rotation of the pusher. These actions rotate the prongs into the vascular tissue and secure the prongs against the ring. An incision is made and the patient's previous heart valve is exposed and removed. A heart valve with a cam/pusher of the present invention is placed adjacent to the patient's annulus such that the ring of the heart valve substantially contacts the annulus. The pusher slides upward off the base of the cam in an axial direction. This action lifts the loop of each prong and in turn causes the hooks to be deployed into an engaged state, thereby piercing into the tissue. The pusher extends outward due to the ankle being pushed out by the sloping shaft and greater shaft of the cam. This causes the toe face to push on loop out past or flush with the bump, *i.e.* beyond the plane of the ring. Each foot simultaneously drives the rotation of the prongs, such that each of the prongs moves in unison. In addition, the feet of the pusher would be positioned in the corresponding exposed slots of the ring. Next the pusher rotates the ring such that each bump is placed within the loop of the prong. This may be assisted with an alignment overlay that has marks to align the ring during rotation. Once aligned the pusher is removed and the loops snap back to latch the bump on the rim. To complete the insertion the cam is removed and the incision is repaired.

[0074] Prior to completion the surgeon may inspect the attachment and re-adjust as necessary until the ring is in an acceptable position relative to the annulus or vascular tissue. Also after the surgery is completed the heart valve may be reset by using a similar pusher and cam to retract the prongs.

[0075] FIGS. 3A1 through 3F2 illustrate various actions of the operation of the pusher and prongs of the attaching the heart valve in accordance with embodiments of the present invention. Each action is shown in a side view 3x1 and corresponding top view 3x2 to highlight the movements used during insertion. It should be understood that the actions for the remaining prongs are similar since the pusher will operate in a similar manner with respect to each prong. In addition, FIGS. 3A1 through 3F2 illustrate the operation outside of the patient for convenience, but it should be understood that when implanted the prongs engage and pull tissue towards the ring.

[0076] An exemplary heart valve insertion system 300 is placed in the patient's aorta by a surgeon as shown in FIGS. 3A1 and 3A2. A heart valve insertion system 300 includes heart valve 304, and a cam 306 and pusher 308 within the ring 310 of heart valve 304. Ring 310 is an unlocked position. Prongs 340 surround pivot bar 342 of ring 310 and are shown in the relaxed position. Foot 324 of pusher 308 rests on base 316 of cam 306. Ankle 326 of pusher 308 is adjacent to lesser shaft 318 of cam 306. Cylinder 330 of pusher 308 is adjacent to greater shaft 320. Cylinder 330 may have slits (not shown) between each set of ankle 326, foot 324 and apron 328 and are oriented along the vertical axis of cylinder 330. These slits allow pusher 308 to flex outward in a radial direction as cylinder 330 is drawn upwards and ankles 326 comes into contact with sloping shaft 322. Loop 344 of prong 340 start within each corresponding cavity 332 of pusher 308 in a relax state. The placing of loop 344 in cavity 332 helps to align pusher 308 such that each foot 324 will be a position to complete the driving of each prong 340. In the relaxed state, apron 328 and foot 324 are not within the exposed slot 350 of ring 310. Heart valve 304 is in the relaxed state as shown in FIGS. 3A1 and 3A2 may be implanted in the patient adjacent to the annulus and/or vascular tissue.

[0077] To begin operation of heart valve insertion system 300, a pusher 308 is pulled upwardly by actuating a lever device (not shown) along an axial direction shown by arrow 368. The lever device may be operated by the surgeon to pull pusher 308 away from base 316 as shown by arrow 368 (see FIG. 3B1). As pusher 308 moves upwardly, cylinder 330 travels along less shaft 318 in the same direction as arrow 368. In addition, ankles 326 travel in the direction of arrow 368 until each ankle 326 contacts sloping shaft 322, as shown in FIG. 3B1. During the movement of pusher 308 from base 316 to the point where ankle 326 contacts sloping shaft 322, foot 324 pushes loop 344 in the same direction as arrow 368.

Loop 344 is deployed from its starting relax state into a deployed engaged state. Cam 306 remains stationary within ring 310 while pusher 308 is moved upwardly.

[0078] FIGS. 3B1 and 3B2 show pusher 308 being moved until the upper surface 334 of ankle 326 contacts the sloping shaft 322. Once this happens, the rotation of prong 340 nears a mid-point of the deployment. At this point prong 340 may engage vascular tissue and is in an engaged state. As pusher 308 is pulled further upward, pusher 308 travels outwardly along sloping shaft 322 as cylinder 330 expands in diameter due to the slits (not shown), as shown in Fig. 3C1. The upward motion of pusher 308 and outward motion of cylinder 330 cause feet 324 to move upwardly and outwardly, until each foot extends outwardly through a respective opening in ring 310. The upward and outward motion of each foot 324 forces loop 344 to rotate around a pivot bar 342 in the direction shown by arrow 370 so that each loop 344 rotates through slot 350 as loop 344 is deployed. As each loop 344 rotates through slot 350, a respective prong 340 rotates so that hooks 346 pierce vascular tissue (not shown in FIG. 3C1) and pull the tissue towards ring 310. Each prong 340 may flex at pivot region 354, causing gap 366 between flex stoppers 364 to narrow. Flex stoppers 364 prevent further flexing of prong 340 by contacting each other. This contact increases the stiffness of prong 340 and this may assist hooks 346 in piercing the vascular tissue as prong 340 continues to rotate in the engaged state.

[0079] After pusher 308 and prongs 340 reach the position shown in FIG. 3C1, prongs 340 are locked in an engaged state by the following steps. First, each foot 324 is forced out in the direction shown by arrow 372 when pusher 308 slides up against greater shaft 320, such that foot 324 contacts wall 353 of ring 310. Pusher 308 is rotated about its axis in the direction shown by arrow 373. As pusher 308 rotates, each foot 324 presses against a wall 353 of a respective slot 350 of ring 310, causing ring 310 to rotated from an unlocked to locked position in the direction of arrow 373. When ring 310 is rotated, prongs 340 remain secured in the tissue as a respective pivot bar 342 slides through hoop 362 until ring 310 and prongs 340 reach the position shown in FIGS. 3E1 and 3E2. This allows ring 310 to independently move without moving prongs 340 to prevent any tearing of the tissue by hooks 346.

[0080] To assist in rotating ring 310, a transparent alignment overlay 374 is used as shown in FIGS. 3D1 and 3D2. Overlay 374 assists the surgeon to guide loop 344 over bump 338. On alignment overlay 374 there is a line 376 that aligns with marking 378 on ring 310. In

addition, alignment overlay 374 may have an opening 380 which has the approximate width as apron 328. A surgeon can visually identify when line 376 aligns with marking 378 and thereby cease the rotation. Further, the surgeon can also identify an alignment when apron 328 aligns with opening 380 as shown in FIGS. 3E1 and 3E2.

[0081] During the rotation, toe face 336 maintains a force on loop 344, even though prong 340 remains stationary relative to ring 310. The force on loop 344 maintains the spring tension of prong 340 since flex stoppers 364 remain in closer contact with each other and narrows gap 366. To release the spring tension, pusher 308 is pulled further up by the surgeon. Once toe face 336 no longer contacts loop 344 the some of spring tension in prong 340 releases and loop 344 is forced against ring 310 as shown in FIGS. 3F1 and 3F2. The remaining spring tension in prong 340 keeps the pressure on ring 310 such that prong 340 does not rotate off bump 338. Each loop 344 snaps over the corresponding bump 338 on ring 310 to reduce lateral movement of prongs. To complete the operation, a surgeon removes cam 306 and repairs the incision.

[0082] The mechanical interaction of the heart valve insertion system near the annulus is shown in FIGS. 3A1-3F2. Additional mechanical operations of the cam and pusher near the handle may also be used to further assist the surgeon in performing the operation.

[0083] All documents, patents, journal articles and other materials cited in the present application are hereby incorporated by reference.

[0084] Although the present invention has been fully described in conjunction with several embodiments thereof with reference to the accompanying drawings, it is to be understood that various changes and modifications may be apparent to those skilled in the art. Such changes and modifications are to be understood as included within the scope of the present invention as defined by the appended claims, unless they depart therefrom.

WHAT IS CLAIMED IS:

1. An apparatus for securing a medical device to vascular tissue comprising:

a ring having a plurality of rotatable prongs, each prong having at least one hook for engaging the vascular tissue; and

a pusher for driving the rotation of the plurality of prongs from a relaxed state to an engaged state when the pusher is moved in an axial direction and for driving the rotation of the ring from an unlocked to locked position when the pusher is rotated about the axis of the pusher, wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state.

2. An apparatus for securing a medical device to vascular tissue comprising:

a ring; and

a plurality of prongs rotatably engaging the ring, each prong having at least one hook for engaging the vascular tissue, wherein the plurality of prongs include means for engaging a pusher that allow the plurality of prongs to be driven by the pusher from a relaxed state to an engaged state when the pusher is moved in an axial direction, wherein the ring includes means for engaging the pusher that allow the ring to be driven by the pusher from an unlocked to locked position when the pusher is rotated about the axis of the pusher, and wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state.

3. The apparatus according to any one of claims 1 or 2, wherein the pusher is slidably mounted on a cam.

4. The apparatus according to claim 3, wherein the cam comprises a base plate, a first shaft and a second shaft, wherein the first shaft is smaller than the second shaft and wherein there is a sloping shaft that transitions from the first shaft to the second shaft.

5. The apparatus according to any one of claims 1 or 2, wherein the pusher further comprises a plurality of feet that are connected together at one end.

6. The apparatus according to claim 5, wherein each of the plurality of feet correspond to one of the plurality of rotatable prongs.

7. The apparatus according to claim 5, wherein each of the plurality of feet are at least partially inserted in the engaging means of the ring when the pusher drives the rotation of the ring.

8. The apparatus according to any one of claims 1 or 2, wherein the pusher is rotated less than approximately 10° about the axis of the pusher.

9. The apparatus according to any one of claims 1 or 2, wherein the pusher simultaneously drives the rotation of each of the plurality of rotatable prongs.

10. The apparatus according to any one of claims 1 or 2, wherein the ring circumferentially surrounds one or more valves.

11. The apparatus according to any one of claims 1 or 2, wherein the ring comprises a plurality of pivot bars for rotatably engaging each of the plurality of rotatable prongs.

12. An apparatus for a prosthetic heart valve comprising:

a ring that circumferentially surrounds one or more valves having a plurality of pivot bars; and

a plurality of rotatable prongs rotatably engaging each of the plurality of pivot bars, wherein each of the plurality of rotatable prongs rotate about the plurality of pivot bars to engage vasualar tissue and wherein the ring rotates independently of the plurality of rotatable prongs and in a direction that is orthogonal to the direction of the rotation of the rotatable prongs.

13. The apparatus according to any one of claims 10 or 12, wherein the one or more valves are mounted within the ring.

14. The apparatus according to any one of claims 10 or 12, wherein the one or more valves are mounted within a housing that is releasably placed within the ring.

15. The apparatus according to any one of claims 1, 2 or 12, wherein each of the plurality of prongs further comprises a loop on an end opposite to the at least one hook.

16. The apparatus according to claim 15, wherein the ring further comprises a bump for engaging the loops of each of the plurality of prongs.

17. The apparatus according to any one of claims 1, 2, or 12, wherein each of the plurality of prongs has a substantially smooth surface.

18. The apparatus according to any one of claims 1, 2, or 12, wherein the plurality of prongs have a fixed shape that is capable of flexing.

19. An apparatus for securing a medical device to vascular tissue comprising:

first means for driving the rotation of a plurality of prongs from a relaxed state to an engaged state when the first driving means is moved in an axial direction; and

second means for driving the rotation of a ring from an unlocked to locked position when the second driving means is rotated about the axis of the second driving means, wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state, and wherein each of the plurality of prongs rotatably engage the ring.

20. The apparatus according to claim 19, wherein the first driving means is slidably mounted on a first shaft of a cam.

21. The apparatus according to claim 19, wherein the second driving means is rotatably mounted on a second shaft of a cam.

22. The apparatus according to claim 19, wherein the first driving means drives each of the plurality of prongs in unison.

23. The apparatus according to claim 19, wherein when the ring is rotated to the locked position, the second driving means does not move the plurality of prongs.

24. The apparatus according to claim 19, wherein the first driving means and second driving means are the same apparatus and wherein the first driving means is expanded into the second driving means.

25. A method for securing a medical device to vascular tissue comprising the steps of:

rotating a plurality of prongs from a relaxed state to an engaged state by moving a pusher an axial direction; and

rotating a ring from an unlocked to locked position when the pusher is rotated about the axis of the pusher, wherein when the ring is in a locked position, the plurality of prongs are locked in the engaged state, and wherein each of the plurality of prongs rotatably engage the ring.

26. The method of claim 25, further comprising the step of:

inserting a ring having a plurality of prongs into an aorta valve after removing the patient's valves.

27. The method of claim 25, further comprising the step of:

removing the pusher once the ring is in the locked position.

28. The method of claim 25, wherein the pusher rotates the plurality of prongs in unison.

29. The method of claim 25, further comprising the steps of:

rotating the ring from the locked position to the unlocked position using the pusher;

rotating the plurality of prongs from the engaged state to the relax state using the pusher; and

adjusting the position of the ring.

30. The method of claim 25, further comprising the steps of:

rotating the ring from the locked position to the unlocked position using the pusher;

rotating the plurality of prongs from the engaged state to the relax state using the pusher; and

removing the ring.

31. A prosthetic heart valve system comprising:

an annulus ring comprising:

at least one valve leaflet mounted within the annual ring;

a plurality openings each bisected by a pivot bar;

a plurality of bumps; and

a plurality of rotatable prongs, each prong having dual hooks for engaging the vascular tissue and a loop that connects the dual hooks, wherein the number of the plurality of openings is the same as the number of the plurality of bumps and plurality of rotatable prongs; and

a removable insertion device comprising:

a cam having a lesser shaft and greater shaft; and

a pusher having a plurality of feet, wherein the pusher drives the rotation of the plurality of prongs from a relaxed state to an engaged state when the pusher is moved in an axial direction along the lesser shaft and for driving the rotation of the annulus ring from an unlocked to locked position when the pusher is rotated about the axis of the pusher on the greater shaft, wherein when the annulus ring is in a locked position, each of the plurality of prongs is snapped over each corresponding bump of the plurality of bumps to lock the plurality of prongs in the engaged state when the pusher is removed.

FIG. 1A

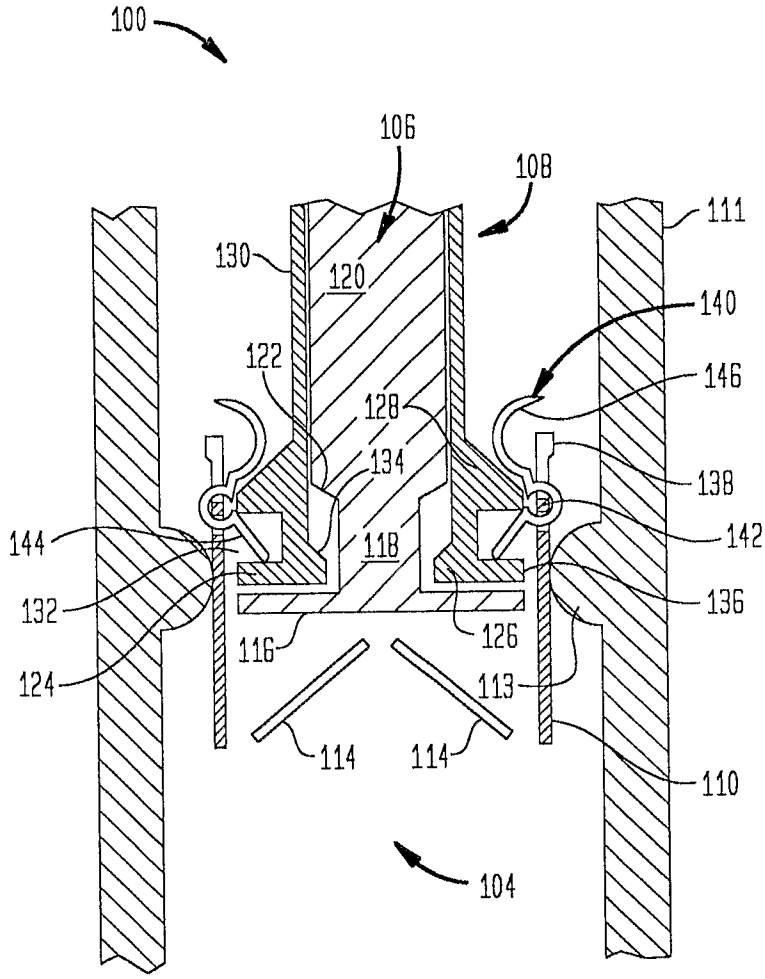

100
106
108
111
130
120
140
122
146
128
134
138
144
118
142
132
136
116
126
124
113
114
114
110
104

FIG. 1B

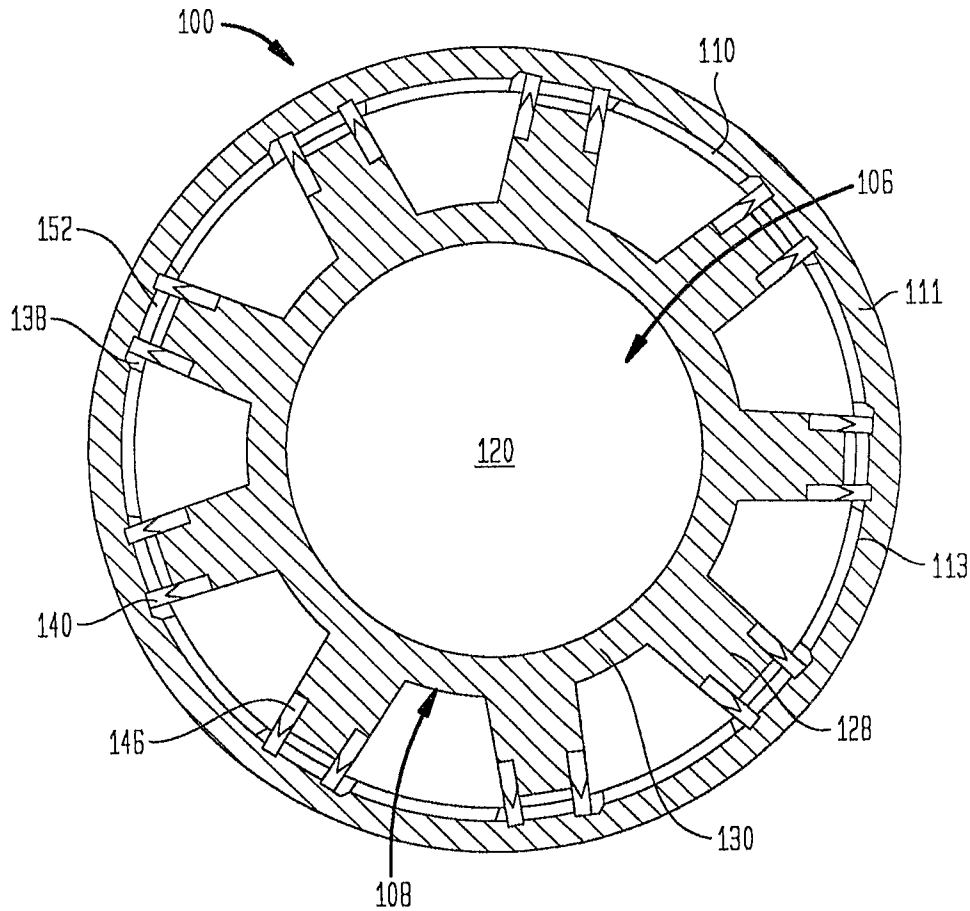


FIG. 1C

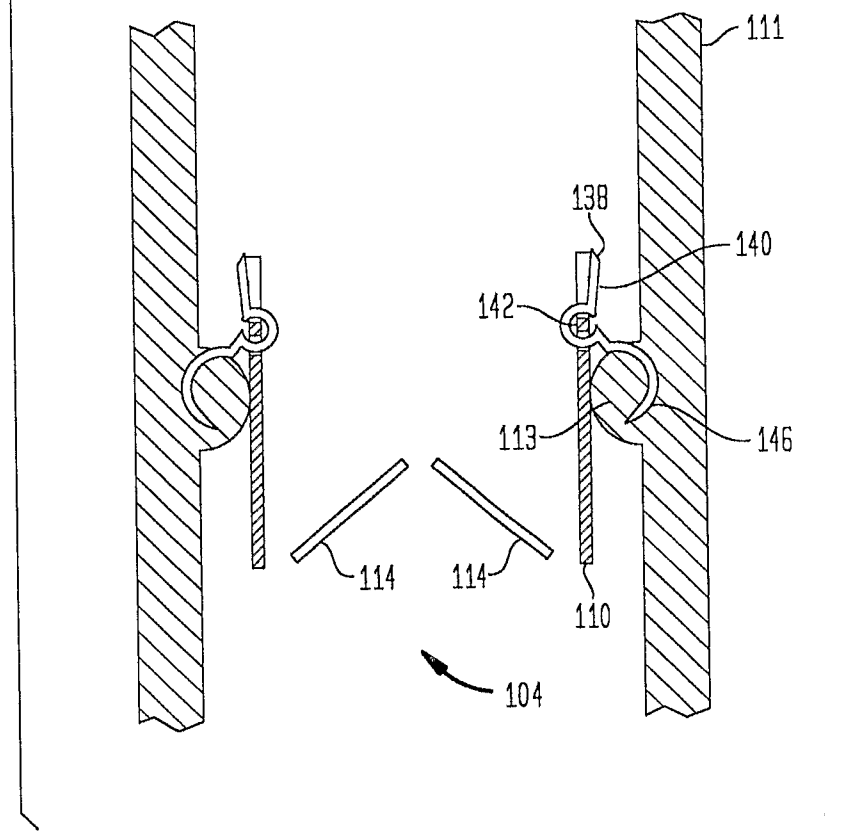


FIG. 1D

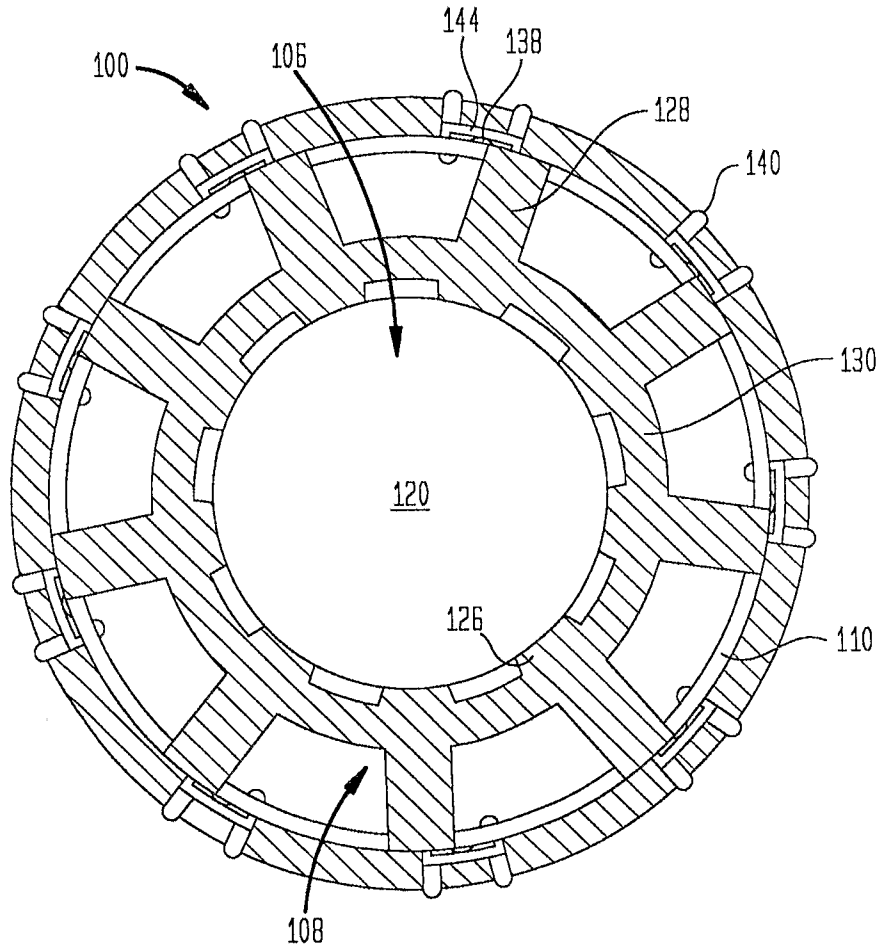


FIG. 1E

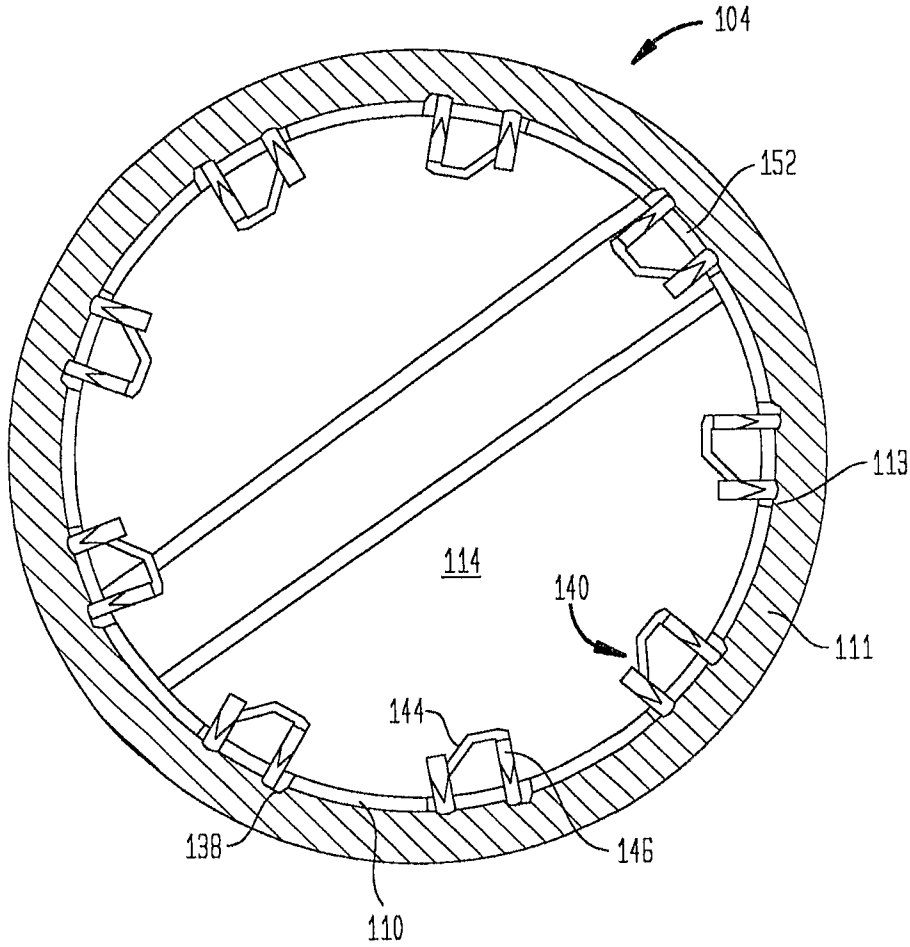


FIG. 1F

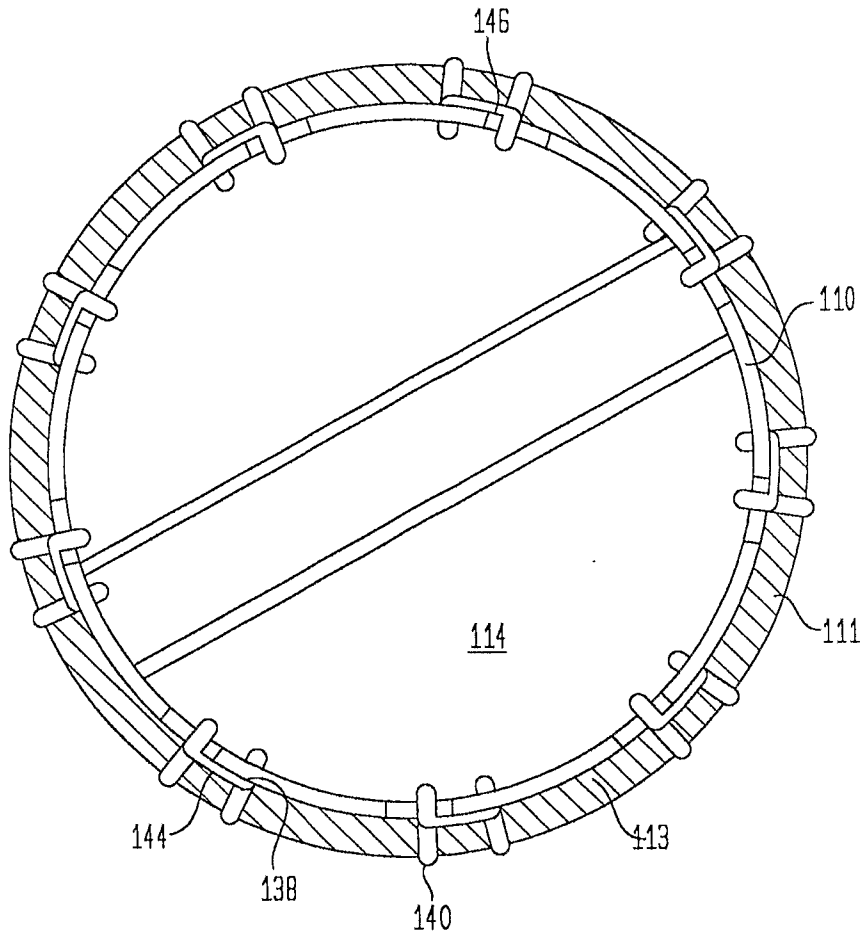


FIG. 1G

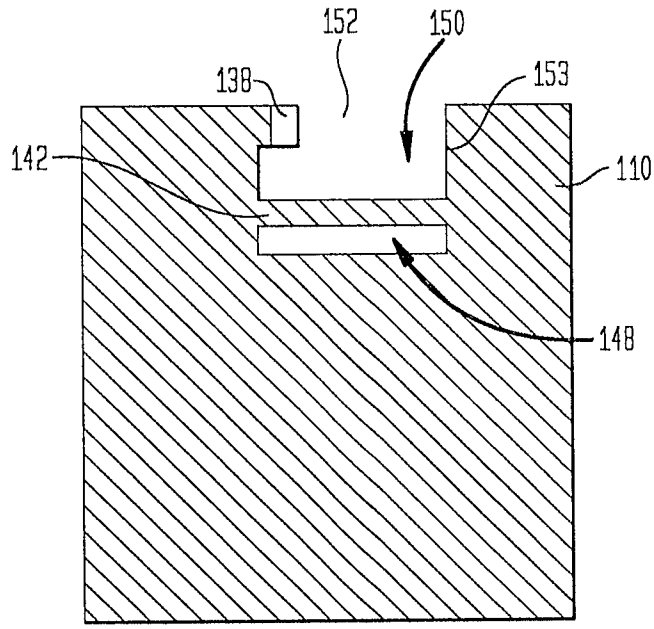


FIG. 2A

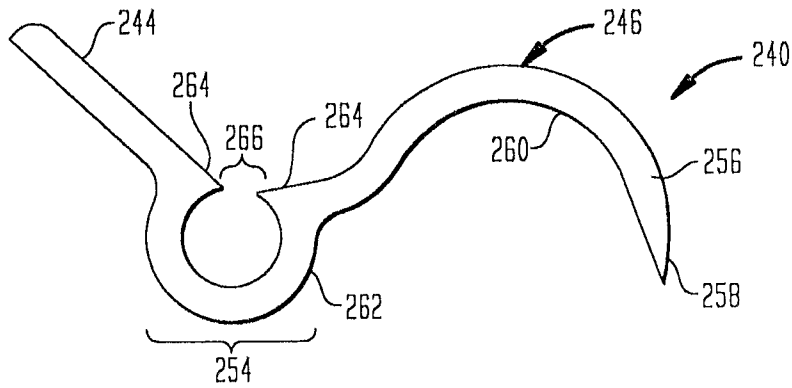


FIG. 2B

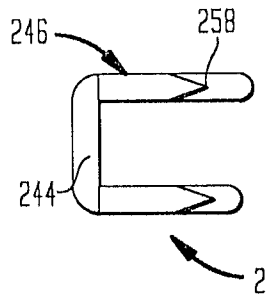


FIG. 2C

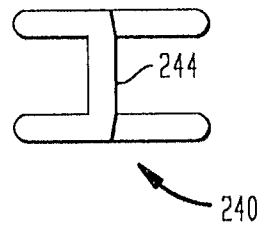


FIG. 2D

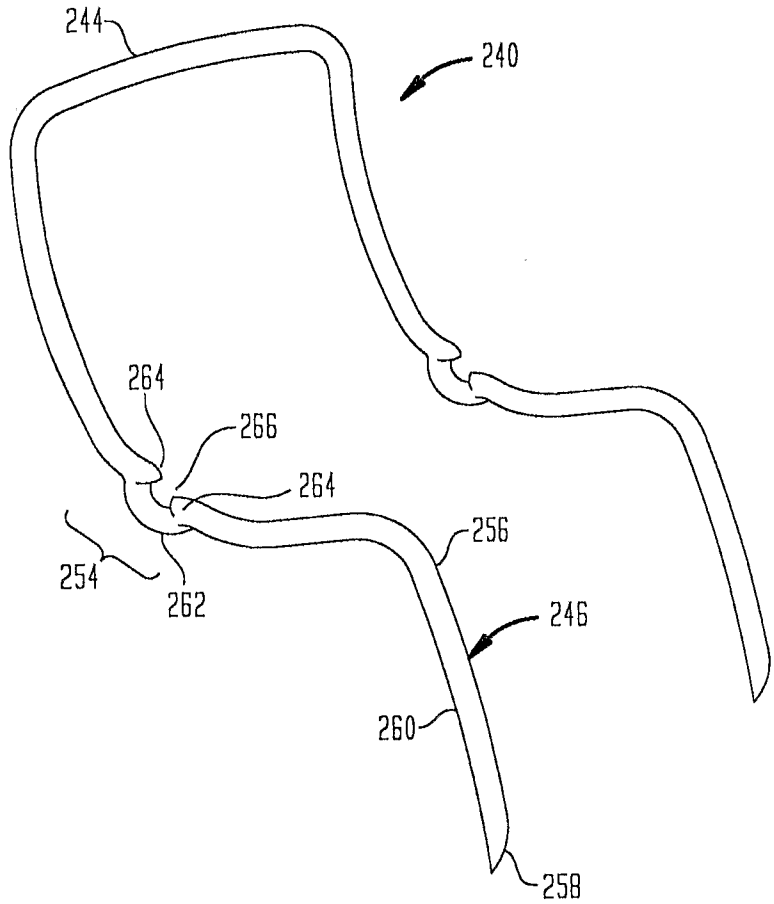


FIG. 3A1

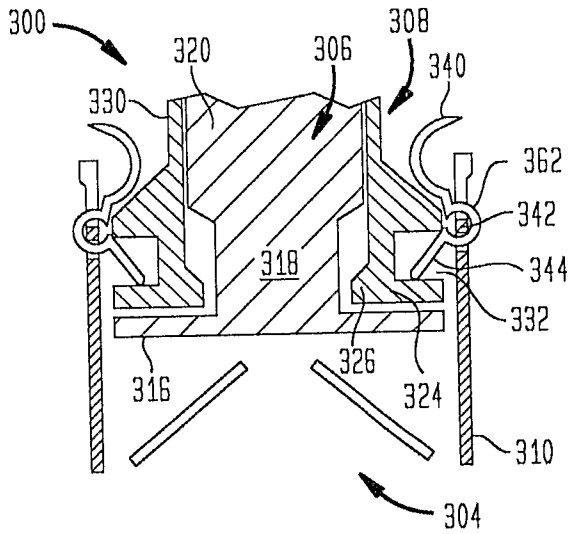


FIG. 3A2

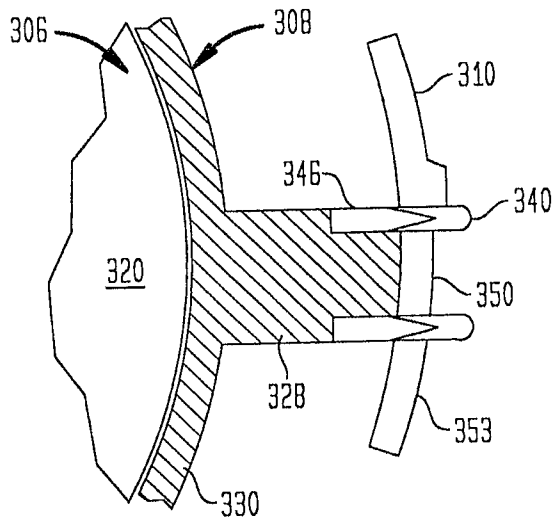


FIG. 3B1

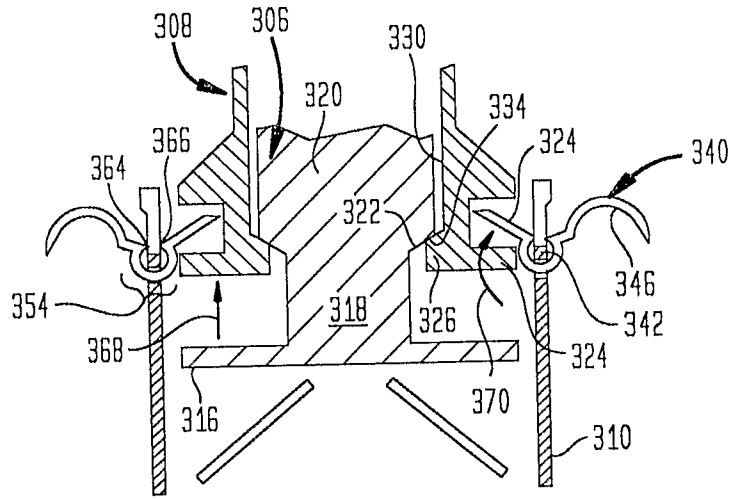


FIG. 3B2

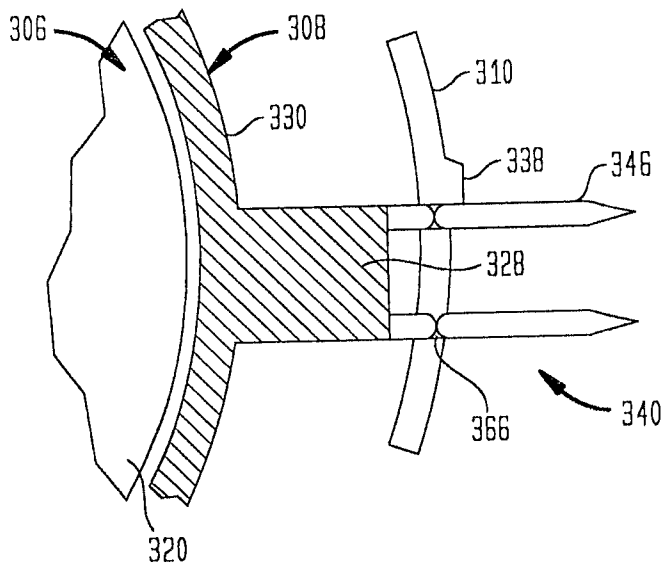


FIG. 3C1

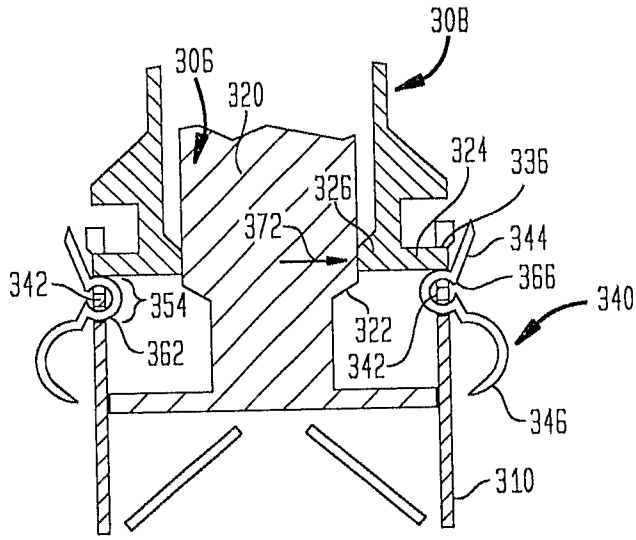


FIG. 3C2

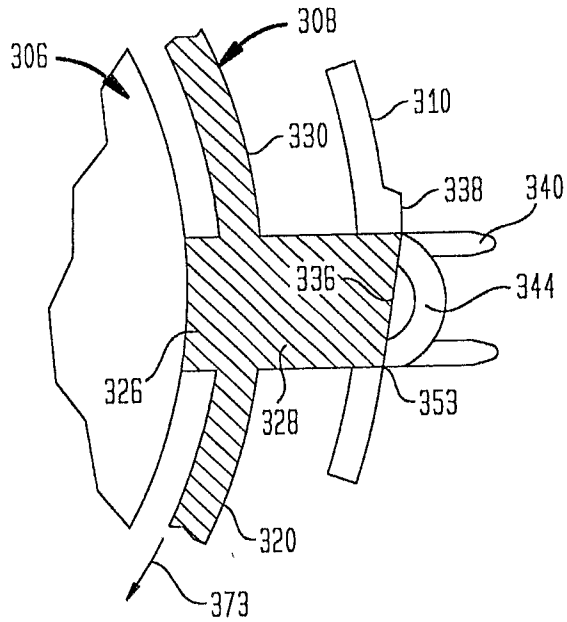


FIG. 3D1

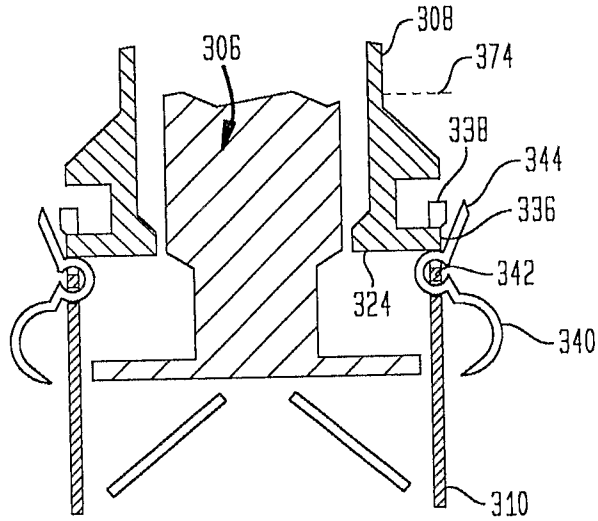


FIG. 3D2

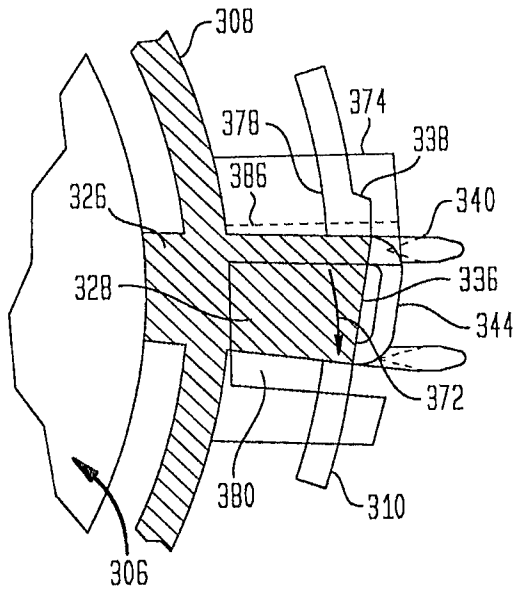


FIG. 3E1

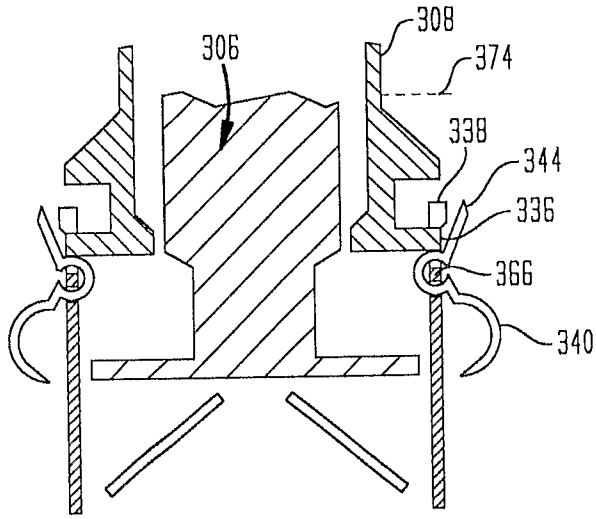


FIG. 3E2

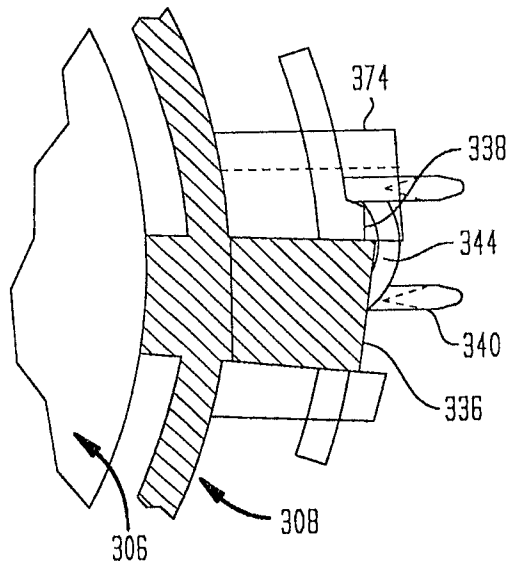


FIG. 3F1

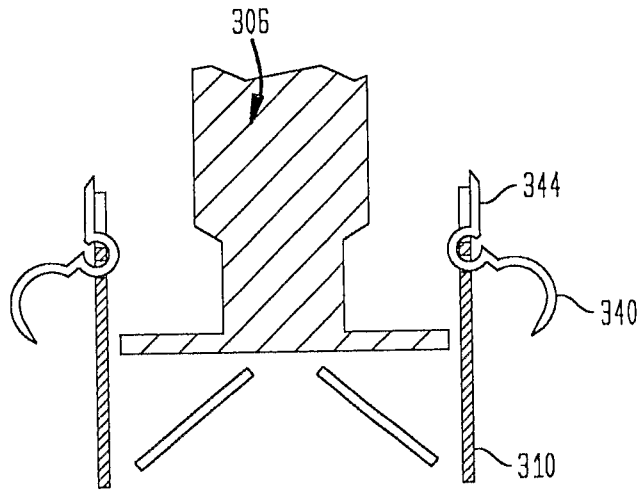


FIG. 3F2