US 20180098777A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2018/0098777 A1

GABBAY (43) Pub. Date: Apr. 12, 2018

(54) **DEVICES AND METHODS FOR IMPROVING TRANSCATHETER AORTIC VALVE IMPLANTATION**

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(21) Appl. No.: **15/290,803**

(22) Filed: **Oct. 11, 2016**

Publication Classification

(51) **Int. Cl.**

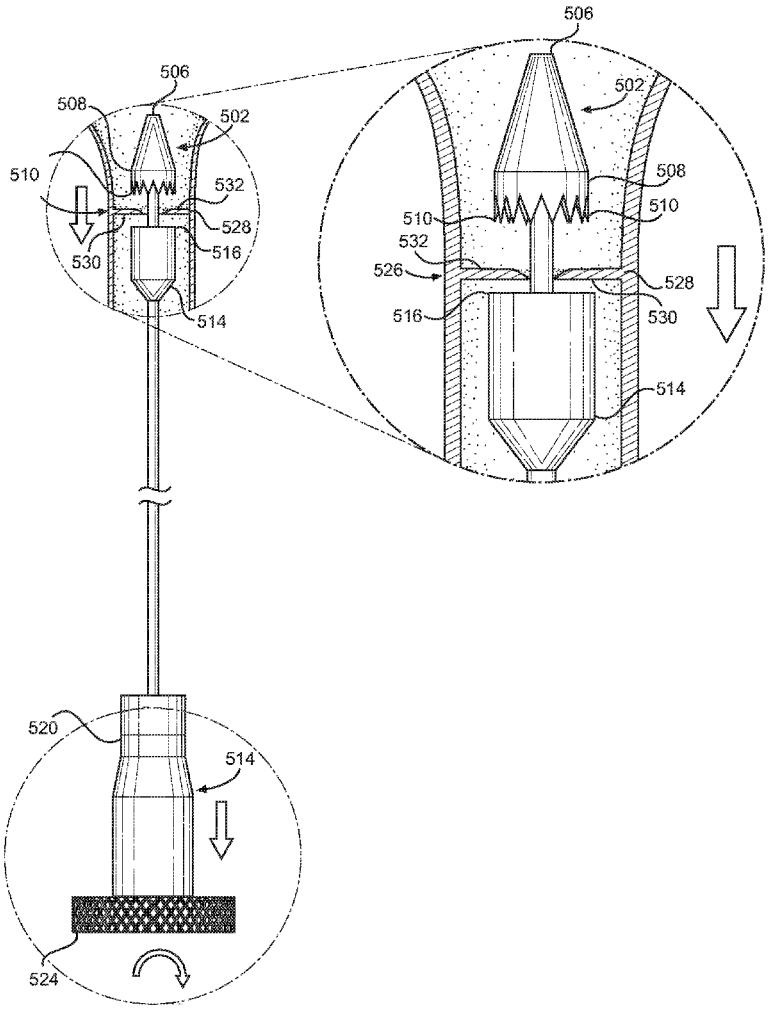
A61B 17/22	(2006.01)
A61F 2/01	(2006.01)
A61F 2/24	(2006.01)
A61B 17/221	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/22*** (2013.01); ***A61F 2/013*** (2013.01); ***A61F 2/2433*** (2013.01); *A61B 2017/00398* (2013.01); *A61F 2002/016* (2013.01); *A61B 2017/22098* (2013.01); *A61B 2017/22051* (2013.01); ***A61B 17/221*** (2013.01)

(57) **ABSTRACT**

A method and device for perforating an aortic valve to remove excessive calcium deposits on aortic valve leaflets improves the implantation of TAVI replacement valves in patients. By removing excessive calcium deposits, the radial pressure exerted by implanted TAVI replacement valves is reduced, such that there is less blood leakage around the valve and less stress on the cardiac conductive system. A device with a fusiform punch is inserted into the aortic valve. The punch is separable such that the aortic valve leaflets are positioned between at least two elements of the punch. The two elements then compress together with the leaflets between them, causing the aortic valve to be perforated. A circumferential ring of the remaining aortic valve and calcium deposits are left to provide stability for the TAVI replacement valve.



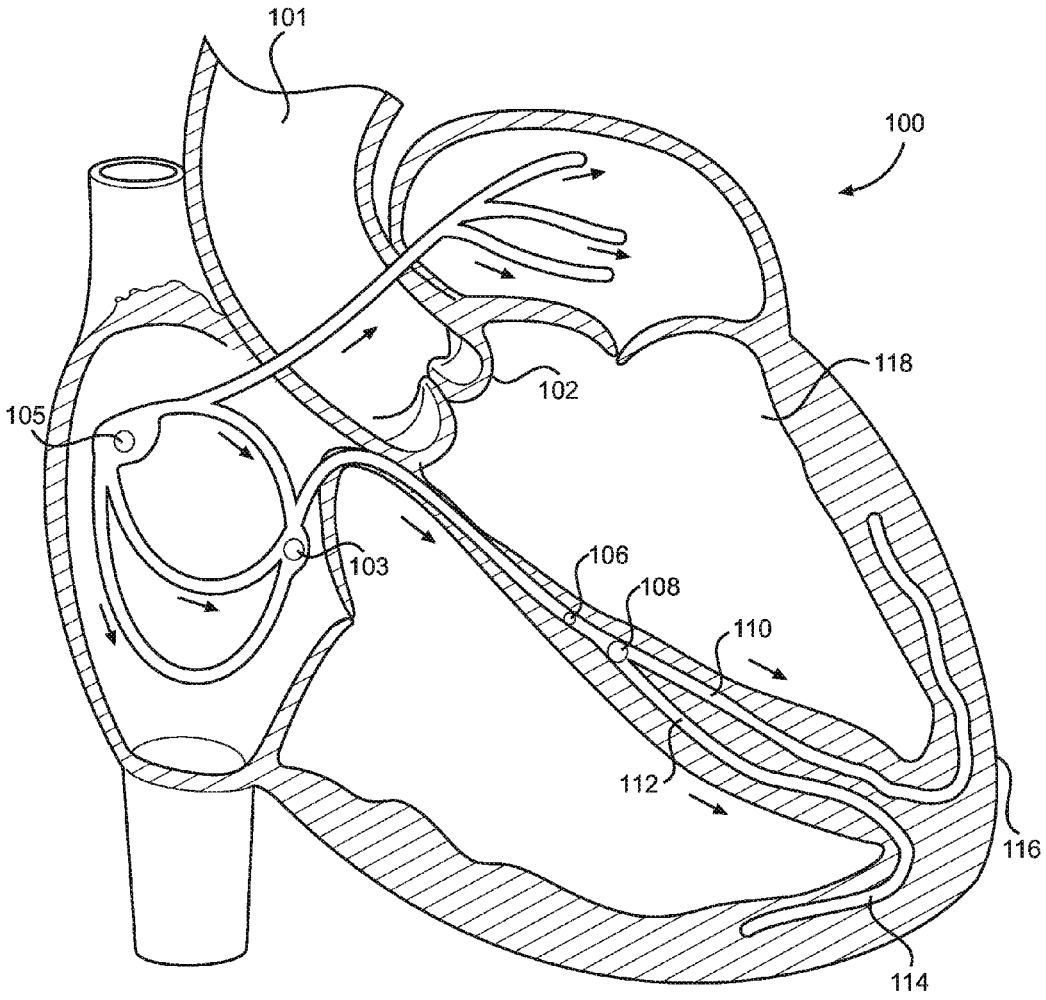


FIG. 1

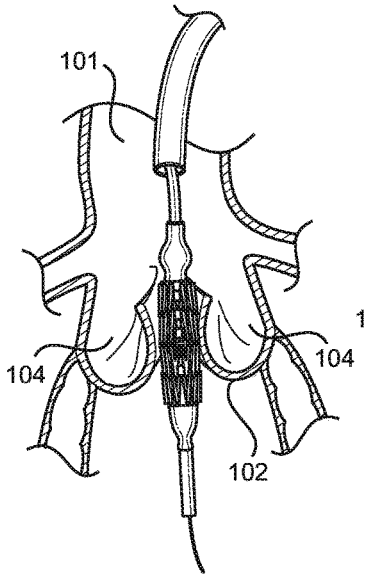


FIG. 2A

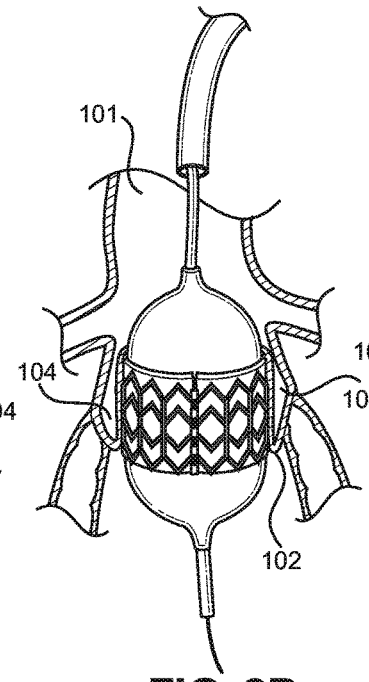


FIG. 2B

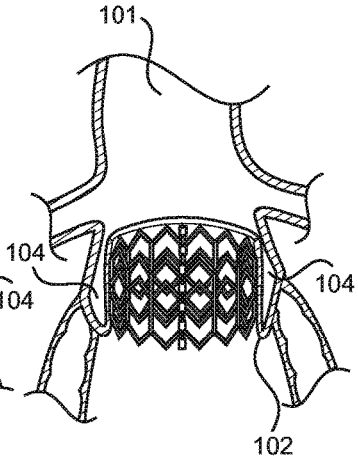


FIG. 2C

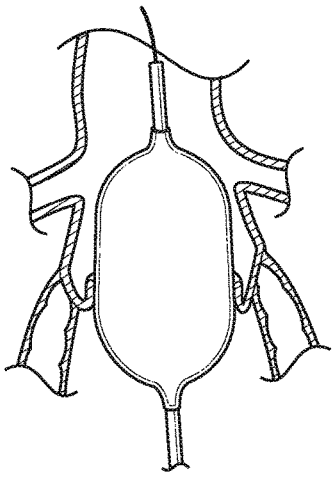


FIG. 3A

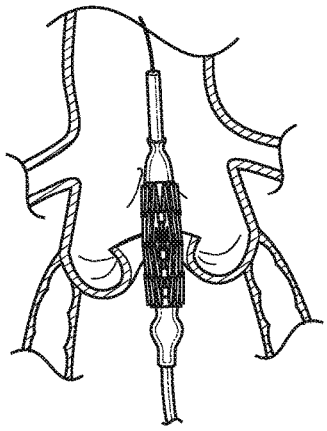


FIG. 3B

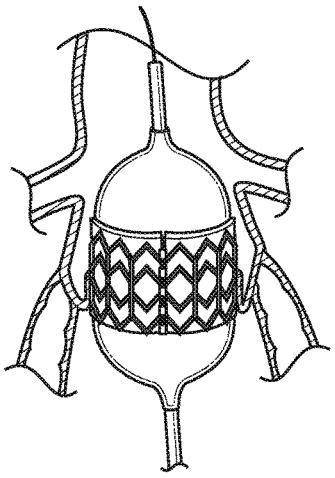


FIG. 3C

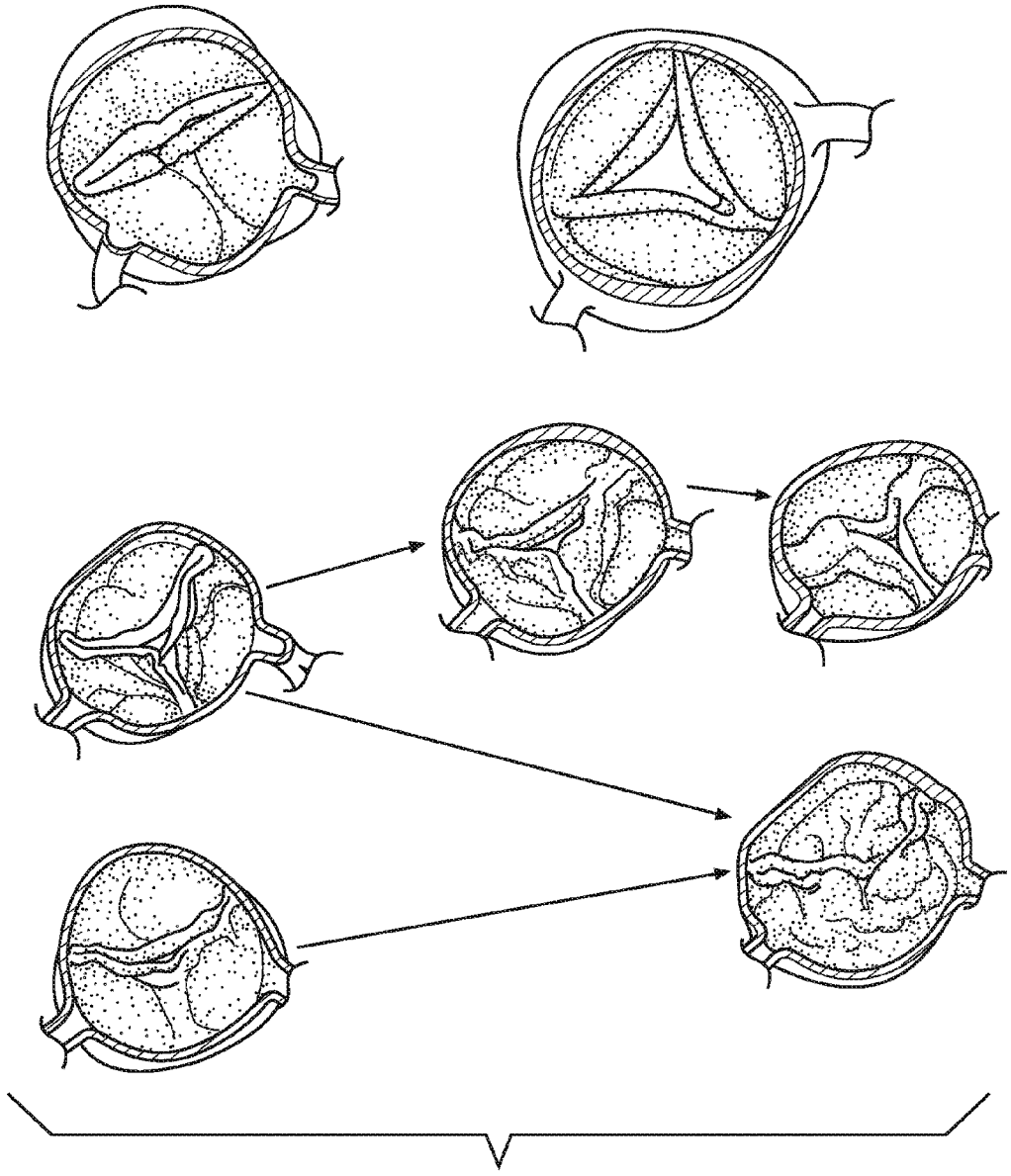


FIG. 4

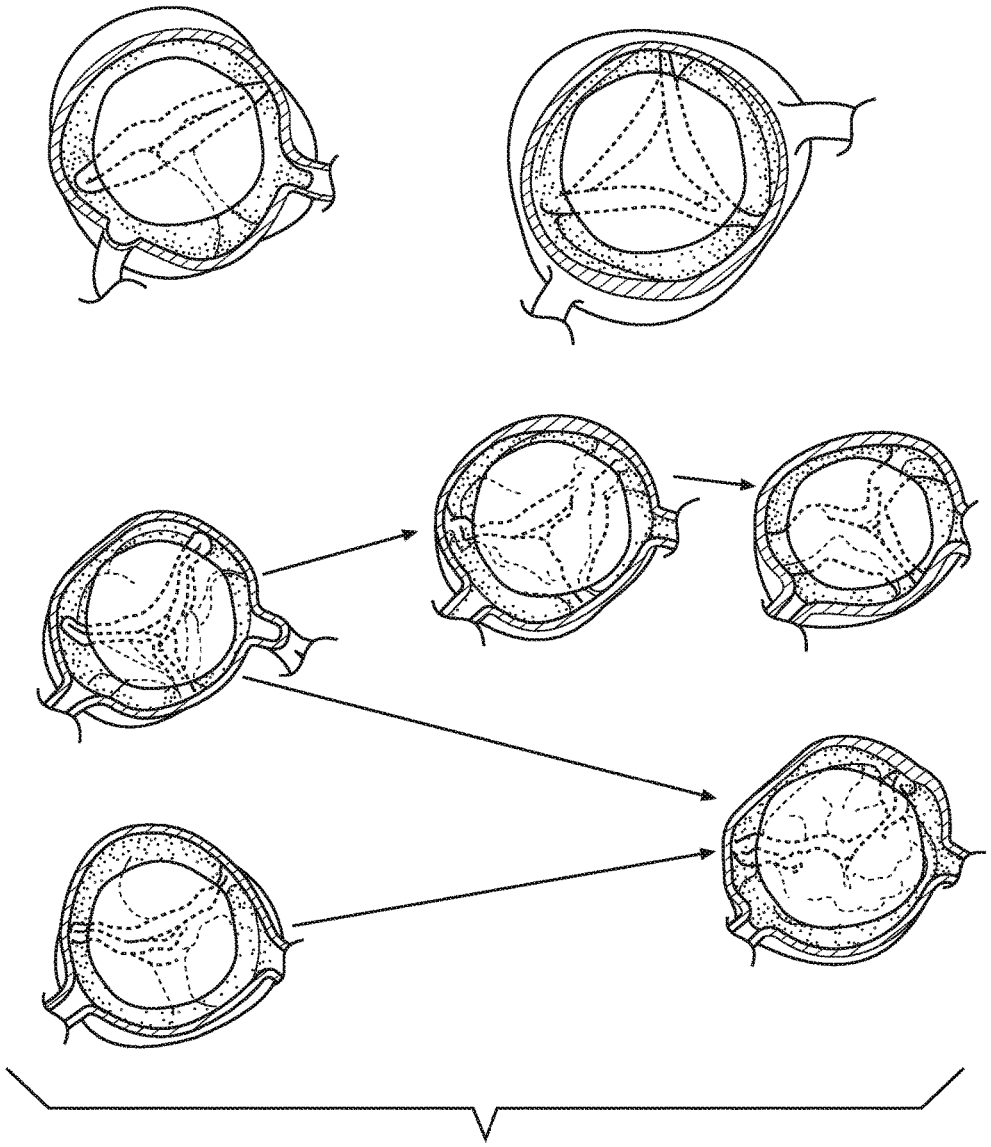


FIG. 5

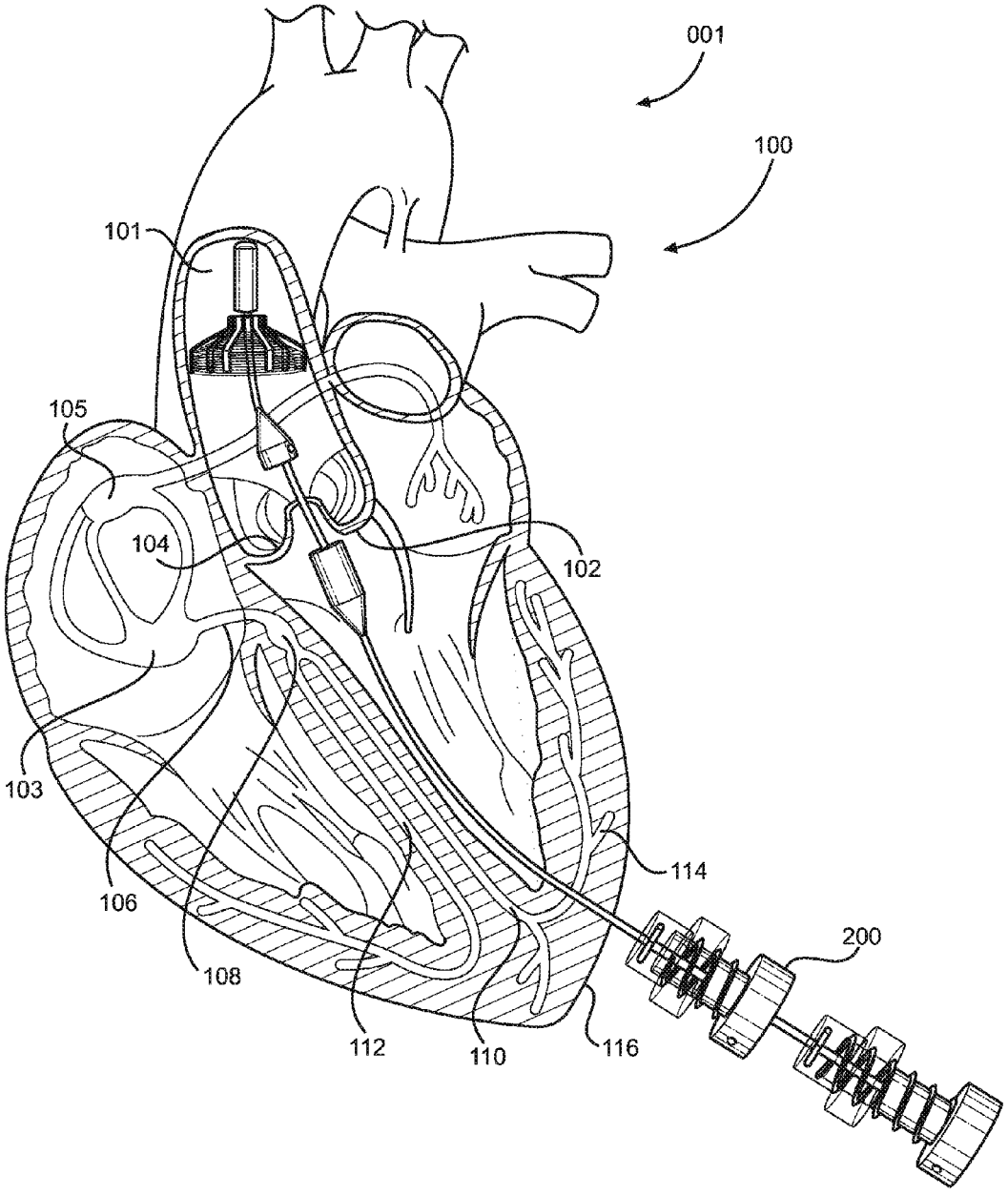


FIG. 6A

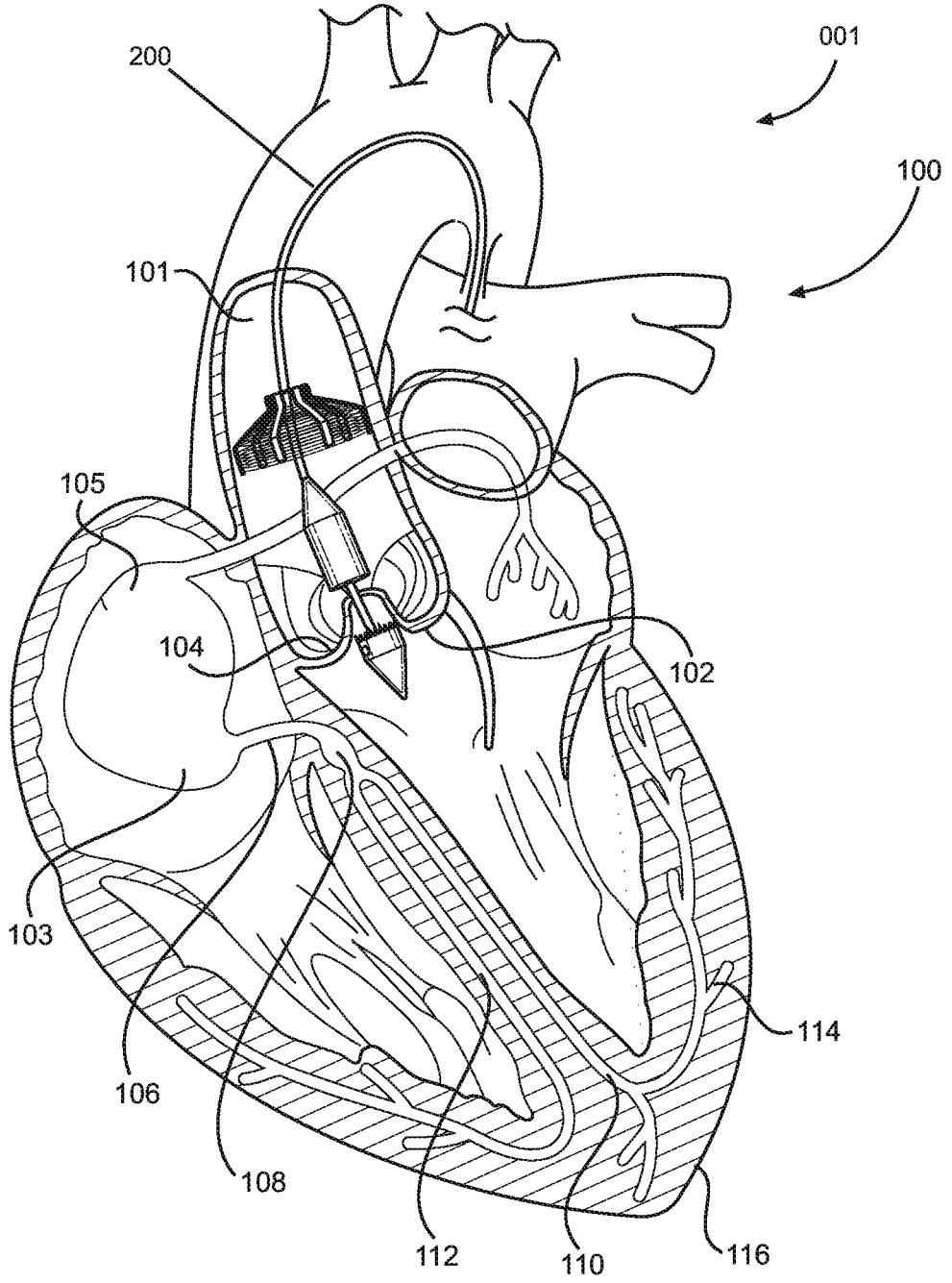


FIG. 6B

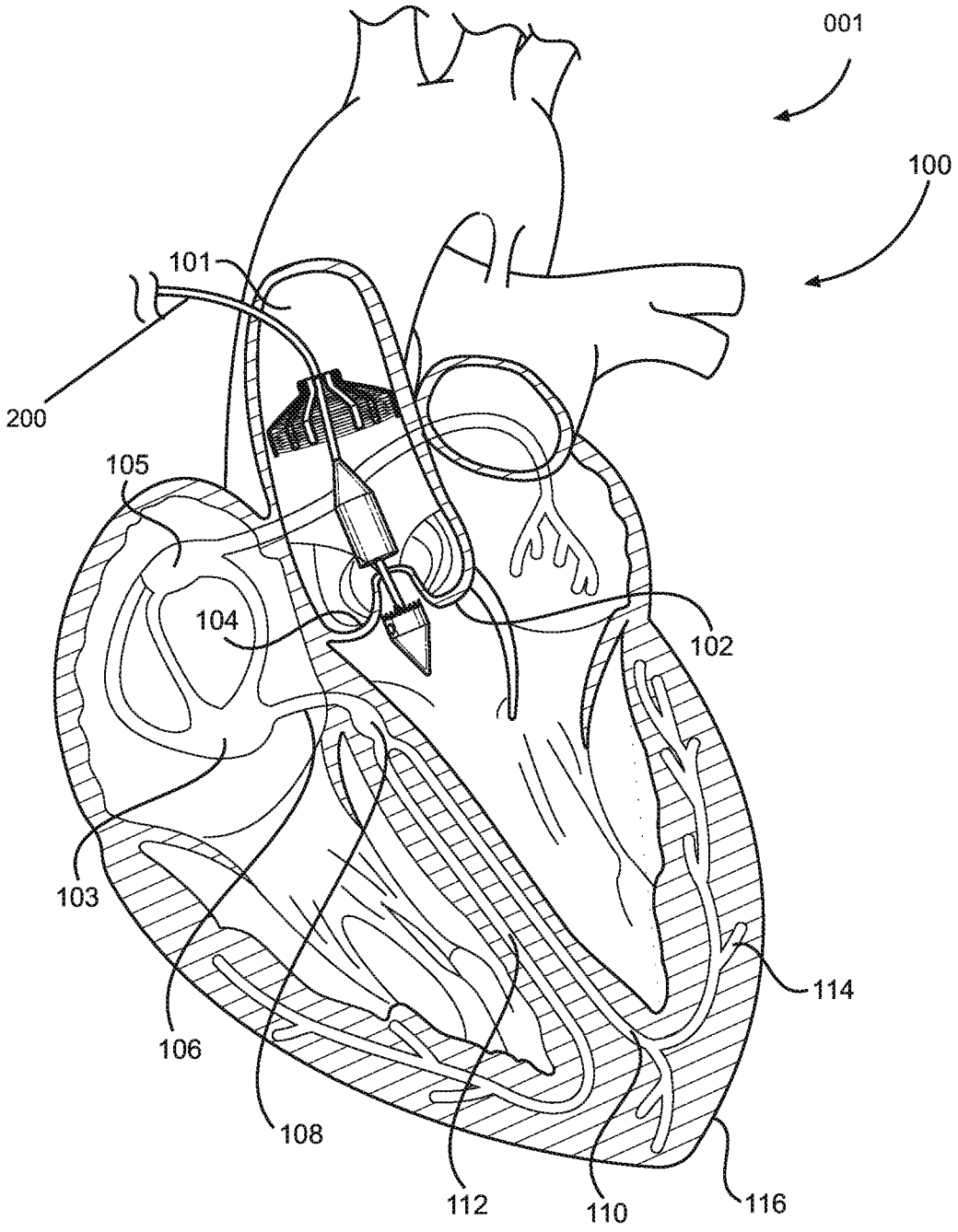


FIG. 6C

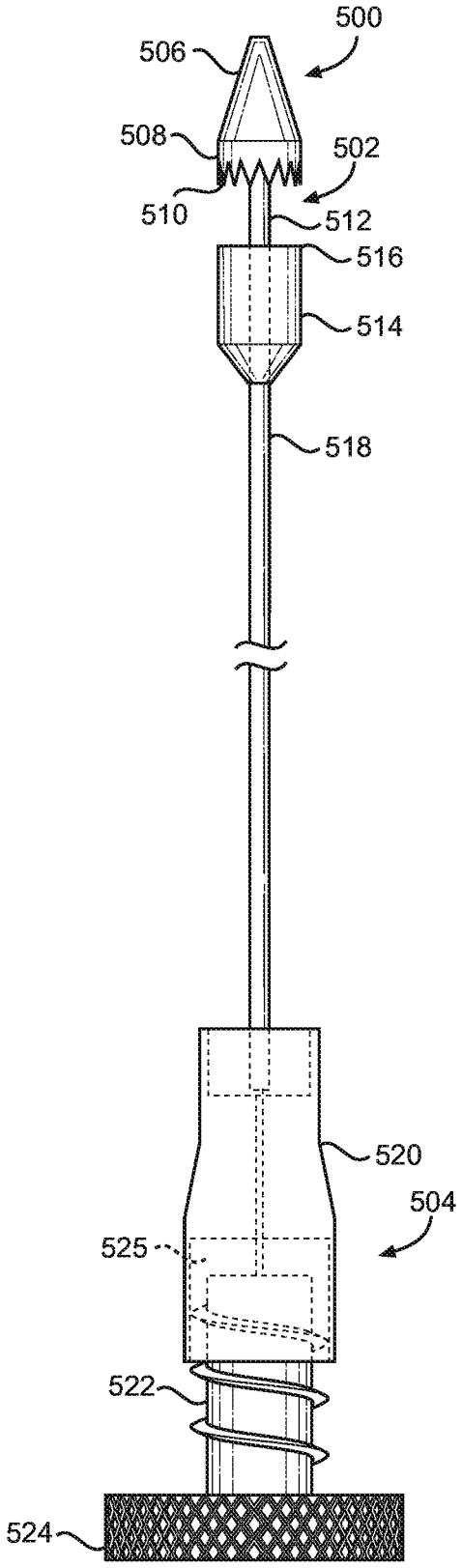


FIG. 7

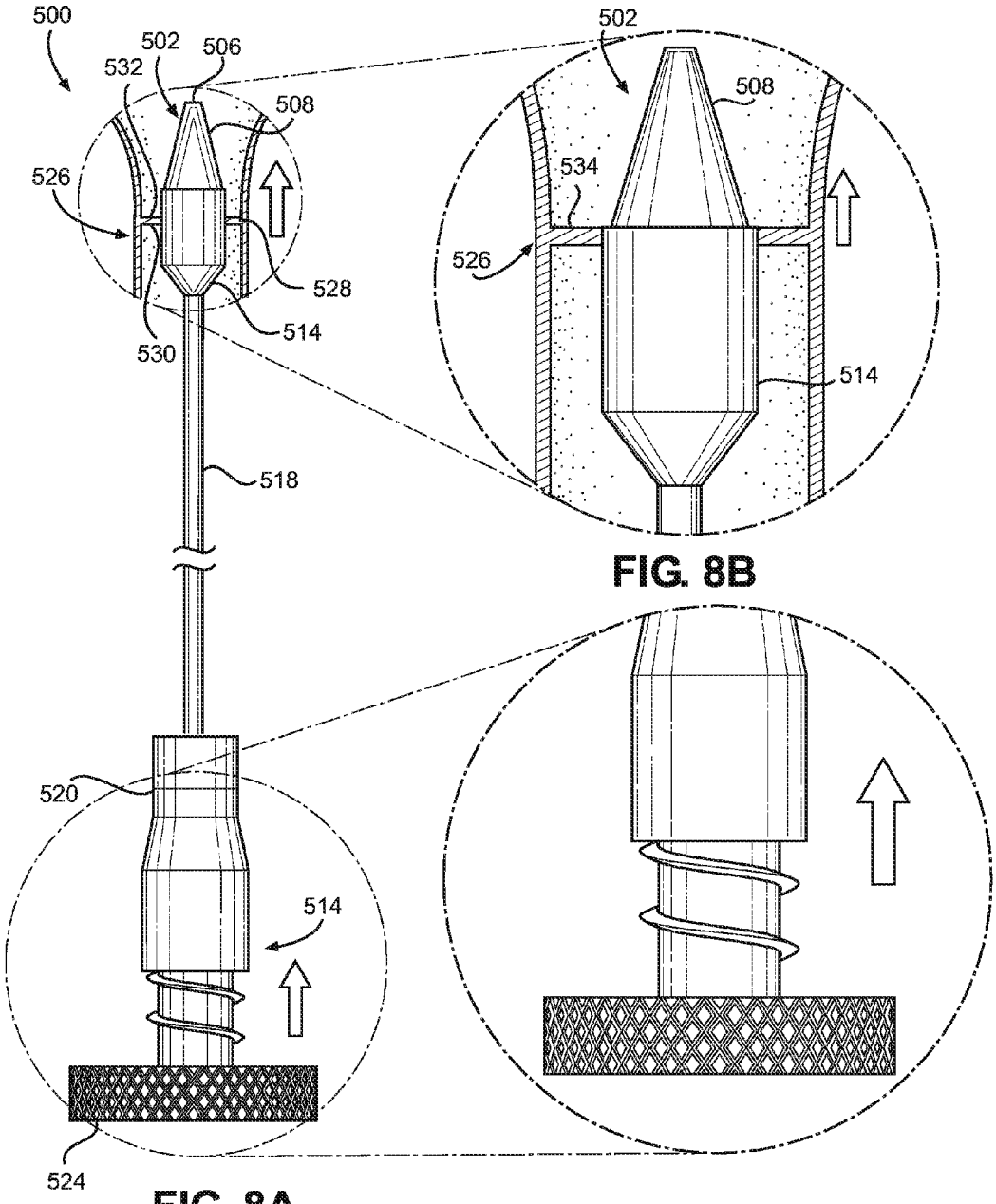


FIG. 8A

FIG. 8B

FIG. 8C

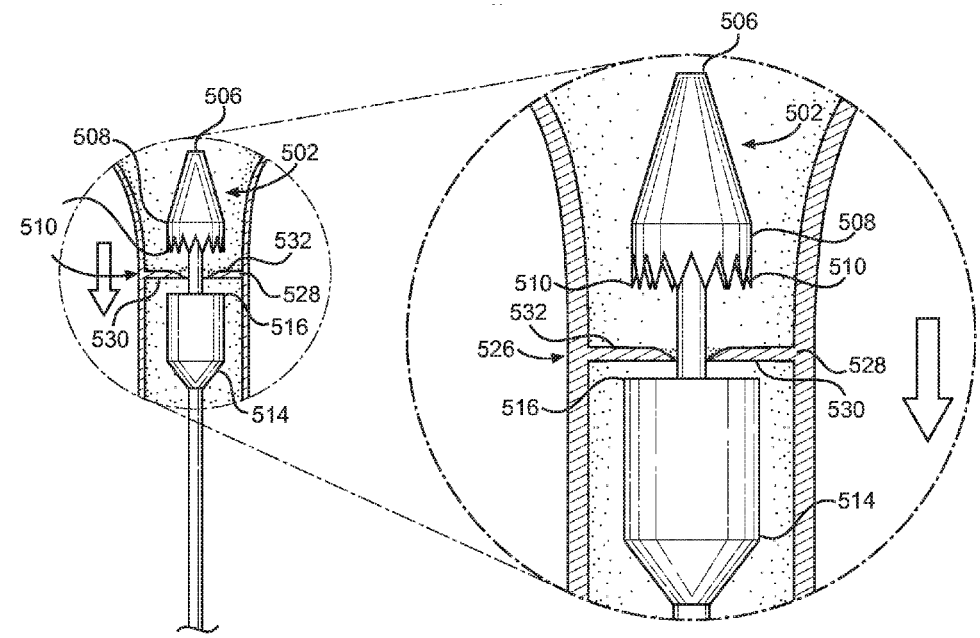


FIG. 9B

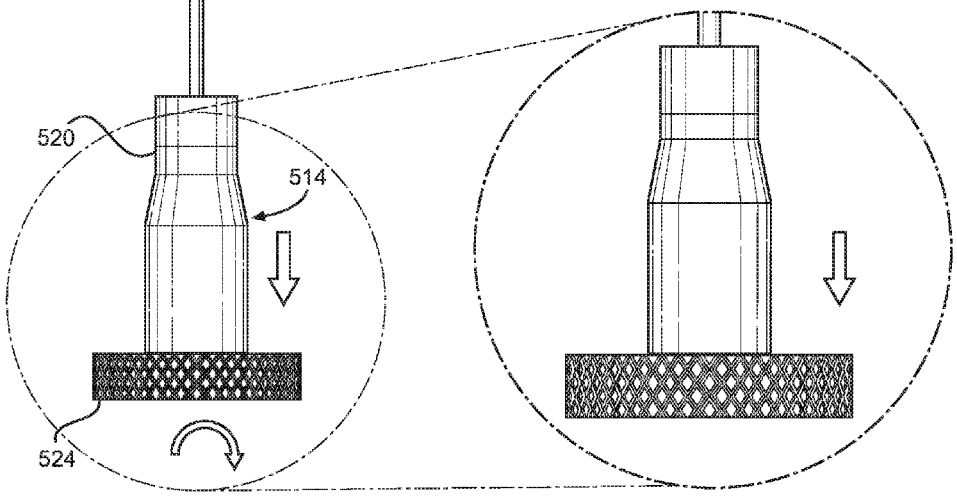


FIG. 9A

FIG. 9C

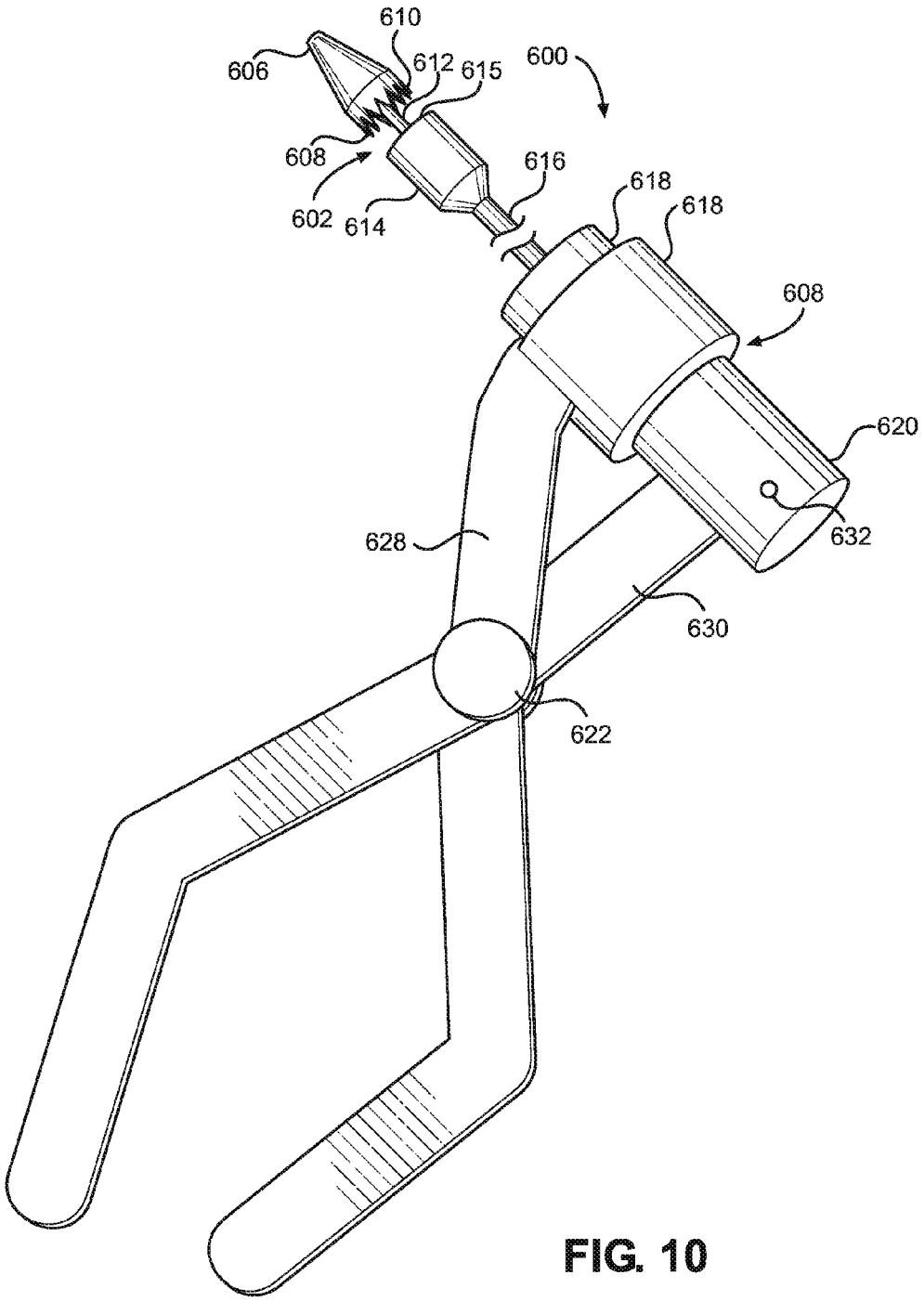

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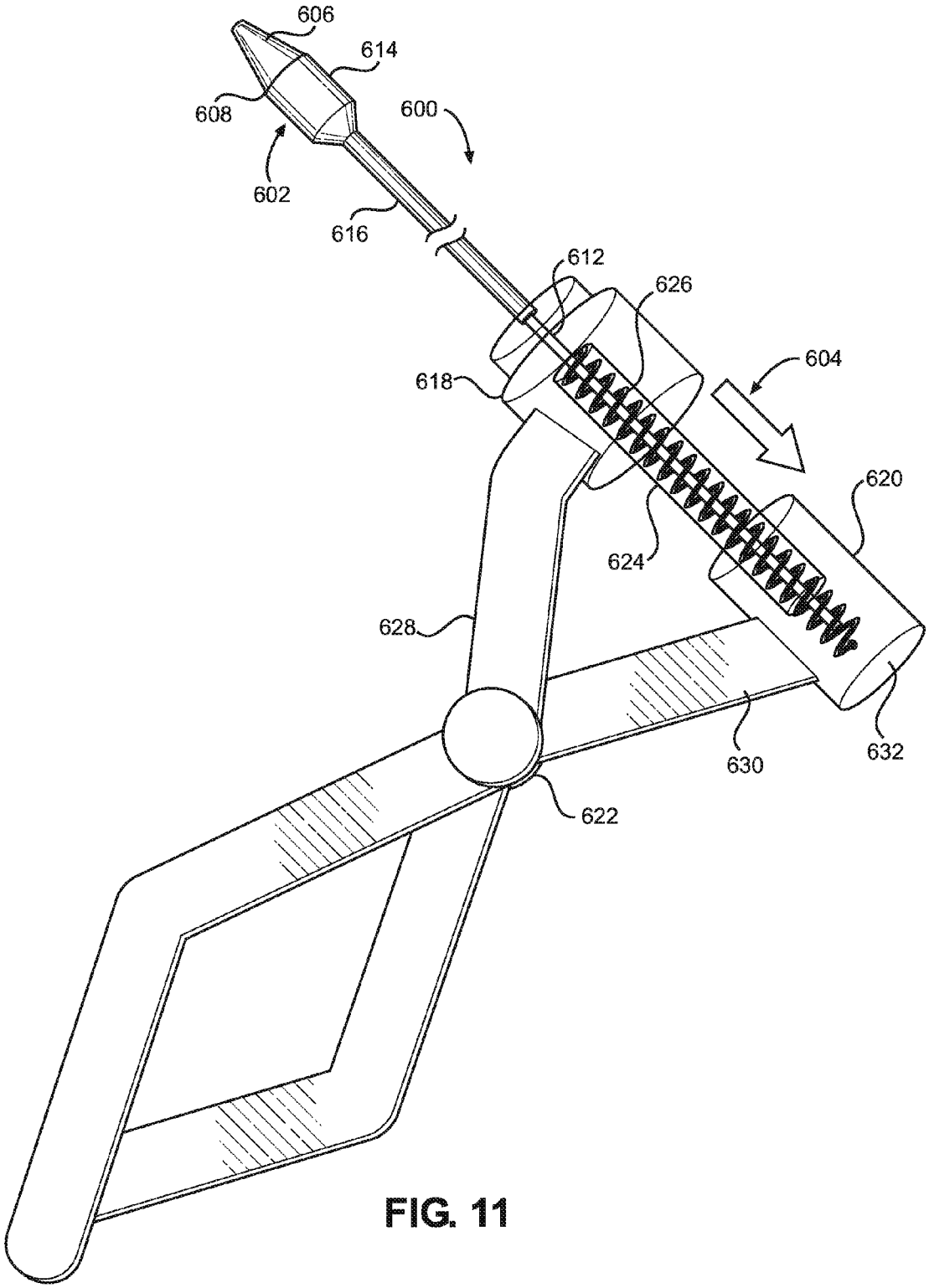
FIG. 10



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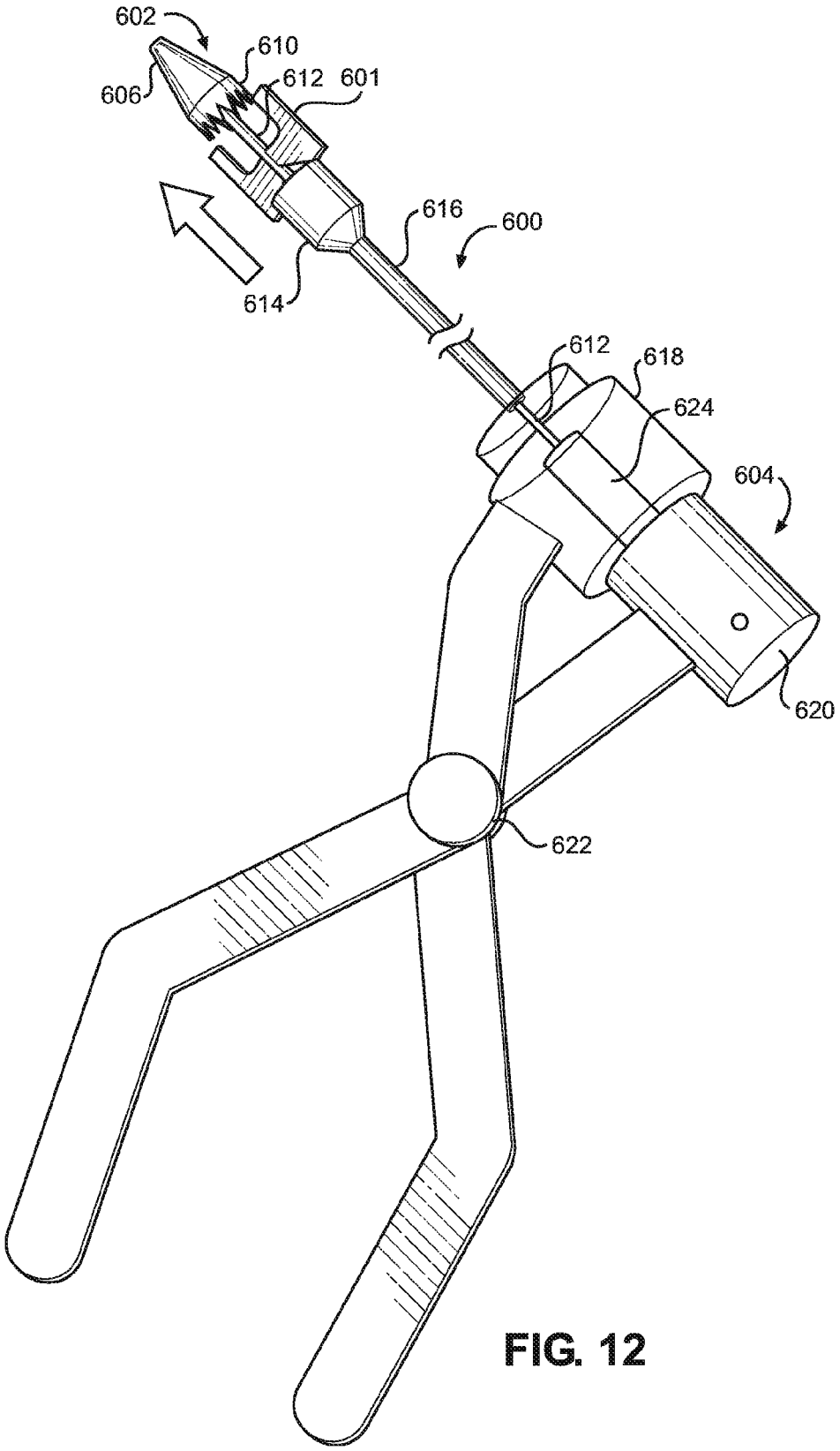

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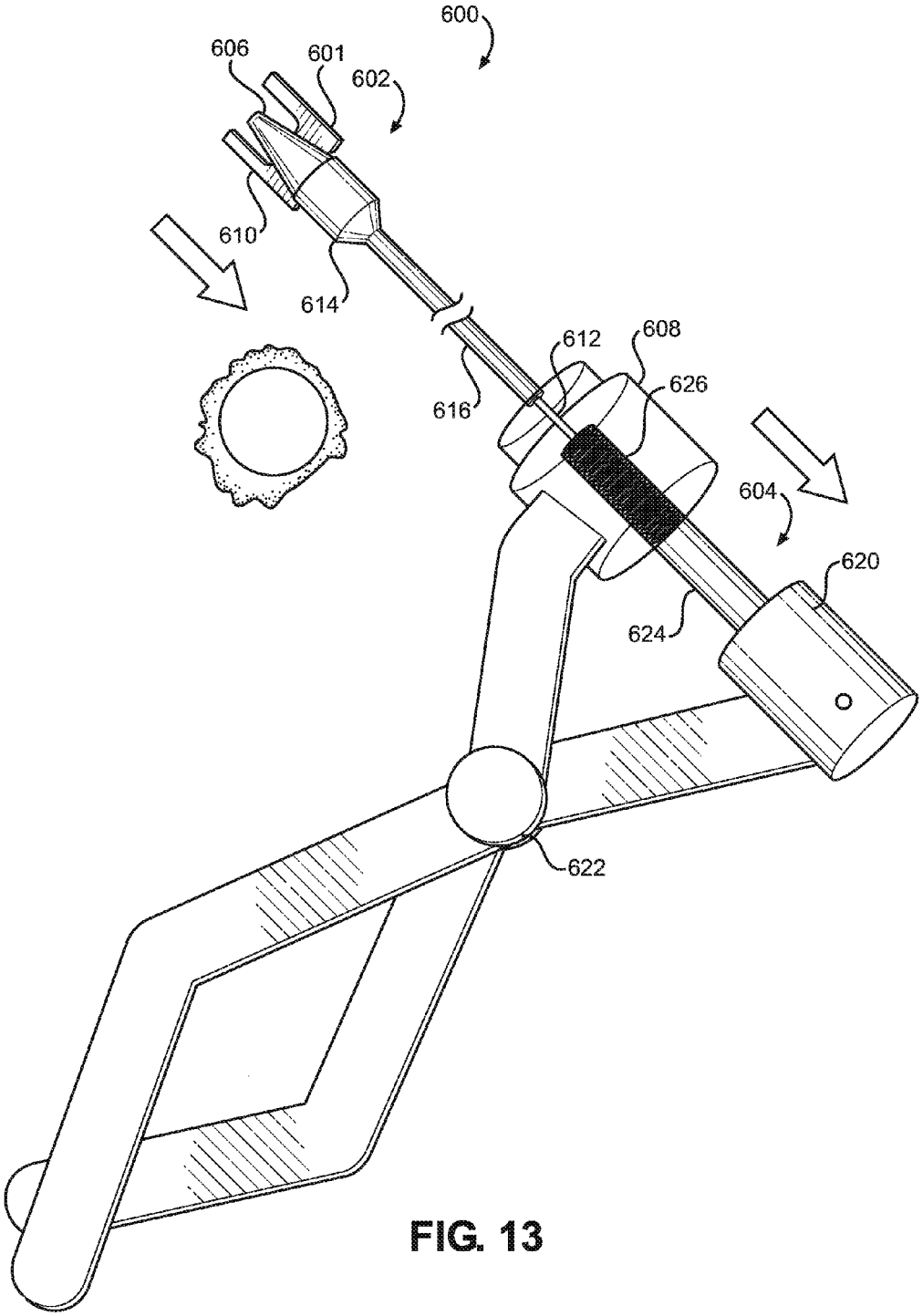

FIG. 13

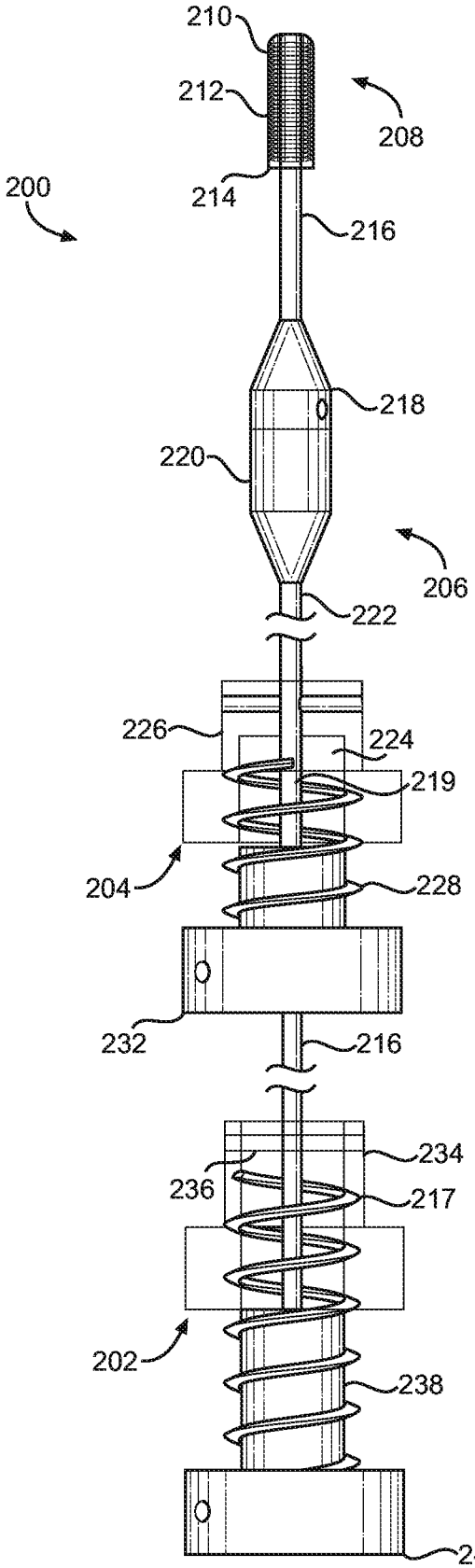
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FIG. 14

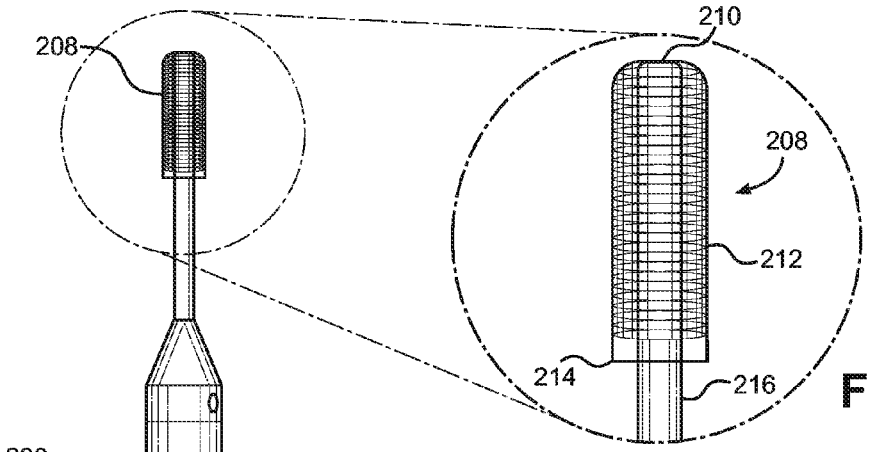

FIG. 15B

FIG. 15A

FIG. 15C

FIG. 15D

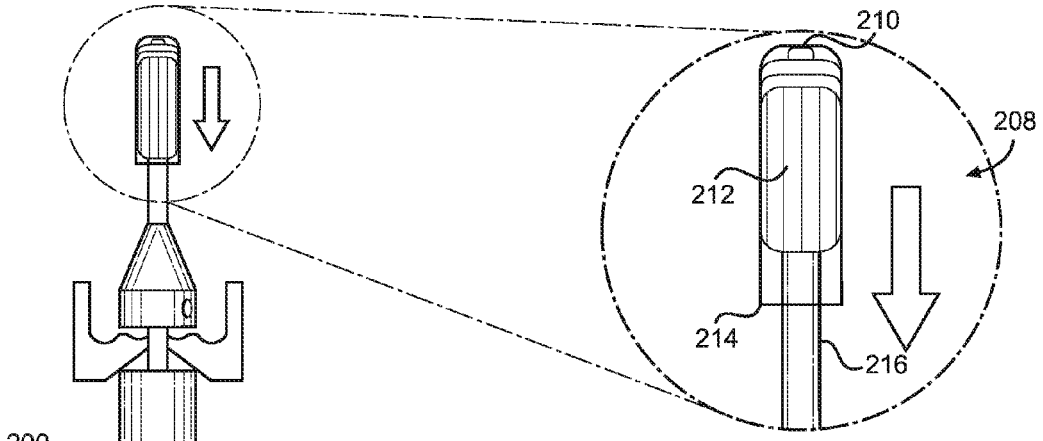

FIG. 16B

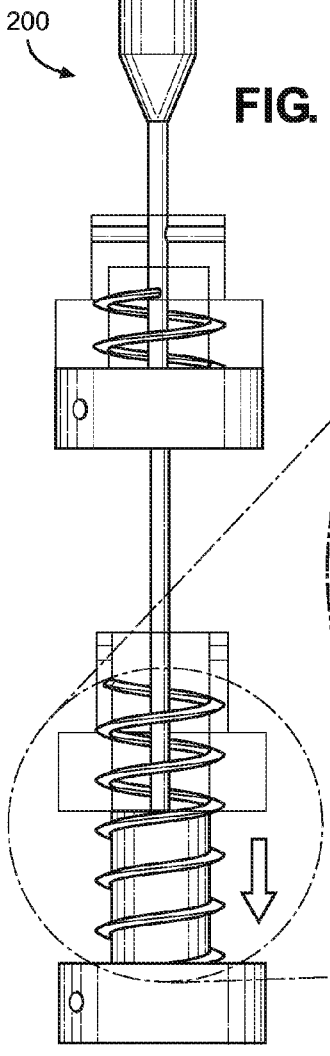

FIG. 16A

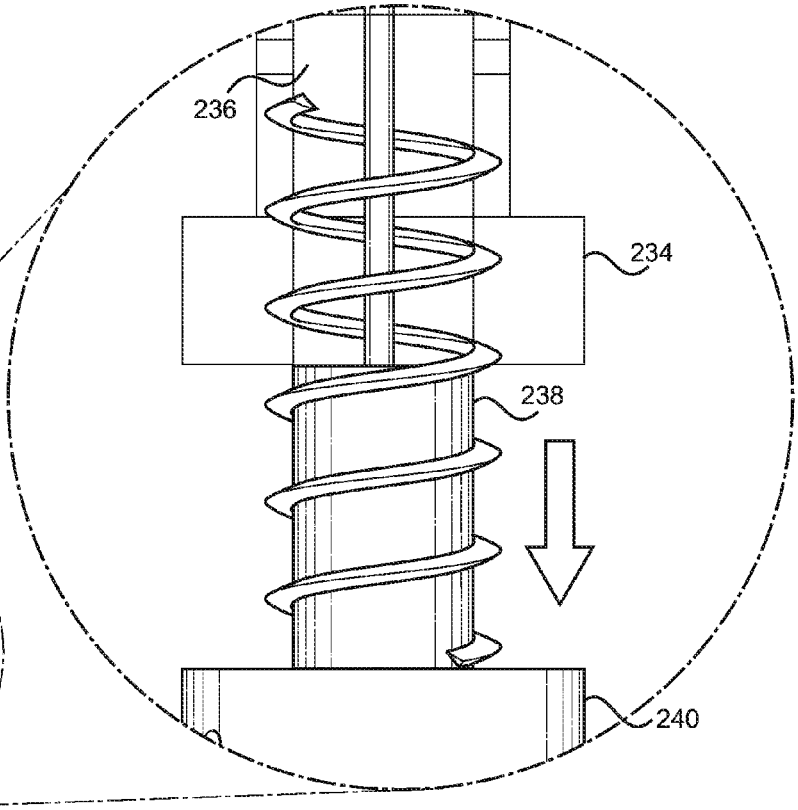

FIG. 16C

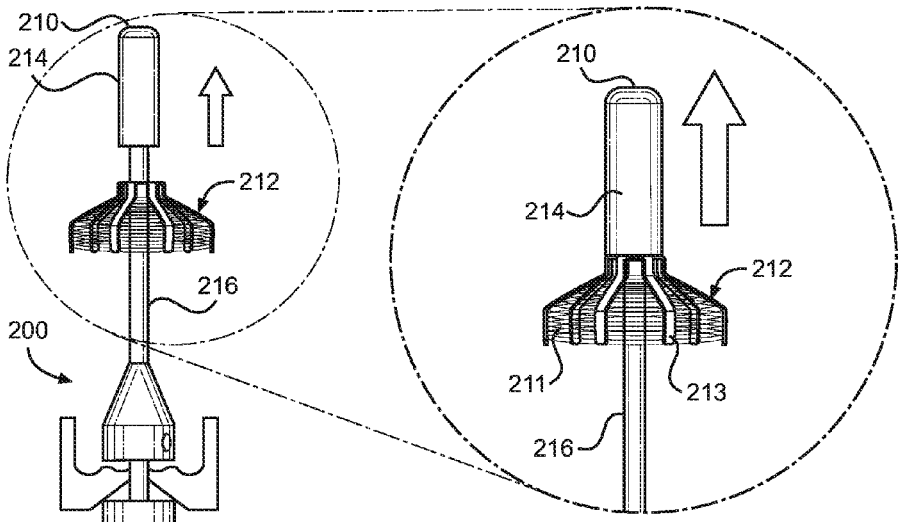

FIG. 17B

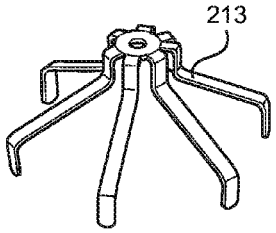

FIG. 17D

FIG. 17A

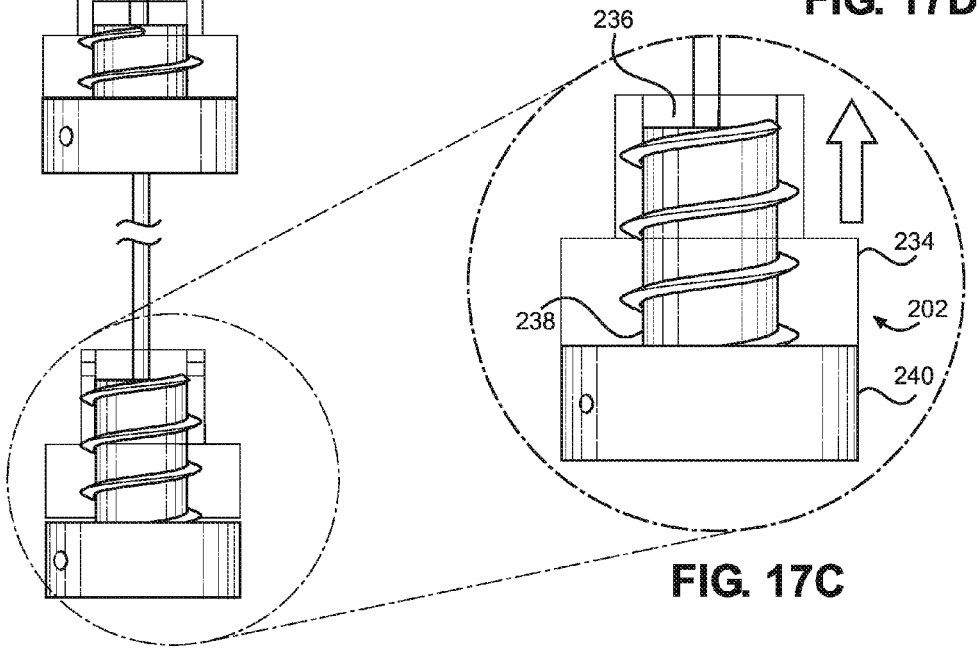

FIG. 17C

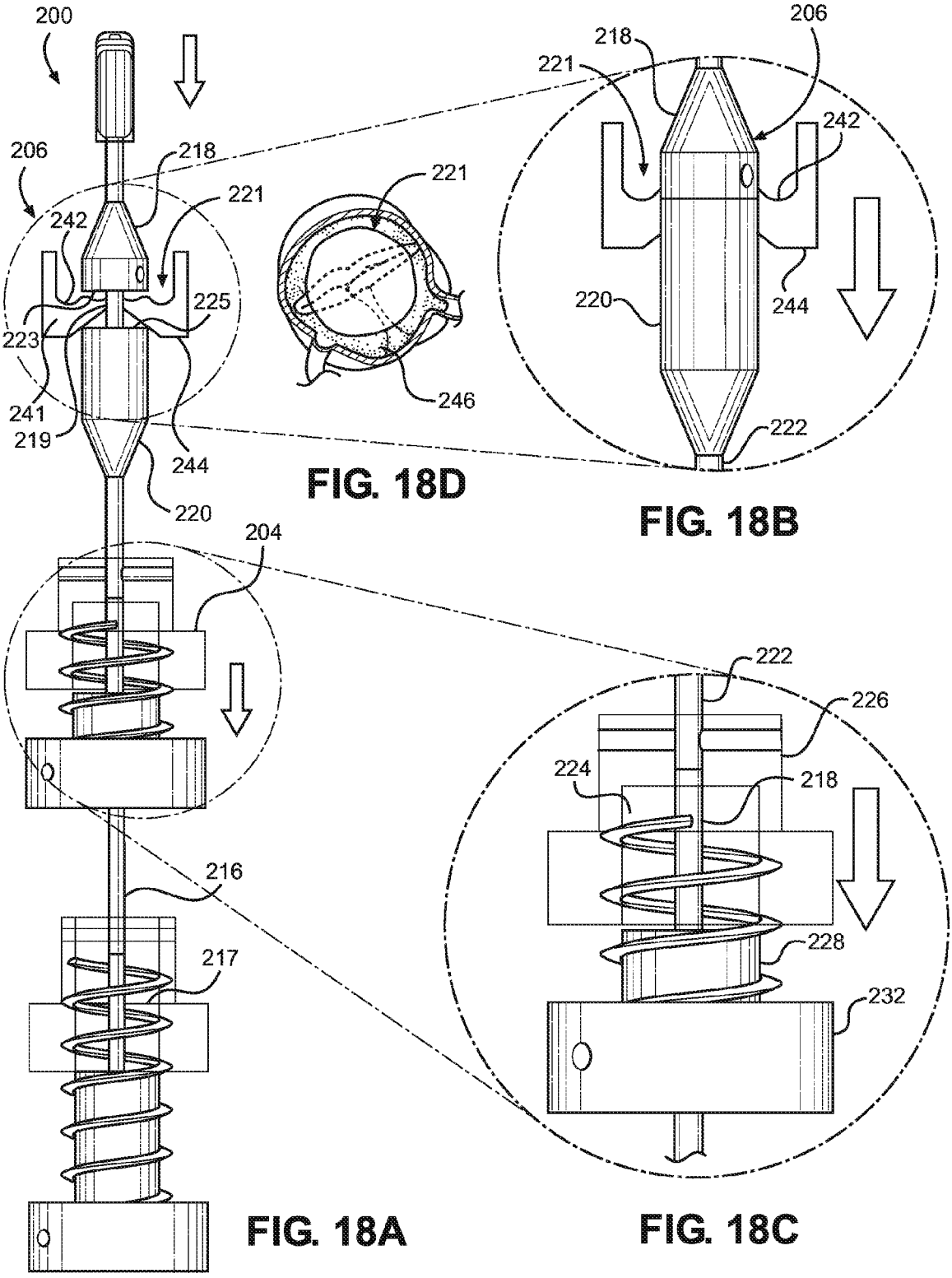

FIG. 18A

FIG. 18B

FIG. 18C

FIG. 18D

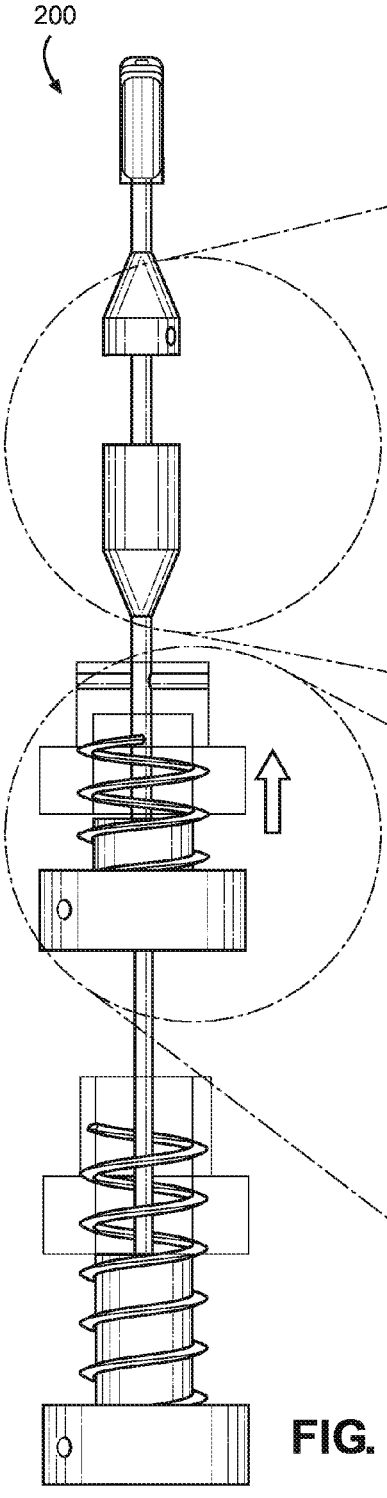

FIG. 19A

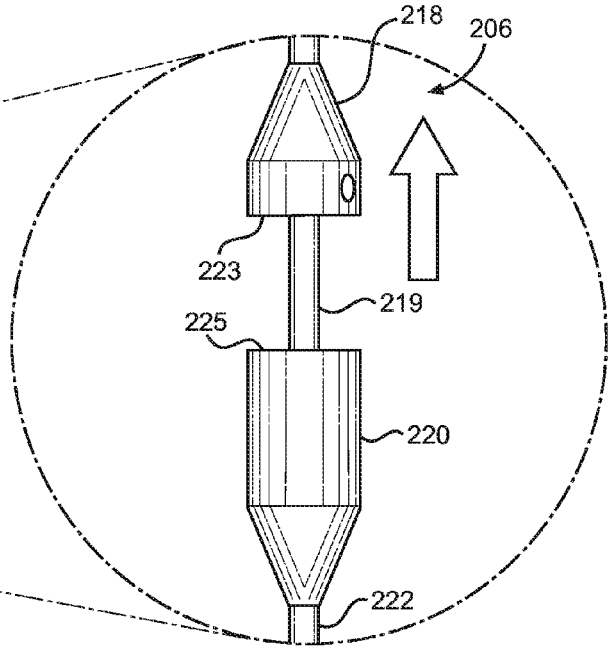

FIG. 19B

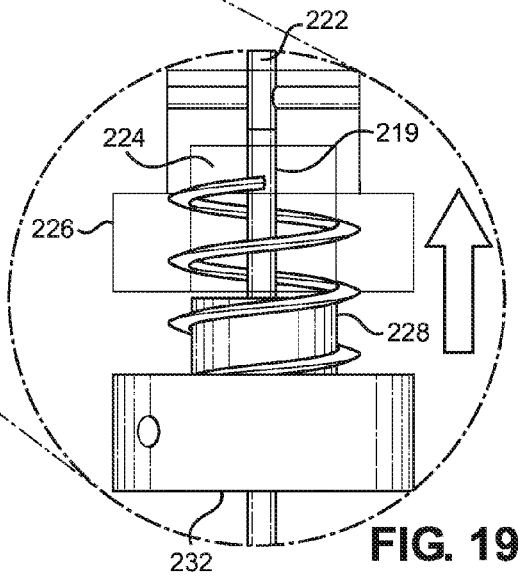

FIG. 19C

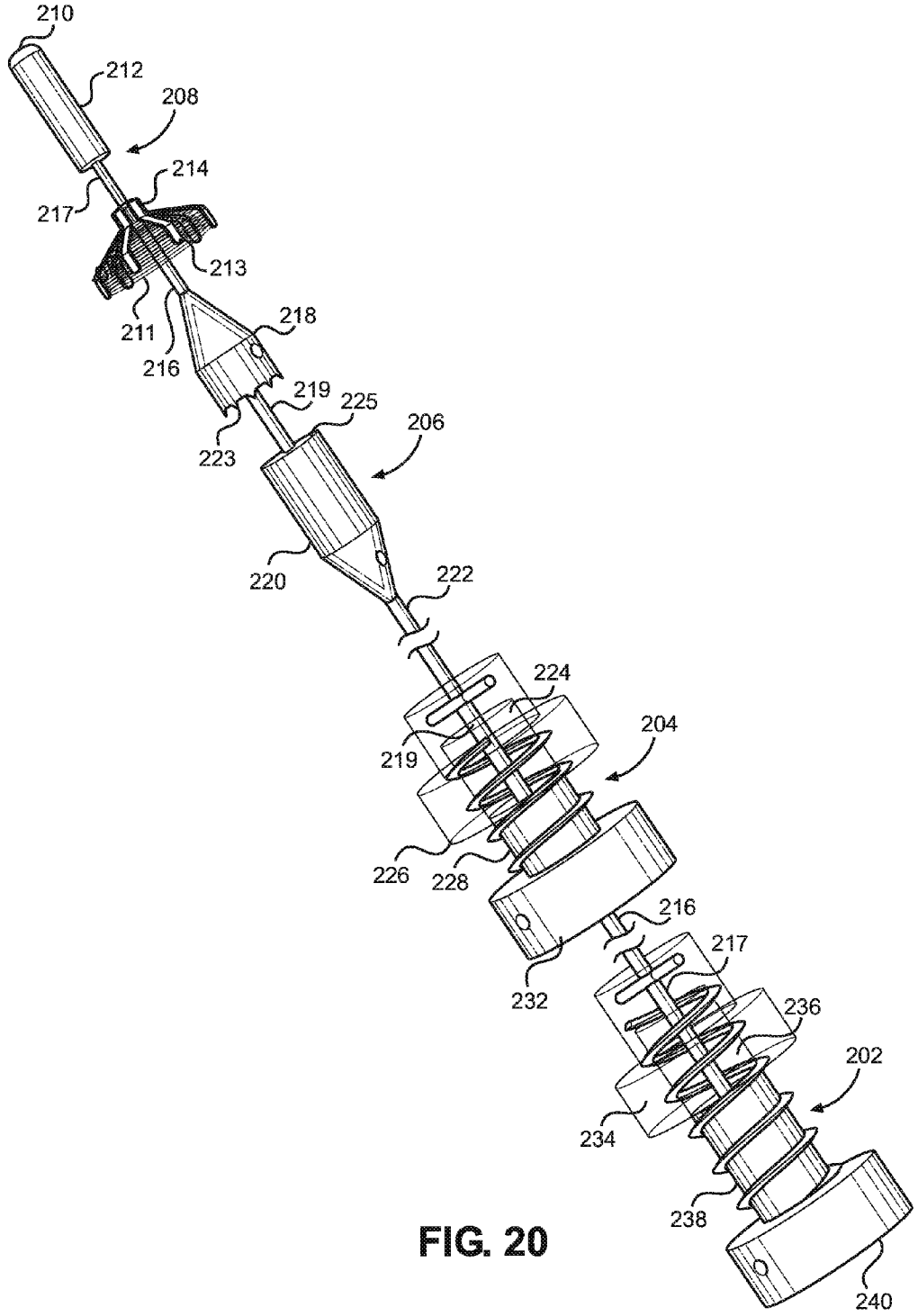
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FIG. 20

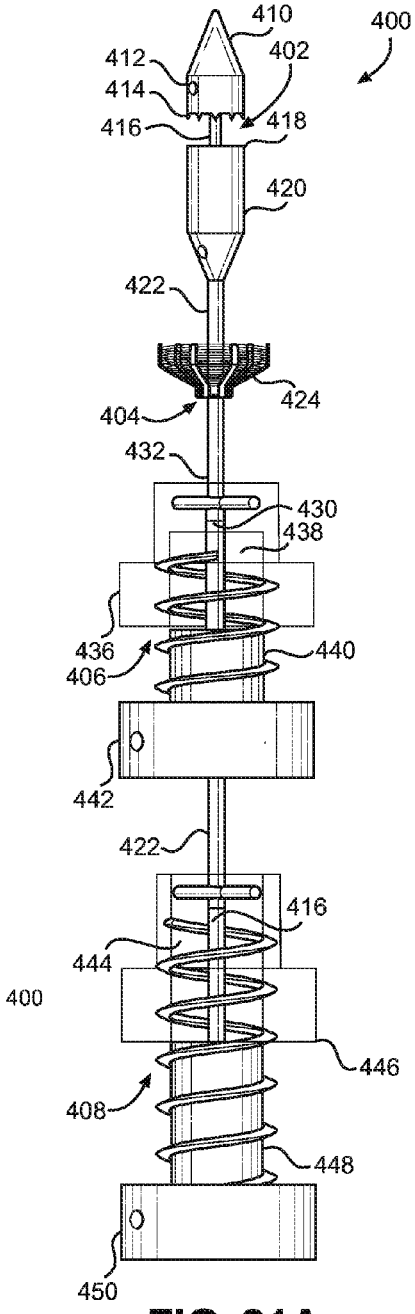
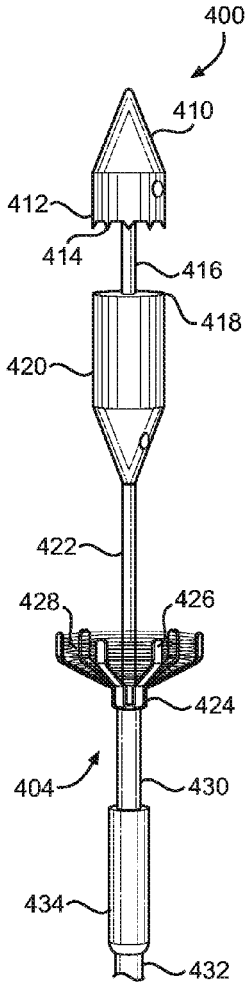


FIG. 21A



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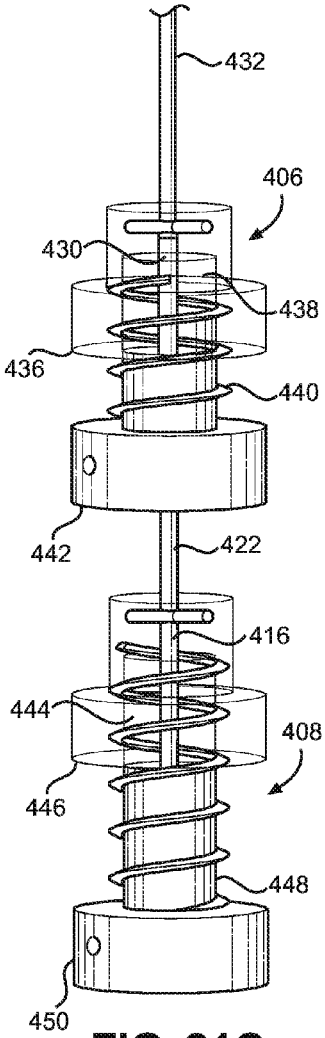

FIG. 21C

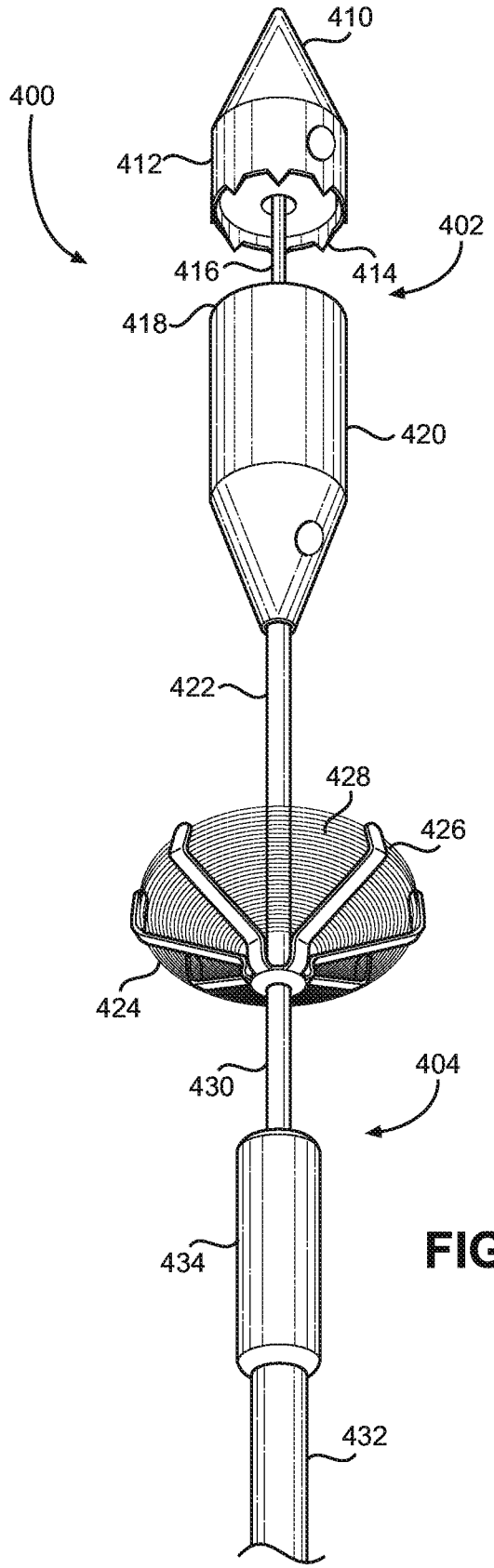

FIG. 22

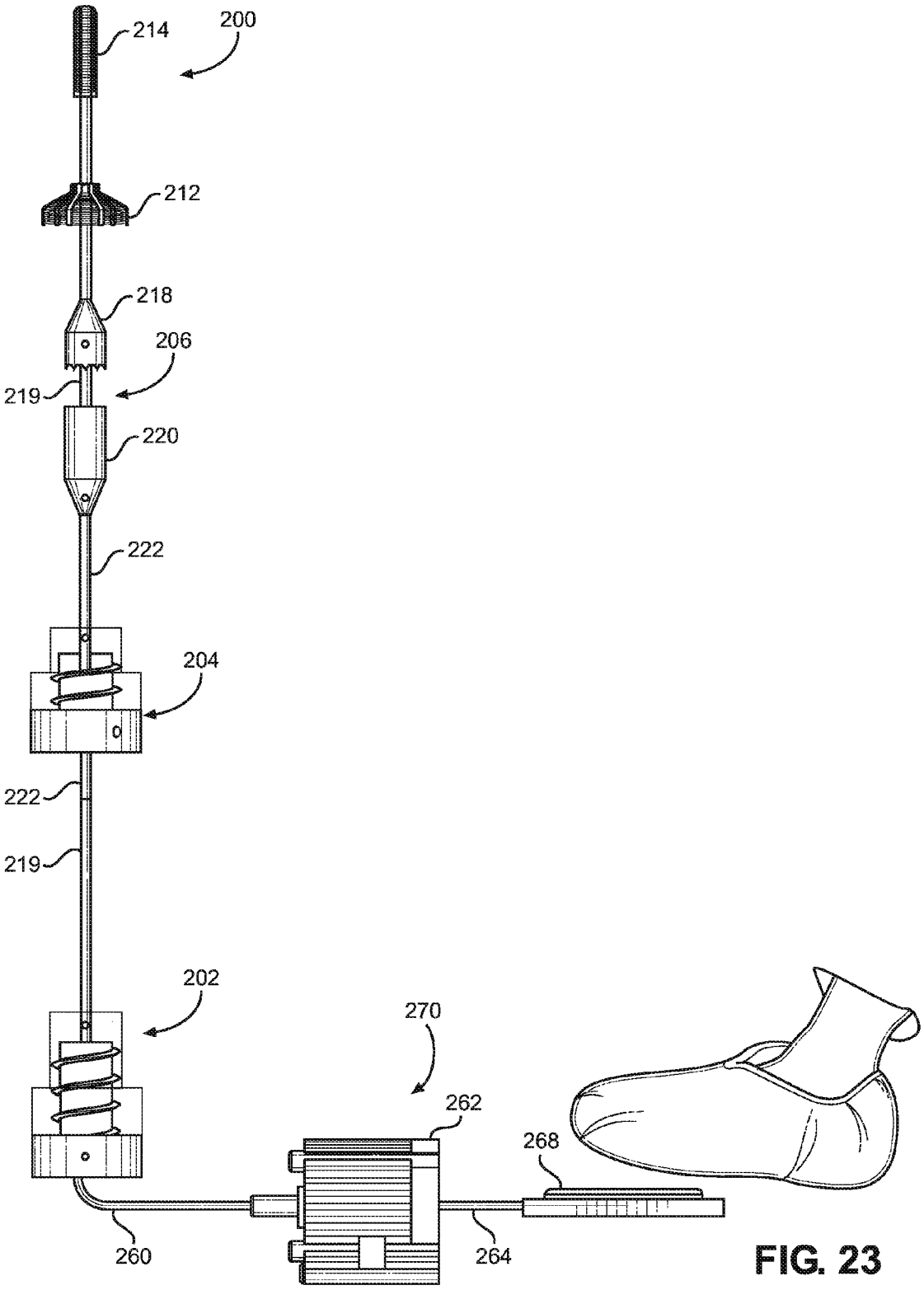
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FIG. 23

DEVICES AND METHODS FOR IMPROVING TRANSCATHETER AORTIC VALVE IMPLANTATION

TECHNICAL FIELD

[0001] The inventions described herein relate to the technical field of medical methods and devices known as Transcatheter Aortic Valve Implantation (TAVI) or Transcatheter Aortic Valve Replacements (TAVR). Specifically, the present inventions relate to methods and devices for improving the implantation of transcatheter aortic replacement valves.

BACKGROUND OF INVENTION

[0002] TAVI is an alternative method to traditional valve replacement. Traditionally, open-heart surgery with cardiopulmonary bypass is required to replace an aortic valve, wherein a patient's native aortic valve is surgically removed and replaced with an artificial mechanical valve. While mechanical valves were popular in the past, today about 70% of replacement valves are biological valves using biological tissue from other sources. The increased use of biological valves has increased the need for better, more effective methods of biological replacement valve implantation.

[0003] TAVI uses minimally invasive methods to replace a native aortic valve by injecting a transcatheter biological replacement valve over the native aortic valve without surgically removing the native aortic valve. A transcatheter aortic replacement valve is generally structured by a stent-like metal frame, which is collapsible and is either self-expandable or expanded by a balloon catheter. The metal frame is sutured to and supports tissue leaflets, typically bovine or porcine tissue, which act as biological valve replacements. During implantation of the replacement valve, a catheter is inserted into the aorta transfemorally, transapically, or transaortically. The catheter contains a compressed replacement valve and delivers the compressed replacement valve to the aortic valve, where the replacement valve is positioned within the aortic valve and released. The released replacement valve expands within the native aortic valve and radial pressure from the expandable metal frame situates the replacement valve within the native aortic valve by folding the leaflets against the aortic wall. Some calcification of the aortic valve leaflets is necessary to provide stability for the replacement valve and to hold the replacement valve in place.

[0004] FIG. **2**A demonstrates an insertion of a catheter with a collapsed TAVI replacement valve into an aortic valve **102** using the traditional approach to the procedure. The catheter, with a contracted TAVI replacement valve coaxially attached around an outside surface is positioned within the aortic valve **102** along a guidewire. FIG. **2**B shows expansion of a balloon, which expands the replacement valve within the aortic valve **102** without surgical removal of the native valve. The expansion of the balloon causes the replacement valve to fold the valve leaflets **104** upward and outward into the aorta **101**, effectively sandwiching the leaflets between the aorta and replacement valve. FIG. **2**C shows the resulting expanded implanted TAVI replacement valve in aortic valve, which uses only radial pressure to secure the replacement valve over the native valve **102**.

[0005] Valvuloplasty is used to widen a stenotic aortic valve using a balloon catheter. The TAVI replacement valve's wire-mesh metal frame is positioned around the balloon catheter such that the balloon catheter simultaneously widens both the aortic valve and TAVI replacement valve for implantation. Therefore, correct placement of the replacement valve within the native aortic valve is crucial to long-term success of the replacement valve.

[0006] Two medical device companies have FDA-approved TAVI devices on the market. Edwards Lifesciences first introduced the SAPIEN THV, approved on Nov. 2, 2011, and has since introduced the approved SAPIEN 3 and SAPIEN XT. Medtronic produces a second type of TAVI replacement valve, the CoreValve, which was first approved on Jan. 17, 2014. As is typical of TAVI replacement valves, the SAPIEN devices and the CoreValve primarily use radial pressure to secure the replacement valve within the native valve without use of additional sutures or connections.

[0007] Based on data collected from the FDA Manufacturer and User Facility Device Experience (MAUDE) database from February 2014 to December 2015, the Edwards PARTNER Trial, and other published studies the implantation of current TAVI replacement valves requires further improvement to reduce complications and improve patient outcome. Nearly 20 percent of the FDA MAUDE complaints analyzed involved replacement valve implanting and positioning errors, including misplacement and embolization, incomplete inflation, or dislodgement of the replacement valve after implantation. Varying severities of paravalvular leaks often follow improper implantation of replacement valves in the annulus. Incomplete expansion of the replacement valve within the annulus allows high pressure blood to leak between the outer surface of replacement valve and the annulus. Depending on the patient's health, a second or third replacement valve may have to be inserted. Duplicating such procedures can increase the risk of further complications.

[0008] Further, conductive issues with the electrical conduction system of the heart can arise due to excessive radial pressure applied by the replacement valve to calcium deposits on the aortic leaflets sandwiched between the aorta and replacement valve. As shown in FIG. **1**, the cardiac conduction system is crucially important because it signals distribution of oxygenated blood to the various tissues of the human body. The cardiac conduction pathway **100** begins at the sinoatrial (SA) node **105**, often referred to as the pacemaker. An electrical signal travels from the SA node **105** down the atrium to the atrioventricular (AV) node **103** where it reaches the Bundle of His **108** in the interventricular septum **106**. The electrical signal then splits into the left and right bundle branches **110** and **112** that travel the left and right sides of the heart. Purkinje fibers **114** derived from the left and right pathways translate the electrical signal to the cardiomuscular tissue of the heart, which contract in response causing blood to be quickly pumped out of the ventricles and out of arteries and to the rest of the body. Disruption of the electrical signal of the cardiac conduction system can interrupt cardiomuscular contractions. Critical issues can result with the heart and the rest of the body, as blood flow is interrupted or, at worst, stopped.

[0009] Traditional TAVI can exacerbate cardiac conduction system interruption in patients with TAVI replacement valves. Aortic stenosis, or the narrowing of the aortic valve **102**, can be congenital or acquired and occurs when at least two of the three aortic valve leaflets **104** begin to, or are fully, fused together. FIG. **4** shows a representative sampling

of various types of stenotic valves. A stenotic valve is prevented from fully opening, which in turn restricts the flow of oxygenated blood exiting the left ventricle **118**. The heart must pumper harder to keep the body sufficiently oxygenated to compensate for the reduced blood flow through the aorta **101** due to a stenotic valve. This leads to hypertrophy of the left ventricle **118** and of the septum **106**, which may in turn bring the conductive system closer to the implanted replacement valve. As hypertrophy of the left ventricle **118** and of the septum **106** thickens the walls of the heart, the radial pressure of a typical TAVI replacement valve applies radial force in the opposite direction and effectively squeezes the Bundle of His **108**, bundle branches **110** and **112**, and Purkinje fibers **114**. This in turn can lead to serious cardiac complications.

[0010] Calcium build-up on the aortic valve leaflets can also cause stenosis. Atherosclerosis along the aortic surface of the valve calcifies subsequent to aortic valvular osteoblast differentiation to create a calcific area. In time, the calcific area can grow to between 1.0 cm and 1.7 cm in diameter. Calcific stenosis occurs when enough calcium has accumulated along the surface of the aortic valve leaflets to impede the flow of blood out of the left ventricle. If a patient has a calcific aortic valve, the current TAVI procedure and corresponding replacement valves can cause further complications during implantation. Since the TAVI replacement valves currently on the market push the aortic valves upward and outward, such that the native aortic valve forms a coaxial layer between the aorta and replacement valve, calcium build up can increase the radial pressure applied to the AV node, Bundle of His, and Purkinje fibers.

[0011] Heavily calcified aortic valves cannot be dilated evenly during valvuloplasty due to the uneven size and distribution of calcium deposits on calcific aortic valves. Uneven dilation of the native aortic valve alone can result in dislodgement of the TAVI replacement valve or paravalvular leaks. Coupled with unevenly shaped and distributed calcium deposits, uneven dilation can cause aortic dissection with crashing of the Bundle of His or left Bundle due to the radial pressure of the TAVI replacement valve pushing calcium deposits on the native aortic valve into sensitive areas of the cardiac conductive system. Resulting cardiac conditions may include Left Bundle Branch Block (LBBB), Right Bundle Branch Block (RBBB), and Atrioventricular Block (AVB). Patients who undergo the TAVI procedure and develop arrhythmias or one of the aforementioned blocks often require permanent pacemakers to maintain consistent and regular heart rates. By relieving the restriction of blood flow caused by aortic stenosis, the current TAVI method and replacement valves may cause other critical cardiac issues for patients without any prior history of arrhythmias or conductive conditions.

[0012] The biggest consequence of current TAVI replacement valve issues is the additional medical procedures and equipment needed to counteract conduction problems. In nearly 70% of patients currently receiving a TAVI replacement valve, an artificial pacemaker must be inserted to rectify conduction issues caused largely by calcium deposits on the native aortic valve crushing the cardiac conductive system during the implantation of the TAVI replacement valve.

[0013] The inventions and embodiments described herein solve current issues with TAVI procedures by largely removing calcium deposits from the aortic valve.

SUMMARY OF INVENTION

[0014] The present invention solves the problem of improper implantation of current TAVI replacement valves by disclosing a method and device for removing a significant portion of calcific deposits on a native aortic valve to lower conductive interference, while preserving enough calcific deposits around the circumference of the native aortic valve to aid in the stabilization of the TAVI replacement once implanted.

[0015] An embodiment of the process of removing calcific deposits on the native aortic valve includes:

[0016] inserting a device through a native aortic valve, wherein the device has a filter umbrella attached to a punch having a male element and a female element separable along a plane perpendicular to connection;

[0017] positioning the punch within the native aortic valve, wherein the male element and female element are fusiform;

[0018] positioning the filter umbrella in an aorta downstream of blood flow through the native aortic valve, such that the filter umbrella allows blood to pass beyond the aorta and catches dislodged calcium particles;

[0019] opening the punch within the native aortic valve such that aortic valve leaflets are positioned between the male element and the female element;

[0020] closing the punch over the aortic valve leaflets so that the male element applies force to a superior surface of the aortic valve leaflets and the female element applies force to an inferior surface of the aortic valve leaflets;

[0021] removing calcium deposits from center of native aortic valve by perforation; and

[0022] leaving a ring of calcium deposits along the circumference of the native aortic valve.

[0023] An embodiment of the device used to remove calcium from the aortic valve includes:

[0024] a tip attached to a distal end of a primary tube having a circumference large enough to at least allow a guide wire to pass through;

[0025] a self-expandable stent covered with a perforated mesh, with the self-expandable stent attached to a distal end of a secondary tube positioned coaxially around an outer surface of the primary tube;

[0026] a punch system, having a male element, with a proximal end connected to a tertiary tube, and a female element, having a proximal end connected to a quaternary tube, which is positioned coaxially around an outer surface of the tertiary tube, which is positioned coaxially around an outer surface of the primary tube;

[0027] a punch control element connected at a distal end to the quaternary tube, having a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contain a centered coaxial hole to allow the tertiary tube to pass through and connect to the punch spindle, and the punch spindle and punch dial contain a centered coaxial hole to allow the primary tube to pass through, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the tertiary tube relative to the female element; and

[0028] a stent control element, having a stent dial attached to a proximal end of a reversely-threaded stent spindle, a

stent receptacle with an inner cylindrical area open at a proximal end and threaded to accept the stent spindle, wherein the stent receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the stent spindle, and wherein the stent dial is configured to turn either clockwise or counterclockwise to raise or depress the stent spindle within the inner cylindrical area of the stent receptacle, which in turn raises and lowers the self-expandable stent covered with perforated mesh relative to the tip.

[0029] Another embodiment of the device for removing calcium deposits from the aortic valve includes:

[0030] a punch system, having a male element with a proximal end connected to a distal end of a primary tube and a conically-shaped distal end, a female element, having a proximal end connected to a secondary tube, which is positioned coaxially around an outer surface of the primary tube, which is positioned coaxially around an outer surface of the primary tube;

[0031] a self-expandable stent covered with a perforated mesh, with the self-expandable stent attached to a distal end of a tertiary tube positioned coaxially around an outer surface of the secondary tube;

[0032] a stent sheath attached to a distal end of a quaternary tube positioned coaxially around an outer surface of the tertiary tube;

[0033] a stent control element, having a stent dial attached to a proximal end of a reversely-threaded stent spindle, a stent receptacle with an inner cylindrical area open at a proximal end and threaded to accept the stent spindle, wherein a distal end of the stent receptacle is attached to the proximal ends of the secondary and quaternary tubes and contains a centered coaxial hole to allow the tertiary tube to pass through and connect to the stent spindle, and the stent spindle and stent dial contain a centered coaxial hole to allow the primary tube to pass through, and wherein the stent dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the stent receptacle, which in turn raises the stent out of the stent sheath allowing expansion of the stent and lowers the stent into the stent sheath whereby a circumferential edge of the stent sheath causes the stent to contract as the stent spindle is raised; and

[0034] a punch control element, having a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the punch spindle, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the primary tube relative to the female element.

[0035] Yet another embodiment of the device for removing calcium deposits from a valve includes:

[0036] a punch system, having a male element with a proximal end connected to a distal end of a primary tube and a conically-shaped distal end, a female element, having a proximal end connected to a secondary tube, which is positioned coaxially around an outer surface of the primary tube, which is positioned coaxially around an outer surface of the primary tube;

[0037] a punch control element attached to the primary and secondary tubes and end opposite to the punch element, wherein the punch control element is configured to move the male element in relation to the female element.

[0038] Other embodiments of these processes and devices are described herein. These embodiments are not exclusive of the only possible embodiments. A further understanding of the structural, functional, and advantageous aspects of the disclosure can be realized by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF DRAWINGS

[0039] Figures accompanying the specification show and describe the inventions, as follows:

[0040] FIG. **1** shows a representation of the cardiac conduction system;

[0041] FIG. **2**A shows a traditional implantation of TAVI replacement valve, namely a catheter with a collapsed replacement valve attached coaxially around an outside surface positioned within an aortic valve;

[0042] FIG. **2**B shows a traditional implantation of TAVI replacement valve, namely expansion of the replacement valve within the aortic valve via a balloon catheter;

[0043] FIG. **2**C shows a traditional implantation of TAVI replacement valve, namely the TAVI replacement valve fully expanded and implanted within a native aortic valve;

[0044] FIG. **3**A shows expansion of a balloon catheter inside an aortic valve perforated by the improved process to demonstrate the reduced radial pressure due to shorter aortic leaflets;

[0045] FIG. **3**B shows an improved implantation of TAVI replacement valve, namely a catheter with a collapsed replacement valve attached coaxially around an outside surface positioned within a perforated aortic valve;

[0046] FIG. **3**C shows an improved implantation of TAVI replacement valve, namely expansion of the replacement valve within the aortic valve via a balloon catheter;

[0047] FIG. **4** shows a representative sampling of different stenotic aortic valves;

[0048] FIG. **5** shows a representative sampling of the different stenotic aortic valves that have been perforated by the improved method and disclosed devices;

[0049] FIG. **6**A shows a representative procedure using an inventive device inserted apically up through the left ventricle and into the aorta;

[0050] FIG. **6**B shows a representative procedure using an inventive device inserted transfemorally through the femoral artery, up through the aorta and down into the aortic valve;

[0051] FIG. **6**C shows a representative procedure using an inventive device inserted transaortically through the aorta artery and down into the aortic valve;

[0052] FIG. **7** shows a representation of a preferred embodiment of a device for perforating an aortic valve;

[0053] FIG. **8**A shows the preferred embodiment of FIG. **7** in operation, with a punch closed in an aortic valve;

[0054] FIG. **8**B shows an enlarged view of the punch of FIG. **8**A;

[0055] FIG. **8**C shows an enlarged view of a punch control element of FIG. **8**A, positioned such that the punch is correspondingly closed, for either insertion or perforation;

[0056] FIG. **9**A shows the preferred embodiment of FIG. **7** in operation, with the punch opened in an aortic valve;

[0057] FIG. **9**B shows an enlarged view of the punch of FIG. **9**A;

[0058] FIG. **9**C shows an enlarged view of a punch control element of FIG. **9**A, positioned such that the punch is correspondingly opened, after insertion and in anticipation of perforation;

[0059] FIG. **10** shows a another embodiment of the inventive device, where the punch control element is lever and fulcrum system with a spring, in an open position;

[0060] FIG. **11** shows the embodiment of FIG. **10** in a closed position, and further illustrates the internal structure and operation of the punch control element;

[0061] FIG. **12** shows the operation of the embodiment of FIGS. **10** and **11**, with the release of the punch control element and corresponding opening of the punch within the aortic valve after insertion of a closed punch.

[0062] FIG. **13** shows the operation of the embodiment of FIGS. **10** and **11**, with the closing of the punch control element handle and either corresponding closing of the punch within the aortic valve after insertion of a closed punch, or initial insertion of the punch within the aortic valve.

[0063] FIG. **14** shows an apical embodiment of the aortic valve perforation device;

[0064] FIG. **15**A shows the embodiment of FIG. **14**, with focus on a stent system, punch control system, and stent control system;

[0065] FIG. **15**B shows an enlarged view of the stent system where a stent sheath covers an expandable stent umbrella;

[0066] FIG. **15**C shows an enlarged view of a punch receptacle from the embodiment shown in FIG. **14**;

[0067] FIG. **15**D shows an enlarged view of a stent receptacle from the embodiment shown in FIG. **14**;

[0068] FIG. **16**A demonstrates the structure and corresponding function of the stent system and stent control system of the embodiment shown in FIG. **14**, as the stent sheath is pulled down over the expandable stent umbrella as a stent spindle is removed from the stent receptacle;

[0069] FIG. **16**B demonstrates the stent sheath pulled down over the expandable stent umbrella;

[0070] FIG. **16**C demonstrates the stent spindle removed from the stent receptacle;

[0071] FIG. **17**A demonstrates the structure and corresponding function of the stent system and stent control system of the embodiment shown in FIG. **14**, as the stent sheath is pushed up beyond the expandable stent umbrella the a stent spindle enters the stent receptacle;

[0072] FIG. **17**B demonstrates the stent sheath pushed above the expandable stent umbrella;

[0073] FIG. **17**C demonstrates the stent spindle pushed into the stent receptacle;

[0074] FIG. **17**D shows a perspective view of the stent without a mess umbrella;

[0075] FIG. **18**A demonstrates the structure and corresponding function of a punch and a punch control system of the embodiment shown in FIG. **14**, as a male element of the punch is pulled down to contact a female element and perforate an aortic valve;

[0076] FIG. **18**B shows the male and female elements of FIG. **18**A joining to form a fusiform punch, and thereby perforate the aortic valve;

[0077] FIG. **18**C shows a punch spindle of FIG. **18**A pulled out of a punch receptacle causing the male element to be pulled toward the female element;

[0078] FIG. **18**D demonstrates the resulting perforation of the aortic valve due to the closing of the male element to the female element;

[0079] FIG. **19**A demonstrates the structure and corresponding function of a punch and a punch control system of the embodiment shown in FIG. **14**, as the male element of the punch is pushed up away from the female element;

[0080] FIG. **19**B shows an enlarged view of the punch, namely the male element pushed away from the female element via operating of the punch control system;

[0081] FIG. **19**C shows an enlarged view of the punch control system, where the punch spindle is pushed into the punch receptacle causing the male element to be raised in relation to the female element;

[0082] FIG. **20** shows another embodiment of the apical device, where the male element of the device has teeth along a cutting edge;

[0083] FIG. **21**A shows another embodiment of a device for perforating an aortic valve, where the device is configured to be inserted transfemorally or transaortically;

[0084] FIG. **21**B shows a perspective view of a punch and stent umbrella of the embodiment shown in FIG. **21**A;

[0085] FIG. **21**C shows a perspective view of a punch control system and stent control system of the embodiment shown in FIG. **21**A;

[0086] FIG. **22** shows an enlarged perspective view of a punch and stent umbrella of the embodiment shown in FIG. **21**A; and

[0087] FIG. **23** shows an embodiment of an aortic valve perforation device with a high speed motor and control to rotatably close a punch.

DETAILED DESCRIPTION OF INVENTION

[0088] Various embodiments and aspects of the disclosure are described with reference to details discussed below. The following descriptions and referenced drawings are illustrative of the disclosure and are not to be construed as limiting the disclosure. The drawings are not necessarily to scale. Numerous specific details are described to provide a thorough understanding of various embodiments of the present disclosure. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of embodiments of the present disclosure.

[0089] As used herein, spatial and relative terms such as "proximal" and "distal" are relative to a user of the methods or devices described herein, unless otherwise stated. For example, a distal end of a tube is the end farthest from a user, whereas a proximal end of the same tube is the end closest to the user.

[0090] A preferred embodiment for the method for improving transcatheter aortic valve implantation is shown in FIGS. **7**-**9**C. This method includes inserting a device **500** through a native aortic valve **526**, wherein the device has a punch **502** having a male element **508** and a female element **514** separable along a plane perpendicular to connection. The device **500** may be inserted through the native aortic valve **526** transapically, transaortically, or transfemorally. For reference, FIG. **6**A shows an embodiment of the device **200** inserted transapically through an apex **116** of a heart **001**, FIG. **6**B shows the device **200** inserted transfemorally, and FIG. **6**C shows the device **200** inserted transaortically.

[0091] A next step is positioning the punch **502** within the native aortic valve **526**, wherein the male element **508** and

female element **514** are fusiform, as shown in FIG. **23**A. The male **508** and female **514** elements are fusiform during insertion and positioning of the punch **502** in the native aortic valve **526** to minimize the detachment of calcium deposits from the aortic leaflets **528** in the aorta. Otherwise, cutting edges of the male and female elements **510** and **516**, respectively, may inadvertently catch on and dislodge calcium from the native aortic valve **526** if not fusiform, thereby increasing the risk of an embolism.

[0092] A further step includes opening the punch **502** within the native aortic valve **526** such that aortic valve leaflets **528** are positioned between the cutting edge **510** of the male element **508** and the cutting edge **516** of the female element **514**. FIG. **8** shows the full device **500** as the fusiform punch is positioned within the native aortic valve **526**. FIG. **9** shows the punch **502** opened to position the aortic leaflets **528** between the male **508** and female **514** elements.

[0093] A next step includes closing the punch **502** over the aortic valve leaflets **528** so that the male element **508** applies force along the cutting edge **510** to a superior surface **532** of the aortic valve leaflets **528** and the female element **514** applies force along the cutting edge **516** to an inferior surface **530** of the aortic valve leaflets **528**.

[0094] Another step includes perforating the native aortic valve **526** via the punch **502** to remove calcium deposits from the native aortic valve. FIG. **5** shows representations of the perforation of the native aortic valve **526** once the device **500** is removed. The perforation of the native aortic valve **526** should leave a circumferential ring of the remaining tissue of the native aortic valve with a preferable length of 2-3 millimeters.

[0095] The final step includes leaving a ring of calcium deposits **534**, as shown in FIG. **5**, along the circumference of the native aortic valve **526**. A semi-rigid ring composed of the remaining aortic valve is useful in stabilizing any TAVI replacement valve during and after implantation. Additionally, less radial pressure is ultimately placed on the heart conduction system as the majority of the calcium deposits are removed from the native aortic valve that would otherwise be folded upward between a replacement valve and aorta. Further, the chance of paravalvular leaks is reduced, as the shortened aortic leaflets make proper insertion of replacement valves easier and more successful.

[0096] FIGS. **3**A-**3**C show the implantation of a TAVI replacement valve after using the process described herein. FIG. **3**A shows insertion of a balloon catheter and replacement valve into the perforated aortic valve. FIG. **3**B shows the inflation of the catheter and resulting expansion of the replacement valve. FIG. **3**C shows the replacement valve implanted over the perforated aortic valve, with the remaining circumferential ring of the aortic valve, with some calcification, providing a structural support for the replacement valve. FIG. **5** shows the same stenotic valves shown in FIG. **4** after the application of the described process for removing calcium deposits from aortic valves.

[0097] Another embodiment for the method for improving transcatheter aortic valve implantation is shown in FIGS. **6**A and **18**A-**18**D, which encompasses the preferred embodiment with additional features. This method includes inserting a device through a native aortic valve, wherein the device has a filter umbrella attached to a punch having a male element and a female element separable along a plane perpendicular to connection. The device is inserted transapically in FIG. **6**A, through the apex **116** of the heart into the left ventricle **118** and up through the aortic valve **102** and into the aorta **101**. However, the device may be inserted transapically, transaortically, or transfemorally.

[0098] The arrangement of elements of the device must change due to direction of bloodflow when the device is inserted transaortically or transfemorally, as compared to transapically. A suitable embodiment of a device **400** for use in inserting via the aorta or femoral artery is show in FIG. **21**A. The primary difference between the device when inserted transaortically or transfemorally, as opposed to transapical insertion, is the orientation of the filter umbrella and punch. As the filter umbrella is used to catch any debris, including calcium buildup that is dislodged during perforation of the native aortic valve, and blood flows out of the left ventricle into the aorta through the aortic valve, the filter umbrella must be positioned in the aorta downstream of the aortic valve. In transaortic and transfemoral insertion, the filter umbrella **424** is therefore positioned behind the punch **402** along the device **400** or proximal to the user of the device relative to the punch **402**, as demonstrated in FIG. **22**. In contrast, the transapical device **200** is oriented such that the filter umbrella **212** is positioned in front of the punch **206**, or distal to the user of the device **200** relative to the punch **206**, as shown in FIG. **17**A.

[0099] A next step is positioning the punch **206** within the native aortic valve, wherein the male element and female elements are fusiform. The male **218** and female **220** elements are fusiform during insertion and positioning of the punch **206** in the native aortic valve to minimize the detachment of calcium deposits from the aortic leaflets before the engagement of the filter umbrella **212** in the aorta. Otherwise, cutting edges of the male and female elements **223** and **225** may inadvertently catch on and dislodge calcium from the native aortic valve, thereby increasing the risk of an embolism.

[0100] The method then includes positioning the filter umbrella **212** in an aorta down-stream of the aortic valve. The filter umbrella is disengaged, or closed, during insertion to prevent any accidental damage to surrounding tissue or dislodgement of calcium deposits, similar to the punch **206**. This is achievable through a slidable hood **214**, as shown in FIGS. **16**A-**16**B for transapical devices, or a slidable hood **434**, as shown in FIG. **21**B for transaortic or transfemoral devices.

[0101] A further step is engaging the filter umbrella **212** such that the filter umbrella **212** allows blood to pass beyond the aorta, but catches dislodged calcium particles to prevent such particles from passing through the rest of the body via the aorta. This step is achievable via the slidable hood **214** or **434** sliding over the filter umbrella **212** or **424** such that the filter umbrella **212** or **424** is allowed to expand circumferentially to encompass the circumference of the aorta.

[0102] Another step includes opening the punch **206** within the native aortic valve **221** such that aortic valve leaflets **241** are positioned between the cutting edge **223** of the male element **218** and the cutting edge **225** of the female element **220**. FIG. **18**A shows the punch **206** opened to position the aortic leaflets between the male **218** and female **220** elements.

[0103] A next step includes closing the punch **206** over the aortic valve leaflets **241** so that the male element **218** applies force along the cutting edge **223** to a superior surface **242** of the aortic valve leaflets **241** and the female element **220**

applies force along the cutting edge **225** to an inferior surface **244** of the aortic valve leaflets **241**. FIG. **18**B demonstrates the closing of the punch **206**.

[0104] Another step includes perforating the native aortic valve **221** via the punch **206** to remove calcium deposits from the native aortic valve. FIG. **18**D shows the perforating of the native aortic valve **221** by the punch **206**.

[0105] The final step includes leaving a ring of calcium deposits **246** along the circumference of the native aortic valve **221**. The perforation of the native aortic valve **246** should leave a circumferential ring of the remaining tissue of the native aortic valve with a preferable length of 2-3 millimeters. Further, the perforation is preferably centered such that the resulting circumferential ring of tissue is uniform in radial length. As previously explained, a semi-rigid ring composed of the remaining aortic heart is useful in stabilizing any TAVI replacement valve during and after insertion. Additionally, less radial pressure is ultimately placed on the heart conduction system as the majority of the calcium deposits are removed from the native aortic valve. Further, the chance of paravalvular leaks is reduced, as the shortened aortic leaflets make insertion of replacement valves easier and more successful.

[0106] There are multiple embodiments for removing calcium deposits from aortic valves. A preferred embodiment of a device **500** for improving transcatheter aortic valve implantation is shown in FIG. **7**. The device includes a punch **502**, having a tip **506** attached to or formed by a male element **508** connected to a distal end of a primary tube **512** and a female element **514**, having a proximal end connected to a distal end of a secondary tube **518**, which is positioned coaxially around an outer surface of the primary tube **512**. The device **500** further includes a punch control element **504**, having a punch dial **524** attached to a proximal end of a punch spindle **522**, and a punch receptacle **520** with an inner cylindrical area **525** open at a proximal end to accept the punch spindle **522**, wherein the punch receptacle is connected to the secondary tube **518** and contains a centered coaxial hole to allow the primary tube **512** to pass through and attach to the punch spindle. As shown in FIGS. **8**C and **9**C, the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle. This action in turn raises and lowers the male element **508** via the primary tube **512** relative to the female element **514**, as shown in FIGS. **8**B and **9**B. The action of raising and lowering the male element **508** allows the device to perforate biological tissue, specifically, valve leaflets. FIGS. **8**A and **9**A show representations of the entire device **500**, as it is operated within a native aortic valve **528**.

[0107] The punch **502**, primary tube **512**, and punch control element **504** can also have a continuous, coaxially-centered hole through each enumerated element such that the device **500** can be run over a guide wire.

[0108] The punch **502** can be made of medical grade plastics or metals, as typically used in similar invasive devices. At least the male element **508** has a cutting edge **510** used to perforate an aortic leaflet or other biological tissue. The cutting edge **510** is typically located around a circumference of the male element **508**, and can be shaped in different manners, including, but not limited to, a uniform circle about a plane, a plurality of teeth in sine wave, square, triangle, or sawtooth pattern, or similar orientation.

[0109] The female element **514** can also have a cutting element **516** shaped to accept the pattern of the male cutting element **510** to allow the male **508** and female element to form a fusiform punch **502** during insertion of the device **500** through the aortic valve without snaring or otherwise inadvertently damaging tissue during insertion or positioning of the device. The female element **514** may likewise contain a receptacle for accepting the male cutting element **510**.

[0110] The tip **506** is conically shaped to pierce at least the heart at the apex and allow entry of the device **500** into the left ventricle and aortic valve. The tip **506** could also be used to pierce arterial walls, for example the aorta or femoral artery.

[0111] The primary **512** and secondary **518** tubes can be made from medical grade plastics, metals, or combinations thereof. While the secondary tube **518** must be hollow with a diameter large enough for the primary tube **512** to slide through, the primary tube **512** need not be hollow. There is no set length for either the primary tube **512** or the secondary tube **518**. However, the primary tube **512** is necessarily longer that the secondary tube **518**, and both should be long enough to comfortably allow the insertion and positioning of the punch **502** in the aortic valve, while simultaneously allowing a user to operate the punch control element **504**.

[0112] The punch control element **504** can be made from medical grade plastics, metals, or combinations thereof. The punch spindle **522** is preferably reversely-threaded and the inner cylindrical area **525** is preferably threaded to accept the reversely-threaded punch spindle **522**. However, other interactions are possible, for example, where the punch spindle **522** slidably engages the cylindrical area **525** and frictional forces from a rubber ring or equivalent maintain punch spindle position within the cylindrical area. The punch dial **524** need not be of any specific shape or size, but only sized and shaped to allow a user to manipulate the punch **502** via the primary tube **512**, punch spindle **522**, and punch control element **504**, generally.

[0113] Another embodiment of a device **600** for improving transcatheter aortic valve implantation is shown in FIGS. **10**-**13**. As shown in FIG. **10**, the device includes a punch **602**, having with a tip **606** attached to or formed by a male element **608** connected to a distal end of a primary tube **612** and a female element **614** having a proximal end connected to a distal end of a secondary tube **616**, which is positioned coaxially around an outer surface of the primary tube **612**. The device **600** further includes a punch control element **604**, having a first lever housing **618** attached to a first lever **628** and connected to a proximal end of the secondary tube **616**, wherein an opening in the first lever housing at a connection point between the secondary tube and the first lever housing allows the primary tube **612** to pass through the first lever housing and through the secondary tube. As shown in FIG. **11**, the first lever housing **618** slidably engages a spring housing **624** through an opening in the first lever housing opposite to the opening for the connection point between the secondary tube and first lever housing, such that the primary tube **612** passes continuously through the secondary tube, first lever housing, and spring housing. A spring **626** is attached at an end to the first lever housing **618**, and is positioned coaxially within the spring housing **624** and coaxially around the primary tube **612**. A second lever housing **620** is attached to the terminal end of each the primary tube **612**, the spring **626**, and the spring housing

624. The primary tube **612** and the spring **626** attach to the second lever housing **620** through an opening at the connection point between the spring housing **624** and the second lever housing. A second lever **630** is pivotably attached to the second lever housing **624** at an internal fulcrum point **632**. The first lever **628** and second lever **630** are pivotably connected at an external fulcrum point **622**.

[0114] Force applied to the second lever **630** in a direction toward the first lever **628** causes the second lever to pivot at the external fulcrum point **622**. The pivot motion at the external fulcrum point **622** in turn causes the second lever **630** to pivot at the internal fulcrum point **632**, where the second lever is attached to the second lever housing **620**. The pivoting at the internal fulcrum point **632** causes the second lever housing **620** to pull directly away from the first lever housing **618**, thereby stretching the spring **626** and pulling the primary tube **612** in the same direction until the male element **608** mates with the female element **614** preventing further sliding. The spring housing **624** is also pulled in the same direction causing the spring housing to slide within the first lever housing **620**. As force on the second lever **630** is reduced, the elastic force from the spring **624** pulls the second lever housing **620** back towards the first lever housing **618**, causing the spring housing **624** to slide farther inside the first lever housing **618** and the male element **608** to decouple from the female element **614**.

[0115] FIG. **12** shows the device **600** after the punch **602** has been inserted inside an aortic valve **601** and the second lever **630** has been release to allow the male element **608** to separate from the female element **614**. Aortic valve leaflets are then positioned between the male element **608** and the female element **614**.

[0116] FIG. **13** shows the device **600** perforating the aortic valve **601** as the second lever **630** is moved at the external fulcrum point **622** toward the first lever **628** activating the punch control element **604** and closing the male element **608** against the female element **614**. The cutting element **610** of the male element then perforates as the male element **608** is pulled against the female element **614**.

[0117] The punch **602**, primary tube **612**, and punch control element **604** can also have a continuous, coaxially-centered hole through each enumerated element such that the device **600** can be run over a guide wire.

[0118] The punch **602** can be made of medical grade plastics or metals, as typically used in similar invasive devices. At least the male element **608** has a cutting edge **610** used to perforate an aortic leaflet or other biological tissue. The cutting edge **610** is typically located around a circumference of the male element **608**, and can be shaped in different manners, including, but not limited to, a uniform circle about a plane, a plurality of teeth in sine wave, square, triangle, or sawtooth pattern, or similar orientation.

[0119] The female element **614** can also have a cutting element **615** shaped to accepted the pattern of the male cutting element **610** to allow a fusiform punch **602** during insert of the device **600** through the body and heart and into the aortic valve without snaring or otherwise inadvertently damaging tissue during insertion or positioning of the device. The female element **614** may likewise contain a receptacle for accepting the male cutting edge **610**.

[0120] The tip **606** is conically shaped to pierce at least the heart at the apex and allow entry of the device **600** into the left ventricle and aortic valve. The tip **606** could also be used to pierce arterial walls, for example the aorta or femoral artery.

[0121] The primary **612** and secondary **616** tubes can be made from medical grade plastics, metals, or combinations thereof. While the secondary tube **616** must be hollow with a diameter large enough for the primary tube **612** to slide through, the primary tube **612** need not be hollow. There is no set length for either the primary tube **612** or the secondary tube **616**. However, the primary tube **612** is necessarily longer that the secondary tube **616**, and both should be long enough to comfortably allow the insertion and positioning of the punch **602** in the aortic valve, while simultaneously allowing a user to operate the punch control element **604**.

[0122] The punch control element **604** can be made from medical grade plastics, metals, or combinations thereof. The first lever **628** and second lever **630** do not have a set length, shape or size, but should be long enough for a user to comfortably grasp and operate the levers **628** and **630** in one hand. The spring housing **624** should be of an appropriate diameter to allow the spring **626** to easily expand and contract during use, while simultaneously preventing the spring from bowing or bending substantially outward from the length of the spring.

[0123] The embodiment of the device **600** shown in FIGS. **10-13** can be used both in open-heart and closed-heart surgical operations. Namely, the device **600** can be inserted percutaneously through the femoral artery and up the aorta, or it can be inserted apically in a direct view approach, as well as transaortically.

[0124] Another embodiment of a device **200** is shown in FIGS. **14-19**C. FIG. **14** is representative of the device **200**. This embodiment includes stent system **208** having a stent sheath **214** attached at a closed end to a distal end of a primary tube **217** having a diameter large enough to allow at least a guide wire to pass coaxially through its center. The stent sheath **214**, as shown in FIG. **15**A and enlarged in FIG. **15**B, is open at an opposite end and positioned coaxially around the primary tube **217** with enough space for a stent **213**, a perforated mesh **211**, and a secondary tube **216** to be slidably positionable between the stent sheath and primary tube. A tip **210** is connected to, or formed from, the closed end of the stent sheath **214**. The stent **213** is covered with the perforated mesh **211** to form a perforated umbrella **212**, with the stent attached to a distal end of the secondary tube **216** positioned coaxially around an outer surface of the primary tube **217**.

[0125] A punch **206** has a male element **218** connected at a distal end to a proximal end of the secondary tube **216** and connected at a proximal end to a distal end of a tertiary tube **219**, which is positioned coaxially around an outer surface of the secondary tube **216**, and a female element **220** connected at a proximal end to a distal end of a quaternary tube **222**, which is positioned coaxially around an outer surface of the tertiary tube **219**.

[0126] The device **200** further includes a punch control element **204**, having a punch dial **232** attached to a proximal end of a punch spindle **228**, and a punch receptacle **226** with an inner cylindrical area **224** open at a proximal end to accept the punch spindle, wherein the punch receptacle is connected to a proximal end of the quaternary tube **222** and contains a centered coaxial hole to allow the tertiary tube

219, secondary tube 216, and primary tube 217 to pass through. The tertiary tube 219 attaches to the punch spindle 228 at a proximal end.

[0127] The punch dial 232 is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle 228 within the inner cylindrical area 224 of the punch receptacle 226, which raises and lowers the male element 218 via the tertiary tube 217 relative to the female element 220. As shown in FIGS. 18B and 18C, rotably removing the punch spindle 228 from the punch receptacle 226 pulls the male element 218 into contact with the female element 220 for either perforation or fusiform insertion. FIGS. 19B and 19C shows that rotatably depressing the punch spindle 228 into the punch receptacle 226 pushes the male element 218 away from the female element 220 for positioning of valve leaflets between the male and female element in anticipate of perforation. The action of raising and lowering the male element 218 allows the device to perforate biological tissue, specifically, valve leaflets. Further, the punch spindle 228 and punch dial 232 contain a centered coaxial hole to allow the primary and secondary tubes 217 and 216 to pass through.

[0128] The device 200 further includes a stent control element 202, having a stent dial 240 attached to a proximal end of a stent spindle 238, and stent receptacle 234 with an inner cylindrical area 236 open at a proximal end to accept the stent spindle, wherein the stent receptacle connects to a distal end of the secondary tube 216 which contains a centered coaxial hole to allow the primary tube 217 to pass through. The primary tube 217 attaches at a proximal end to the stent spindle 238.

[0129] The stent dial 240 is configured to turn either clockwise or counterclockwise to raise or depress the stent spindle 238 within the inner cylindrical area 236 of the stent receptacle 234, which in turn slides the stent sheath 214 relative to stent 213. FIG. 17C shows the depression of the punch spindle 238 in the punch receptacle 234 to raise the stent sheath 214. FIG. 17A shows the interaction of the stent expansion along the device 200, as a whole. Once the stent sheath 214 slides away from the stent 213 far enough, the stent is exposed and allowed to expand, as shown in FIG. 17B. The expansion of the stent 213 in turn expands the perforated mesh 211 circumferentially to allow the perforated umbrella 212 to encompass the cross-sectional area of an artery. FIG. 17D shows one possible shape of the stent 213. The stent 213 can be shaped in other ways, as long as circumference of the stent can encompass the aorta to catch any debris from passing through and forming embolisms.

[0130] As shown in FIG. 16A, to contract the perforated umbrella 212, the stent dial 240 rotates in the opposite direction such that the stent spindle 238 is pulled out of the stent receptacle 236. FIG. 16C shows the stent spindle 238 rotating out of the stent receptacle 234. The primary tube 217 is thereby pulled in the same direction as the stent spindle 238, and the stent sheath 214 slides back over the stent 213 compressing the stent and perforated mesh 211 between the stent sheath and secondary tube 216, as shown in FIG. 16B.

[0131] The punch 208 can be made of medical grade plastics or metals, as typically used in similar invasive devices. At least the male element 218 has a cutting edge 223 used to perforate an aortic leaflet or other biological tissue, as shown in FIGS. 18B and 18D. The cutting edge 223 is typically located around a circumference of the male element 218, and can be shaped in different manners, including, but not limited to, a uniform circle about a plane, a plurality of teeth in sine wave, square, triangle, or sawtooth pattern, or similar orientation. FIG. 20 shows an embodiment of the device 200 where the male cutting edge 223 has teeth in a sawtooth pattern.

[0132] The female element 220 can also have a cutting element 225 patterned to accepted the pattern of the male cutting element 223 to allow a fusiform punch 208 during insert of the device 200 through the aortic valve without snaring or otherwise inadvertently damaging tissue during insertion or positioning of the device, as shown as FIG. 18B. The female element 220 may likewise contain a receptacle for accepting the male cutting element 223.

[0133] The tip 210 may be conically shaped to pierce at least the heart at the apex and allow entry of the device 200 into the left ventricle and aortic valve. Alternatively, the tip 210 may be flattened with sufficiently rounded edges to prevent damage to tissue during insertion or removal of the device from the body.

[0134] The primary 217, secondary 216, tertiary 219, and quaternary 222 tubes can be made from medical grade plastics, metals, or combinations thereof. There is no set length for any of the tubes 216, 217, 219, and 222. However, the primary tube 217 is necessarily longer that the secondary tube 216, and the tertiary tube 219 is necessarily longer than the quaternary tube 222. All four tubes 216, 217, 219, and 222 should be long enough to comfortably allow the insertion and positioning of the stent system 208 and punch 206 in the aorta and aortic valve, while simultaneously allowing a user to operate the punch control element 204 and the stent control element 202.

[0135] The punch control element 204 can be made from medical grade plastics, metals, or combinations thereof. The punch spindle 228 is preferably reversely-threaded and the inner cylindrical area 224 of the punch receptacle 226 is preferably threaded to accept and secure the reversely-threaded punch spindle. FIG. 15C shows one embodiment of the punch receptacle 226. However, one possible alternate setup has the punch spindle slidably engaging the cylindrical area and frictional forces from a rubber ring or equivalent formed around the punch spindle maintaining the punch spindle position within the cylindrical area. The punch dial 232 need not be of any specific shape or size, but sized and shaped to allow a user to manipulate the punch 202 via the tertiary tube 219, punch spindle 228, and punch control element 204, generally.

[0136] The stent control element 202 can be made from medical grade plastics, metals, or combinations thereof. The stent spindle 238 is preferably reversely-threaded and the inner cylindrical area 236 of the stent spindle 234 is preferably threaded to accept and secure the reversely-threaded punch spindle. FIG. 15D shows one embodiment of the stent receptacle 234. However, an alternative interaction involves the stent spindle slidably engaging the cylindrical area and frictional forces from a rubber ring or equivalent formed around the stent spindle maintaining the stent spindle position within the cylindrical area. The stent dial 240 need not be of any specific shape or size, but sized and shaped to allow a user to manipulate the stent sheath 214 via the primary tube 217, stent spindle 238, and stent control element 202, generally.

[0137] The device 200 may further include a motor assembly 270, as shown in FIG. 23, used to rotatably close the

punch **206**, in addition to the punch control element **204**. The motor assembly **270** includes an operator control element **268** attached to a high speed motor **262**, which is attached to the male element **218** via cable **260**. The motor assembly **270** can only close the punch **206**, whereas the punch control element **204** can both open and close the punch **206**. The operator control element **268** activates and deactivates the high speed motor **262**, and may be in the form of a foot pedal as seen in FIG. **27**, but may also include a button, a hand-held pedal, or other similar device. The cable **260**, attached at one end to the male element **218** and at an opposite end to the high speed motor **262**, must be of a variable length, such that the male element may be pulled down to the female element **220** to form a fusiform punch **206** and then pushed up via the punch control element **204** to separate the male element from the female element.

[0138] Another embodiment of a device **400** is show in FIGS. **21**A-**22**. Device **400** is similar to device **200** in elements and function, but oriented differently to enter the body and aorta at different locations. The device **400** includes a punch **402** with a male element **412** with a proximal end connected to a distal end of a primary tube **416** and a conically-shaped distal end **410**. The punch element **402** further includes a female element **420**, having a proximal end connected to a secondary tube **422**, which is positioned coaxially around an outer surface of the primary tube **416**, which is positioned coaxially around an outer surface of the primary tube.

[0139] A self-expandable stent **426** covered with a perforated mesh **428** forms a stent umbrella **424**. The stent **426** is attached to a distal end of a tertiary tube **430** positioned coaxially around an outer surface of the secondary tube. A stent sheath **434** is attached to a distal end of a quaternary tube **432**, which is positioned coaxially around an outer surface of the tertiary tube **430**. The stent sheath **434** is open at a distal end and positioned coaxially around the tertiary tube **430** with enough space between the stent sheath and tertiary tube to allow the stent **426**, perforated mesh **428**, and stent umbrella **424** to be slidably positionable between the stent sheath and tertiary tube.

[0140] A stent control element **406** has a stent dial **442** attached to a proximal end of a reversely-threaded stent spindle **440**, a stent receptacle **436** with an inner cylindrical area **438** open at a proximal end and threaded to accept the stent spindle, wherein a distal end of the stent receptacle is attached to the proximal ends of the tertiary and quaternary tubes **430** and **432**, and contains a centered coaxial hole to allow the tertiary tube to pass through and connect to the stent spindle, and the stent spindle and stent dial contain a centered coaxial hole to allow the primary and secondary tube **416** and **422** to pass through. The stent dial **442** is configured to turn either clockwise or counterclockwise to raise or depress the stent spindle **440** within the inner cylindrical area **438** of the stent receptacle **436**, which in turn pushes the stent **426** out of the stent sheath **434** allowing expansion of the stent and pulls the stent into the stent sheath whereby a circumferential edge of the stent sheath causes the stent to contract as the stent spindle is raised.

[0141] A punch control element **408** includes a punch dial **450** attached to a proximal end of a reversely-threaded punch spindle **448**, a punch receptacle **446** with an inner cylindrical area **444** open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contains a centered coaxial hole to allow the primary tube **416** to pass through and attach to the punch spindle. The punch dial **450** is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle **448** within the inner cylindrical area **444** of the punch receptacle **446**, which raises and lowers the male element **412** via the primary tube **416** relative to the female element **420**.

[0142] The punch **402** can be made of medical grade plastics or metals, as typically used in similar invasive surgical devices. At least the male element **412** has a cutting edge **414** used to perforate an aortic leaflet or other biological tissue. The cutting edge **414** is typically located around a circumference of the male element **412**, and can be shaped in different manners, including, but not limited to, a uniform circle about a plane, a plurality of teeth in sine, square, triangle, or sawtooth pattern, or similar orientation.

[0143] The female element **420** can also have a cutting element **418** patterned to accepted the pattern of the male cutting element **414** to allow a fusiform punch **402** during insert of the device **400** through either the body and heart and into the aortic valve without snaring or otherwise inadvertently damaging tissue during insertion or positioning of the device. The female element **420** may likewise contain a receptacle for accepting the male cutting element **414**.

[0144] The tip **410** may be conically shaped to pierce at least the wall of the aorta or femoral artery and allow entry of the device **400** into the aorta and aortic valve. Alternatively, the tip **410** may be flattened with sufficiently rounded edges to prevent damage to tissue during insertion or removal of the device from the body.

[0145] The primary **416**, secondary **422**, tertiary **430**, and quaternary **432** tubes can be made from medical grade plastics, metals, or combinations thereof. There is no set length for any of the tubes **416**, **422**, **430** and **432**. However, the primary tube **416** is necessarily longer that the secondary tube **422**, and the tertiary tube **430** is necessarily longer than the quaternary tube **432**. All four tubes **416**, **422**, **430** and **432** should be long enough to comfortably allow the insertion and positioning of the stent system **404** and punch **402** in the aorta and aortic valve, while simultaneously allowing a user to operate the punch control element **408** and the stent control element **406**.

[0146] The punch control element **408** can be made from medical grade plastics, metals, or combinations thereof. The punch spindle **448** is preferably reversely-threaded and the inner cylindrical area **444** is preferably threaded to accept and secure the reversely-threaded punch spindle. However, a less preferable interaction between the punch spindle **448** and cylindrical area **444** involves the punch spindle slidably engaging the cylindrical area and frictional forces from a rubber ring or equivalent formed around the punch spindle maintaining the punch spindle position within the cylindrical area. The punch dial **450** need not be of any specific shape or size, but sized and shaped to allow a user to manipulate the punch **402** via the primary tube **416**, punch spindle **448**, and punch control element **408**, generally.

[0147] The stent control element **406** can be made from medical grade plastics, metals, or combinations thereof. The stent spindle **440** is preferably reversely-threaded and the inner cylindrical area **438** is preferably threaded to accept and secure the reversely-threaded punch spindle. However, a less preferable interaction between the stent spindle **440** and cylindrical area **438** involves the stent spindle slidably engaging the cylindrical area and frictional forces from a

rubber ring or equivalent formed around the stent spindle maintaining the stent spindle position within the cylindrical area. The stent dial **442** need not be of any specific shape or size, but sized and shaped to allow a user to manipulate the stent sheath **432** via the tertiary tube **430**, stent spindle **440**, and stent control element **406**, generally.

I claim:

1. A device for removing calcium deposits from an artery valve, comprising:

a tip acting as a stent steath attached to a distal end of a primary tube having a circumference large enough to at least allow a guide wire to pass through;

a self-expandable stent covered with a perforated mesh, with the self-expandable stent attached to a distal end of a secondary tube positioned coaxially around an outer surface of the primary tube;

a punch system, having a male element, with a proximal end connected to a tertiary tube, and a female element, having a proximal end connected to a quaternary tube, which is positioned coaxially around an outer surface of the tertiary tube, which is positioned coaxially around an outer surface of the secondary tube;

a punch control element connected at a distal end to the quaternary tube, having a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contain a centered coaxial hole to allow the tertiary tube to pass through and connect to the punch spindle, and the punch spindle and punch dial contain a centered coaxial hole to allow the primary and secondary tubes to pass through, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the tertiary tube relative to the female element; and

a stent control element, having a stent dial attached to a proximal end of a reversely-threaded stent spindle, a stent receptacle with an inner cylindrical area open at a proximal end and threaded to accept the stent spindle, wherein the stent receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the stent spindle, and wherein the stent dial is configured to turn either clockwise or counterclockwise to raise or depress the stent spindle within the inner cylindrical area of the stent receptacle, which in turn raises and lowers the stent sheath relative to the self-expandable stent.

2. The device of claim **1**, wherein the male element has teeth positioned along a circumferential edge of the proximal end, and the female element has groves positioned along a circumferential edge of the distal end positioned to accept the teeth of the male element.

3. The device of claim **1**, further comprising a motor assembly attached to the male element, where the motor assembly includes a high speed motor attached to the male element via a cable and an operator control element is attached to the high speed motor, wherein the operator control element is configured to active or deactivate the high speed motor, which when activated rotatably closes the male element against the female element.

4. A device for removing calcium deposits from an artery valve, comprising:

a punch system, having a tip attached to or formed by a male element with a proximal end connected to a distal end of a primary tube and a conically-shaped distal end, and a female element, having a proximal end connected to a secondary tube, which is positioned coaxially around an outer surface of the primary tube, which is positioned coaxially around an outer surface of the primary tube;

a self-expandable stent covered with a perforated mesh, with the self-expandable stent attached to a distal end of a tertiary tube positioned coaxially around an outer surface of the secondary tube;

a stent sheath attached to a distal end of a quaternary tube positioned coaxially around an outer surface of the tertiary tube;

a stent control element, having a stent dial attached to a proximal end of a reversely-threaded stent spindle, a stent receptacle with an inner cylindrical area open at a proximal end and threaded to accept the stent spindle, wherein a distal end of the stent receptacle is attached to the proximal ends of the secondary and quaternary tubes and contains a centered coaxial hole to allow the tertiary tube to pass through and connect to the stent spindle, and the stent spindle and stent dial contain a centered coaxial hole to allow the primary tube to pass through, and wherein the stent dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the stent receptacle, which in turn raises the stent out of the stent sheath allowing expansion of the stent and lowers the stent into the stent sheath whereby a circumferential edge of the stent sheath causes the stent to contract as the stent spindle is raised; and

a punch control element, having a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the punch spindle, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the primary tube relative to the female element.

5. The device of claim **4**, wherein the male element has teeth positioned along a circumferential edge of the proximal end and the female element has groves positioned along a circumferential edge of the distal end positioned to accept the teeth of the male element.

6. The device of claim **4**, further comprising further comprising a motor assembly attached to the male element, where the motor assembly includes a high speed motor attached to the male element via a cable and an operator control element is attached to the high speed motor, wherein the operator control element is configured to active or deactivate the high speed motor, which when activated rotatably closes the male element against the female element.

7. A method for improving implantation of transcatheter artery valve replacements, comprising:

inserting a device through an artery valve, wherein the device has a filter umbrella for catching debris from operation of the device and a punch for perforating the aortic valve;

positioning the punch within the native aortic valve, wherein the male element and female element are fusiform to avoid inadvertent damage to surrounding tissue;

positioning the filter umbrella in an aorta down-stream of blood flow through the artery valve, such that the filter umbrella allows blood to pass beyond the aorta and catches debris;

perforating the aortic valve to remove calcium deposits from the artery valve; and

leaving a ring of calcium deposits along the circumference of the native aortic valve.

8. The method of claim **7**, wherein the device is inserted through the native aortic valve transapically.

9. The method of claim **7**, wherein the device is inserted through the native aortic valve transfemorally or transaortically.

10. The method of claim **8**, wherein the device used includes,

a tip acting as a stent sheath attached to a distal end of a primary tube having a circumference large enough to at least allow a guide wire to pass through;

a self-expandable stent covered with a perforated mesh, with the self-expandable stent attached to a distal end of a secondary tube positioned coaxially around an outer surface of the primary tube;

a punch system, having a male element, with a proximal end connected to a tertiary tube, and a female element, having a proximal end connected to a quaternary tube, which is positioned coaxially around an outer surface of the tertiary tube, which is positioned coaxially around an outer surface of the secondary tube;

a punch control element connected at a distal end to the quaternary tube, having a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contain a centered coaxial hole to allow the tertiary tube to pass through and connect to the punch spindle, and the punch spindle and punch dial contain a centered coaxial hole to allow the primary and secondary tubes to pass through, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the tertiary tube relative to the female element; and

a stent control element, having a stent dial attached to a proximal end of a reversely-threaded stent spindle, a stent receptacle with an inner cylindrical area open at a proximal end and threaded to accept the stent spindle, wherein the stent receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the stent spindle, and wherein the stent dial is configured to turn either clockwise or counterclockwise to raise or depress the stent spindle within the inner cylindrical area of the stent receptacle, which in turn raises and lowers the stent sheath relative to the self-expandable stent.

11. The method of claim **9**, wherein the male element has teeth positioned along a circumferential edge of the proximal end, and the female element has groves positioned along a circumferential edge of the distal end positioned to accept the teeth of the male element.

12. The method of claim **10**, wherein the device used includes,

a punch system, having a tip attached to or formed by a male element with a proximal end connected to a distal end of a primary tube and a conically-shaped distal end, and a female element, having a proximal end connected to a secondary tube, which is positioned coaxially around an outer surface of the primary tube, which is positioned coaxially around an outer surface of the primary tube;

a self-expandable stent covered with a perforated mesh, with the self-expandable stent attached to a distal end of a tertiary tube positioned coaxially around an outer surface of the secondary tube;

a stent sheath attached to a distal end of a quaternary tube positioned coaxially around an outer surface of the tertiary tube;

a stent control element, having a stent dial attached to a proximal end of a reversely-threaded stent spindle, a stent receptacle with an inner cylindrical area open at a proximal end and threaded to accept the stent spindle, wherein a distal end of the stent receptacle is attached to the proximal ends of the secondary and quaternary tubes and contains a centered coaxial hole to allow the tertiary tube to pass through and connect to the stent spindle, and the stent spindle and stent dial contain a centered coaxial hole to allow the primary tube to pass through, and wherein the stent dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the stent receptacle, which in turn raises the stent out of the stent sheath allowing expansion of the stent and lowers the stent into the stent sheath whereby a circumferential edge of the stent sheath causes the stent to contract as the stent spindle is raised; and

a punch control element, having a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the punch spindle, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the primary tube relative to the female element.

13. The method of claim **11**, wherein the male element has teeth positioned along a circumferential edge of the proximal end, and the female element has groves positioned along a circumferential edge of the distal end positioned to accept the teeth of the male element.

14. A device for removing calcium deposits from a valve, comprising

a punch system, having a male element with a proximal end connected to a distal end of a primary tube and a conically-shaped distal end, a female element, having a proximal end connected to a secondary tube, which is positioned coaxially around an outer surface of the

primary tube, which is positioned coaxially around an outer surface of the primary tube;

a punch control element attached to the primary and secondary tubes and end opposite to the punch element, wherein the punch control element is configured to move the male element in relation to the female element.

15. The device of claim **14**, further comprising further comprising a motor assembly attached to the male element, where the motor assembly includes a high speed motor attached to the male element via a cable and an operator control element is attached to the high speed motor, wherein the operator control element is configured to active or deactivate the high speed motor, which when activated rotatably closes the male element against the female element.

16. The device of claim **14**, wherein the punch control element further comprises:

a punch dial attached to a proximal end of a reversely-threaded punch spindle, a punch receptacle with an inner cylindrical area open at a proximal end and threaded to accept the punch spindle, wherein the punch receptacle contains a centered coaxial hole to allow the primary tube to pass through and attach to the punch spindle, and wherein the punch dial is configured to turn either clockwise or counterclockwise to raise or depress the punch spindle within the inner cylindrical area of the punch receptacle, which raises and lowers the male element via the primary tube relative to the female element.

17. The device of claim **14**, wherein the punch control element further comprises:

a first lever housing attached to a first lever and connected to a proximal end of the secondary tube, wherein an opening in the first lever housing at a connection point between the secondary tubing and the first lever housing allows the primary tube to pass through the first lever housing and through the secondary tube;

a spring housing slidably engaging the first lever housing through an opening in the first lever housing opposite to the opening for the connection point between the secondary tube and first lever housing;

A spring attached at an end to the first lever housing and positioned coaxially within the spring housing and coaxially around the primary tube;

A second lever housing attached to the terminal end of each the primary tube, the spring, and the spring housing, wherein the primary tube and the spring attach to the second lever housing through an opening at the connection point between the spring housing and the second lever housing; and

A second lever pivotably attached to the second lever housing at an internal fulcrum point, wherein the first lever and second lever are pivotably connected at an external fulcrum point.

18. The device of claim **14**, wherein the male element has teeth positioned along a circumferential edge of the proximal end, and the female element has groves positioned along a circumferential edge of the end distal positioned to accept the teeth of the male element.

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