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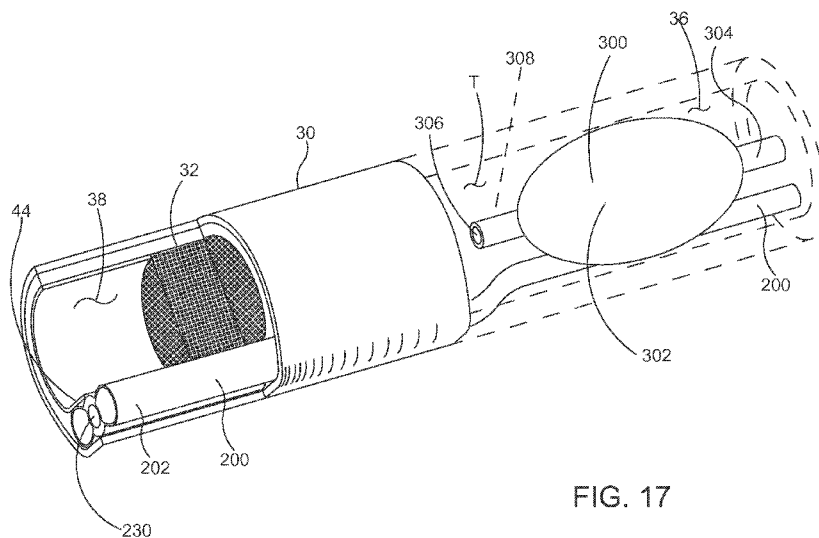


FIG. 17

(57) Abstract: A system and method for treating a blood vessel that is at least partially obstructed by an occlusion which divides the lumen into a proximal lumen segment and a distal lumen segment. The system includes an orienting catheter having an orientation element positionable in an intrawall space of the vessel and an occlusion catheter having an occlusion balloon inflatable in the proximal lumen segment so as to isolate a target volume including the intrawall space. The pressure inside the target volume is reduced to a pressure below the pressure of the distal lumen segment so that the intima presses against the orienting element of the orienting catheter. A distal end of a reentry device may be advanced from the orienting catheter through the intima and into the distal lumen segment.



SYSTEMS, APPARATUS AND METHODS FOR TREATING BLOOD VESSELS**CROSS REFERENCE TO RELATED APPLICATION**

This application claims the benefit of U.S. Provisional Application Serial No. 5 61/781,217, filed March 14, 2013, the entire disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

10 This disclosure relates to systems and devices for treating chronic occlusions in blood vessels and associated methods. More particularly, this disclosure relates to devices for establishing a blood flow path around a chronic total occlusion and methods for fabricating those devices.

BACKGROUND

15 A number of diseases are caused by the build-up of plaque in the arteries. These plaque deposits limit blood flow to the tissues that are supplied by that particular artery. When these deposits build up in the arteries of the heart, the problem is called coronary artery disease (CAD). When these deposits build up in the arteries of a limb, such as a leg, the condition is called peripheral artery disease (PAD).

20 Peripheral artery disease affects 8 to 12 million individuals in the United States and is also prevalent in Europe and Asia. Roughly 30% of the population over the age of 70 suffers from PAD. PAD typically causes muscle fatigue or pain brought about by exertion and relieved by rest. Symptoms of PAD can include leg pain during walking and wounds that do not heal. The inability to walk without leg pain often causes patients to stop exercising and reduces the 25 patient's mobility. When the plaque builds up to the point where an artery is totally occluded, the obstruction is referred to as a Chronic Total Occlusion (CTO). A CTO that occludes the peripheral arteries for PAD patients is extremely serious. PAD patients that suffer from a CTO often enter a downward spiral towards death. Often the CTO in a peripheral artery results in limb gangrene, which requires limb amputation to resolve. The limb amputation in turn causes 30 other complications, and roughly half of all PAD patients die within two years of a limb amputation.

The blood pumping action of the heart muscle is critical to sustaining the life of a patient. In order for the heart to function properly the tissues of the heart muscle must be continuously supplied and re-supplied with oxygen. To receive an adequate supply of oxygen, the heart

muscle must be well perfused with blood. In a healthy heart, blood perfusion is accomplished with a system of arteries and capillaries. However, due to age, high cholesterol and other contributing factors, a large percentage of the population has arterial atherosclerosis that totally occludes portions of the patient's coronary arteries. A chronic total occlusion (CTO) in a coronary artery may cause painful angina, atrophy of cardiac tissue and patient death.

SUMMARY

The disclosure is directed to several alternative designs, materials and methods of manufacturing medical device structures and assemblies, and uses thereof.

Accordingly, one illustrative embodiment is a system for treating a blood vessel including a blood vessel wall defining a blood vessel lumen where the blood vessel lumen is at least partially obstructed by an occlusion. The occlusion divides the lumen into a proximal lumen segment and a distal lumen segment. The system includes an orienting catheter and an occlusion catheter. The orienting catheter includes an orienting catheter shaft carrying an orienting element and a tracking element advanceable along the orienting catheter shaft. The occlusion catheter includes a balloon and a coupling element configured to engage a complementary coupling element of the tracking element to form a connection therebetween. The occlusion catheter defines an inflation lumen disposed in fluid communication with an interior of the balloon so that the balloon can be selectively inflated by injecting an inflation fluid through the inflation lumen. The balloon, when in an inflated state, is sized so as to occlude the blood vessel lumen to isolate a target volume defined by blood vessel tissues. The occlusion catheter defines an aspiration lumen disposed in fluid communication with a distal port positioned so that fluid can be withdrawn from the target volume and into the aspiration lumen.

Another illustrative embodiment is a method for treating a blood vessel including a blood vessel wall defining a blood vessel lumen, where the blood vessel lumen is at least partially obstructed by an occlusion. The occlusion divides the lumen into a proximal lumen segment and a distal lumen segment. The method includes positioning an orienting element of an orienting catheter inside an intrawall space located distal of the occlusion from the proximal lumen segment. The intrawall space is located between an intima and an adventitia of the blood vessel wall. An occluding element of an occlusion catheter is positioned in the proximal lumen segment at a location near the occlusion. The occluding element includes a balloon. The balloon of the occlusion catheter is inflated in the proximal lumen segment so as to isolate a target volume. The target volume includes the intrawall space. The pressure inside the target volume is reduced. The orienting element is deployed in the intrawall space so that the orienting

catheter assumes an orientation in which a port of the orienting catheter is directed toward the distal lumen segment. A distal end of a reentry device is advanced from the port through the intima and into the distal lumen segment.

Yet another illustrative embodiment is a method for treating a blood vessel including a
5 blood vessel wall defining a blood vessel lumen, where the blood vessel lumen is at least partially obstructed by an occlusion. The occlusion divides the lumen into a proximal lumen segment and a distal lumen segment. The method includes positioning an orienting element of an orienting catheter inside an intrawall space located distal of the occlusion from the proximal lumen segment. The intrawall space is located between an intima and an adventitia of the blood
10 vessel wall. An occluding element of an occlusion catheter is positioned in the proximal lumen segment at a location near the occlusion. The occluding element includes a balloon. The balloon of the occlusion catheter is inflated in the proximal lumen segment so as to isolate a target volume. The target volume includes the intrawall space. The volume of the target volume is reduced so that the intima presses against the orienting element of the orienting
15 catheter. The orienting element is deployed in the intrawall space so that the orienting catheter assumes an orientation in which a port of the orienting catheter is directed toward the distal lumen segment. The distal end of a reentry device is advanced from the port through the intima and into the distal lumen segment.

The above summary of some example embodiments is not intended to describe each
20 disclosed embodiment or every implementation of the aspects of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a stylized anterior view showing a human patient. A portion of the patient's arterial system is schematically illustrated in Figure 1.

25 Figure 2A is an enlarged schematic view showing a portion of the arterial system of a patient who has been treated for peripheral artery disease (PAD).

Figure 2B is an enlarged schematic view showing a portion of the arterial system of a patient who has been treated for coronary artery disease (CAD).

30 Figure 3 is a stylized perspective view illustrating a blood vessel having a wall comprising three layers.

Figure 4 is an additional stylized perspective view of a blood vessel having a wall including an adventitia, a media, and an intima.

Figure 5 is a stylized drawing showing a human heart.

Figure 6 is a stylized depiction of a display screen that is part of a fluoroscopy system. In Figure 6 an angiographic image illustrating the vasculature of the heart is projected onto the display screen.

5 Figures 7A-7C diagrammatically illustrate exemplary situations that may disrupt a physician's ability to visualize a portion of a patient's vasculature.

Figure 8A is a stylized depiction of a heart including a blood vessel.

Figure 8B is a stylized depiction of a display screen that is part of a fluoroscopy system. In Figure 8B an angiographic image illustrating the blood vessel shown in Figure 8A is projected onto the display screen.

10 Figure 8C is an additional stylized depiction of the blood vessel and heart shown in Figure 8A.

Figure 8D is a stylized depiction of a display screen that is part of a fluoroscopy system. In Figure 8D an angiographic image illustrating the blood vessel shown in Figure 8C is projected onto the display screen.

15 Figure 9A is a perspective view showing an assembly including an orienting catheter and a re-entry device. The assembly of Figure 9A may be used, for example, to establish a blood flow path between a proximal segment of a blood vessel and a distal segment of a blood vessel that are separated by an occlusion.

20 Figure 9B is an enlarged isometric view further illustrating a portion of the assembly shown in Figure 9A.

Figure 9C is a cross-section view taken along section line C-C shown in Figure 9A.

Figure 9D is a cross-section view taken along section line D-D shown in Figure 9A.

25 Figure 10 through Figure 22 are a series of stylized fragment views illustrating various steps that may be included as part of the methods in accordance with the detailed description. The apparatus described herein may be useful, for example, when performing these methods.

30 Figure 23 is a plan view showing a system that may be useful, for example, when establishing a blood flow path between a proximal segment of a blood vessel and a distal segment of a blood vessel that are separated by an occlusion. The system of Figure 23 may also be used to facilitate visualization of a patient's vasculature using fluoroscopic techniques when conditions arise which interfere with the flow of radiopaque media.

Figure 24A is a plan view showing a system in accordance with the detailed description.

Figure 24B is an enlarged plan view further illustrating a portion of the system shown in Figure 24A.

Figure 25A is an additional plan view illustrating a second configuration of the system shown in Figures 24A-24B.

Figure 25B is an enlarged plan view further illustrating a portion of the system shown in Figure 25A.

5 Figure 26A is a plan view showing a system in accordance with the detailed description.

Figure 26B is an enlarged plan view further illustrating a portion of the system shown in Figure 26A.

Figure 27A is an additional plan view illustrating a second configuration of the system shown in Figures 26A-26B.

10 Figure 27B is an enlarged plan view further illustrating a portion of the system shown in Figure 27A.

Figure 28A is a stylized pictorial view of a blood vessel having a wall including an adventitia, a media, and an intima.

15 Figure 28B is an additional stylized pictorial view of the blood vessel shown in Figure 28A.

DETAILED DESCRIPTION

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are
20 not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

Figure 1 is a stylized anterior view illustrating the cardiovascular system of a human patient. The cardiovascular system of Figure 1 includes a heart 7 that pumps blood and an arterial system that distributes oxygen rich blood throughout the body. During each heartbeat,
25 the left ventricle of heart 7 contracts, pumping blood through the aortic valve and into the ascending aorta 74. Blood from the ascending aorta 74 flows through the aortic arch 76 and down the descending aorta 12 to the lower body. Blood from the ascending aorta 74 also flows into the left coronary artery 70B and the right coronary artery 70A. In a healthy heart, the left coronary artery 70B and the right coronary artery 70A provide a continuous flow of blood to the
30 heart which assures that the heart muscle remains well oxygenated.

The descending aorta 12 gives off numerous branches that supply oxygenated blood to the chest cage and the organs within the chest. The descending aorta 12 continues to the iliac bifurcation 30, which is a branch that splits into the two common iliac arteries 16A and 16B. The iliac arterial vasculature includes two branches continuing from the iliac bifurcation 30.

The right branch includes the right common iliac artery 16A, which bifurcates into the right external iliac artery 25A and the right internal iliac artery 27A. When the right external iliac artery 25A passes posterior to the inguinal ligament, it becomes the right femoral artery 29A of the right leg. The left branch of the iliac arterial vasculature includes the left common iliac artery 16B, which bifurcates into the left external iliac artery 25B and the left internal iliac artery 27B. When the left external iliac artery 25B passes posterior to the inguinal ligament, it becomes the left femoral artery 29B of the left leg.

In the exemplary embodiment of Figure 1, an occlusion 32 is blocking blood flow through a portion of a blood vessel within a target region T of the patient's arterial system. The occlusion 32 is obstructing blood flow between a proximal segment 120 of the blood vessel and a distal segment 138 of the blood vessel. A system in accordance with the present detailed description may be used to establish a blood flow path between proximal segment 120 and distal segment 138.

Figure 2A is an enlarged schematic view showing a portion of the arterial system of a patient who has been treated for peripheral artery disease (PAD). The portion of the arterial system shown in Figure 2A includes the descending aorta 12, the iliac bifurcation 30, the right common iliac artery 16A and the left common iliac artery 16B. In the exemplary embodiment of Figure 2A, the patient's condition has been treated by establishing a blood flow path around an occlusion 32. The blood flow around occlusion 32 is illustrated using arrows in Figure 2A. The portion of the arterial system located in target region T may be treated using a contralateral approach. When using the contralateral approach, an endovascular device may enter the vascular system at an access point P. After entering the arterial system the endovascular device may be advanced through iliac bifurcation 30 to reach the target region T in the leg opposite the leg that is the site of access. In other instances, another approach may be used to reach the target region T.

Figure 2B is an enlarged schematic view showing a portion of the arterial system of a patient who has been treated for coronary artery disease (CAD). The portion of the arterial system shown in Figure 2B includes the aortic valve 72, the right coronary artery 70A, the left coronary artery 70B, the ascending aorta 74, and the aortic arch 76. Left coronary artery 70B and right coronary artery 70A each meet the ascending aorta 74 at an ostium. During the systolic phase of each cardiac cycle, oxygen rich blood from the ascending aorta 74 flows through left coronary artery 70B and right coronary artery 70A. In a healthy heart, this oxygen rich blood is distributed throughout the heart by a network of arteries and capillaries.

In the exemplary embodiment of Figure 2B, the patient's condition has been treated by establishing a blood flow path around an occlusion 32. The blood flow around occlusion 32 is illustrated using arrows in Figure 2B. In the exemplary embodiment of Figure 2B, occlusion 32 is located in left coronary artery 70B. The methodology for treating a coronary artery may include inserting a guide catheter into a femoral artery and advancing the guide catheter such that its distal tip moves through that artery, up the descending aorta, through the aortic arch and ultimately into the ostium of the coronary artery. A system in accordance with this detailed description may then be advanced through the guide catheter into the coronary artery. Once in the coronary artery, the system may be used to establish a blood flow path between a proximal segment of the coronary artery and a distal segment of the coronary artery. In other instances, another approach may be used to treat the coronary artery.

Figure 3 is a stylized perspective view illustrating a blood vessel 30 having a wall 40. In Figure 3, wall 40 of blood vessel 30 is shown having three layers. The outermost layer of wall 40 is the adventitia 42 and the innermost layer of wall 40 is the intima 44. Intima 44 defines a true lumen 34 of blood vessel 30. The tissues extending between intima 44 and adventitia 42 may be collectively referred to as the media M. For purposes of illustration, intima 44, media M and adventitia 42 are each shown as a single homogenous layer in Figure 3. In the human body, however, the intima 44 and the media M each comprise a number of sub-layers. The transition between the external most portion of the intima 44 and the internal most portion of the media M is sometimes referred to as the subintimal space. In the embodiment of Figure 3, an occlusion 32 is blocking the true lumen 34 of blood vessel 30. Occlusion 32 divides true lumen 34 into a proximal lumen segment 36 and a distal lumen segment 38.

Figure 4 is an additional stylized perspective view of a blood vessel 30 having a wall 40 including an adventitia 42, a media M, and an intima 44. In the embodiment of Figure 4, a portion of intima 44 has become separated from the other layers of blood vessel wall 40. This situation may occur, for example, when a physician has passed one or more prolapsed guidewires, or other medical device, between intima 44 and adventitia 42. A prolapsed guidewire is a guidewire having a distal tip that has been bent to form a loop or knuckle. The human heart includes a number of blood vessels having the general structure illustrated in Figure 4. Examples of these blood vessels include the left coronary artery and the right coronary artery.

Figure 5 is a stylized drawing showing a human heart. The heart of Figure 5 includes a plurality of coronary arteries, all of which are susceptible to occlusion. Under certain physiological circumstances and given sufficient time, some occlusions may become total or complete. As used herein, the terms total occlusion and complete occlusion are intended to refer

to the same or similar degree of occlusion with some possible variation in the age of the occlusion. Generally, a total occlusion refers to a vascular lumen that is ninety percent or more functionally occluded in cross-sectional area, rendering it with little to no blood flow therethrough and making it difficult or impossible to pass a conventional guide wire therethrough. Also generally, the older the total occlusion the more organized the occlusive material will be and the more fibrous and calcified it will become. According to one accepted clinical definition, a total occlusion is considered chronic if more than two weeks have passed since the onset of symptoms.

Methods and apparatus disclosed in this detailed description may be useful, for example, to establish a blood flow path around an occlusion (e.g., a total occlusion) in a blood vessel. Methods and apparatus disclosed in this detailed description may also be used to facilitate visualization of a patient's vasculature using fluoroscopic techniques. Fluoroscopy is a medical imaging technique used by physicians to obtain real-time moving images of the internal structures of a patient through the use of a fluoroscope. During a procedure utilizing fluoroscopy, a radio-opaque contrast agent is injected into the blood stream in a selected area of the patient's vasculature. This causes blood flowing through the selected areas to become visible on a display screen.

Figure 6 is a stylized depiction of a display screen FD that is part of a fluoroscopy system. In Figure 6 an angiographic image AI illustrating the vasculature of the heart is projected onto display screen FD. Fluoroscopic systems that may be suitable in some applications are commercially available from GE Healthcare (Chalfont, St. Giles, UK) and Siemens (Munich, Bayern, DE).

A physician's ability to visualize a portion of a patient's vasculature may be disrupted during some medical procedures. In some cases, this disruption may make it difficult or impossible for the physician to successfully complete the procedure. Figures 7A-7C are somewhat symbolic diagrams illustrating exemplary situations that may disrupt a physician's ability to visualize a portion of a patient's vasculature.

Figure 7A is a stylized diagram showing a portion of a blood vessel 30 that is being treated by a physician. In Figure 7A, an occlusion 32 can be seen dividing true lumen 34 of blood vessel 30 into a proximal lumen segment 36 and a distal lumen segment 38. Proximal lumen segment 36 is generally in fluid communication with the left ventricle of the heart. Distal lumen segment 38 is generally in fluid communication with the right atrium of the heart. As the left ventricle pumps blood into proximal segment 36, the fluid in that area of the blood vessel 30 will have a ventral pressure PV. At the same time, the blood in distal segment 38 will have an

atrial pressure PA. Due to the blood pumping action of the heart, ventral pressure PV is generally greater than atrial pressure PA. Accordingly, it will be appreciated that there is a pressure differential across occlusion 32 in the embodiment of Figure 7A.

In the embodiment of Figure 7B, a physician has created an intrawall space S extending
5 between intima 44 and adventitia 42 of blood vessel wall 40. Intrawall space S may be created, for example, by moving one or more prolapsed guidewires, or other medical device, between intima 44 and adventitia 42. A prolapsed guidewire may also be moved between occlusion 32 and adventitia 42, thereby establishing fluid communication between proximal lumen segment 36 and intrawall space S. In the embodiment of Figure 7B, blood from proximal lumen segment
10 36 has filled intrawall space S.

In the embodiment of Figure 7B, the blood inside intrawall space S is generally at ventricle pressure PV and the blood inside distal lumen segment 38 is generally at atrial pressure PA. Accordingly, there is a pressure differential across intima 44 in the embodiment of Figure 7B. This pressure differential has caused intrawall space S to fill with blood from proximal
15 lumen segment 36 in the embodiment of Figure 7B.

Figure 7C is an additional stylized representation of blood vessel 30 and intrawall space S. By comparing Figure 7C with Figure 7B, it will be appreciated that the length L of intrawall space S has become greater. In the exemplary embodiment of Figure 7C, the pressure differential across intima 44 has caused additional dissection of the blood vessel wall. In some
20 cases, the length of a dissection can grow in this way even when that is not the result desired or intended by the physician. As further illustrated in Figure 8, an elongated dissection can interfere with the physician's ability to "see" a portion of the vasculature using fluoroscopic techniques.

Figure 8A is a stylized depiction of a heart H including a blood vessel 30. In the
25 embodiment of Figure 8A, an occlusion 32 is blocking the true lumen 34 of blood vessel 30. Occlusion 32 divides true lumen 34 into a proximal lumen segment 36 and a distal lumen segment 38. During a surgical procedure, a physician may wish to view proximal lumen segment 36 and distal lumen segment 38 of blood vessel 30 using fluoroscopic techniques.

When using fluoroscopic techniques, the physician may inject a radio-opaque contrast
30 agent into the blood stream in the areas near occlusion 32. The radio-opaque contrast agent may be injected into the lumen of blood vessel 30 from both an antegrade direction A and a retrograde direction R. Antegrade direction A and a retrograde direction R are both represented with arrows in Figure 8A.

Figure 8B is a stylized depiction of a display screen FD that is part of a fluoroscopy system. In Figure 8B an angiographic image AI illustrating blood vessel 30 of Figure 8A is projected onto display screen FD. The radio-opaque contrast agent inside blood vessel 30 has made proximal lumen segment 36 and distal lumen segment 38 visible on display screen FD.

5 Figure 8C is an additional stylized depiction of blood vessel 30 and heart H shown in Figure 8A. In the embodiment of Figure 8C, a physician has created an intrawall space S extending between intima 44 and adventitia 42 of blood vessel 30. Intrawall space S may be created, for example, by moving one or more prolapsed guidewires, or other medical device, between intima 44 and adventitia 42. A prolapsed guidewire may also be moved between
10 occlusion 32 and adventitia 42, thereby establishing fluid communication between proximal lumen segment 36 and intrawall space S. In the embodiment of Figure 8C, blood from proximal lumen segment 36 has filled intrawall space S. Also in the embodiment of Figure 8C, there is a pressure differential across intima 44 between intrawall space S and distal segment 38. This pressure differential is due to the fact that the blood inside the true lumen distal of occlusion 32
15 is generally at atrial pressure PA and the blood inside intrawall space S is at ventral pressure PV.

Any radio-opaque contrast agent traveling in the retrograde direction R inside true lumen 34 of blood vessel 30 is unlikely to reach the area of distal lumen segment 38 nearest to occlusion 32 because this area of the true lumen 34 is occupied by intrawall space S. Additionally, any radio-opaque contrast agent travelling in the antegrade direction A inside true
20 lumen 34 of blood vessel 30 is unlikely to enter intrawall space S because no blood is leaving intrawall space S to make room for the entering fluid. If no radio-opaque contrast agent enters intrawall space S, then that area of the vasculature cannot be displayed using fluoroscopic techniques.

Figure 8D is a stylized depiction of a fluoroscopic display screen FD. In Figure 8D an
25 angiographic image AI illustrating blood vessel 30 of Figure 8C is projected onto display screen FD. By comparing Figure 8D with Figure 8B, it will be appreciated that a substantial portion of distal lumen segment 38 is not visible in angiographic image AI. The portion of blood vessel 30 that is not displayed in angiographic image AI generally corresponds to the portion of distal lumen segment 38 that is occupied by intrawall space S.

30 Figure 9A is a perspective view showing an assembly 90 including orienting catheter 200 and re-entry device 100. Assembly 90 may be used, for example, to establish a blood flow path between a proximal segment of a blood vessel and a distal segment of a blood vessel that are separated by a chronic total occlusion. Figure 9B is an enlarged isometric view further illustrating a portion of assembly 90.

Orienting catheter 200 of Figure 9A comprises a shaft assembly 202 and an orienting element 204, such as an orienting balloon, that is carried by shaft assembly 202. Orienting element 204 is capable of assuming both a collapsed shape and an expanded shape. Orienting element 204 may be selectively placed in the collapsed shape, for example, while the orienting element 204 is being advanced past an occlusion. Orienting element 204 may be selectively placed in the expanded shape, for example, while the orienting catheter 200 is being used to direct re-entry device 100 toward the lumen of a blood vessel. Orienting element 204 is shown assuming the expanded shape.

Orienting element 204 of orienting catheter 200 comprises a first portion 206 and a second portion 208. In the embodiment of Figure 9B, first portion 206 of orienting element 204 comprises a first inflatable member 220. Second portion 208 of orienting element 204 comprises a second inflatable member 224 in the embodiment of Figure 9B.

First inflatable member 220 of orienting element 204 extends in a first direction 20 away from longitudinal axis 222 of shaft assembly 202. Second inflatable member 224 of orienting element 204 extends away from longitudinal axis 222 of shaft assembly 202 in a second direction 22. First direction 20 and second direction 22 are represented with arrows in Figure 9A. With reference to Figure 9A, it will be appreciated that second direction 22 is generally opposite first direction 20. In Figure 9A, the arrows representing first direction 20 and second direction 22 are directed about 180 degrees away from one another.

Shaft assembly 202 of Figure 9A defines a first aperture 226 and a second aperture 228 (shown in Figure 9B). In the embodiment of Figure 9A, first aperture 226 extends away from central lumen 230 in a third direction 24. Second aperture 228 extends away from central lumen 230 in a fourth direction 26. Third direction 24 and fourth direction 26 are represented with arrows in Figure 9A. In the embodiment of Figure 9A, third direction 24 and fourth direction 26 extend in generally opposite directions. In Figure 9A, the arrows representing third direction 24 and fourth direction 26 are directed about 180 degrees away from each other and perpendicular to the first and second directions 20, 22.

A hub 236 is fixed to the proximal end of shaft assembly 202. Hub 236 includes an inflation port 238. Inflation port 238 fluidly communicates with an interior of first inflatable member 220 and second inflatable member 224 via inflation lumens IL defined by shaft assembly 202. The inflatable members 220, 224 may be inflated by injecting an inflation media into inflation port 238. Examples of inflation media that may be suitable in some applications include saline, carbon dioxide, and nitrogen.

5 Orienting catheter 200 defines a proximal port 232, a distal port 234 and a central lumen 230 that extends between proximal port 232 and distal port 234. In the embodiment of Figure 9A, proximal port 232 is defined by hub 236 and distal port 234 is defined by shaft assembly 202. Re-entry device 100 may be inserted into proximal port 232, advanced along central lumen 230, and advanced through any one of distal port 234, first aperture 226 and second aperture 228.

10 Figure 9C is a cross-section view of assembly 90 taken along section line C-C shown in Figure 9A. With reference to Figure 9C, it will be appreciated that re-entry device 100 may comprise a core wire 104 that is disposed in a central lumen 230 defined by shaft assembly 202 of orienting catheter 200. Figure 9D is a cross-section view of assembly 90 taken along section line D-D shown in Figure 9A. With reference to Figure 9D, it will be appreciated that the distal portion of shaft assembly 202 defines a central lumen 230. Core wire 104 of re-entry device 100 can be seen residing in central lumen 230 in Figure 9D.

15 Figure 10 through Figure 22 are a series of stylized pictorial views illustrating various steps that may be included as part of the methods in accordance with this detailed description. Methods and apparatus in accordance with the present detailed description may be used, for example, to establish a blood flow path around an occlusion in a blood vessel.

20 Figure 10 is a longitudinal cross-sectional view of a blood vessel 30 having an occlusion 32 blocking the true lumen 34 thereof. Occlusion 32 divides true lumen 34 into a proximal lumen segment 36 and a distal lumen segment 38. In Figure 10, a distal portion of a crossing device 150 is shown extending into proximal lumen segment 36 of true lumen 34. Crossing device 150 may be advanced over a guidewire to the position shown in Figure 10. In the embodiment of Figure 10, crossing device 150 comprises a tip 152 that is fixed to a distal end of a shaft 154. Tip 152 can be seen residing in proximal lumen segment 36 of true lumen 34 in Figure 10.

25 Figure 11 is an additional longitudinal cross-sectional view of blood vessel 30. By comparing Figure 11 with the previous figure, it will be appreciated that tip 152 of crossing device 150 has been advanced in a distal direction D. Distal direction D is illustrated using an arrow in Figure 11. In the embodiment of Figure 11, tip 152 of crossing device 150 is disposed in a position between occlusion 32 and adventitia 42 of blood vessel wall 40. Tip 152 is shown disposed adjacent occlusion 32 in Figure 11. With reference to Figure 11, it will be appreciated that crossing device 150 extends through intima 44 to the position between occlusion 32 and adventitia 42 of blood vessel 30.

Figure 12 is an additional view of blood vessel 30 and crossing device 150 shown in the previous figure. In the embodiment of Figure 12, tip 152 of crossing device 150 has been advanced in distal direction D so that tip 152 is disposed at a location distal of occlusion 32. In the embodiment of Figure 12, crossing device has moved in distal direction D between intima 44 and adventitia 42 as it has advanced distally beyond occlusion 32.

With reference to the sequence of three figures described immediately above, it will be appreciated that methods in accordance with the present detailed description may include the step of advancing a crossing device along a blood vessel to a location near an occlusion. The crossing device may be advanced over a guidewire that has been previously advanced to that location. These methods may also include the step of advancing the distal end of a crossing device (e.g., crossing device 150) between an occlusion and the adventitia of a blood vessel. The crossing device may be advanced beyond the occlusion to establish a blood flow path between a proximal segment on one side of the occlusion and a distal segment on the other side of the occlusion. For example, the crossing device may re-enter the lumen of the blood vessel as it moves past the occlusion. In some cases, the crossing device may advance distally between the intima and the adventitia of the blood vessel. As the tip of the crossing device moves in a distal direction between the intima and the adventitia, the tip may cause blunt dissection of the layers forming the wall of the blood vessel. If the tip of the crossing device does not spontaneously or automatically enter the lumen, a system in accordance with this detailed description may be used to pierce the intima and re-enter the lumen of the blood vessel.

In some useful methods in accordance with this detailed description, the crossing device may be rotated about its longitudinal axis and moved in a direction parallel to its longitudinal axis simultaneously. When this is the case, rotation of the crossing device may reduce resistance to the axial advancement of the crossing device. These methods take advantage of the fact that the kinetic coefficient of friction is usually less than the static coefficient of friction for a given frictional interface. Rotating the crossing device assures that the coefficient of friction at the interface between the crossing device and the surrounding tissue will be a kinetic coefficient of friction and not a static coefficient of friction. The rotating action may also change the direction of force vectors representing the effect of friction on the device.

Rotation of the crossing device can be achieved by rolling a handle portion of the crossing device between the thumb and forefinger of one hand, for example. Two hands may also be used to rotate the crossing device. In some useful methods in accordance with this detailed description, the crossing device is rotated at a rotational speed of between about 2 revolutions per minute and about 200 revolutions per minute. In some particularly useful

methods in accordance with this detailed description, the crossing device is rotated at a rotational speed of between about 50 revolutions per minute and about 150 revolutions per minute. The crossing device may be rotated at a rotational speed that is sufficient to assure that the coefficient of friction at the interface between the crossing device and the surrounding tissue will be a kinetic coefficient of friction and not a static coefficient of friction. It is also contemplated that a mechanical device (e.g., an electric motor) may be used to rotate the crossing device.

Figure 13 is an additional stylized pictorial view of blood vessel 30 and crossing device 150 shown in the previous figure. In the embodiment of Figure 13, tip 152 of crossing device 150 is disposed at a location distal of occlusion 32. Tip 152 can be seen resting in an intrawall space S between the intima 44 and the adventitia 42 of blood vessel 30 in Figure 13.

Figure 14 is an additional stylized pictorial view of blood vessel 30 shown in the previous figure. By comparing Figure 14 with the previous figure, it will be appreciated that a guidewire 999 may remain in the position formerly occupied by crossing device 150. With reference to Figure 14, it will be appreciated that guidewire 999 may rest inside intrawall space S between the intima 44 and the adventitia 42 of blood vessel 30.

In the embodiment of Figure 14, crossing device 150 has been withdrawn from blood vessel 30 while guidewire 999 has remained in the position shown in Figure 14. The position of guidewire 999 shown in Figure 14 may be achieved, for example, by first placing crossing device 150 in the position shown in the previous figure, then advancing guidewire 999 through a lumen defined by shaft 154 of crossing device 150. Alternately, guidewire 999 may be disposed within the lumen of shaft 154 while crossing device 150 is advanced beyond occlusion 32. With guidewire 999 in the position shown in Figure 14, guidewire 999 may be used to direct other endovascular devices into the intrawall volume between occlusion 32 and adventitia 42. Examples of endovascular devices that may be advanced over guidewire 999 include balloon catheters, atherectomy catheters, and stent delivery catheters.

Figure 15 is an additional stylized pictorial view of blood vessel 30 shown in the previous figure. In Figure 15, an orienting catheter 200 is shown residing in the intrawall space previously occupied by guidewire 999. Orienting catheter 200 may be advanced into the position shown in Figure 15, for example, by advancing orienting catheter 200 over guidewire 999 shown in the previous figure. Orienting catheter 200 comprises a shaft assembly 202 and an orienting element 204 that is carried by shaft assembly 202. Orienting element 204 may be capable of assuming both a collapsed shape and an expanded shape. Orienting element 204 may be selectively placed in the collapsed shape, for example, while the orienting element is being

advanced past an occlusion (e.g., occlusion 32 shown in Figure 15). Orienting element 204 may be selectively placed in the expanded shape, for example, while the orienting catheter 200 is being used to direct a re-entry device toward the lumen of a blood vessel. In Figure 15, orienting element 204 is shown assuming the expanded shape.

5 Orienting element 204 of orienting catheter 200 comprises a first portion 206 and a second portion 208. In some instances, orienting element 204 may be an inflatable balloon. In the embodiment of Figure 15, first portion 206 of orienting element 204 comprises a first inflatable member 220. Second portion 208 of orienting element 204 comprises a second inflatable member 224 in the embodiment of Figure 15. First inflatable member 220 of
10 orienting element 204 extends in a first direction 20 away from longitudinal axis 222 of shaft assembly 202. Second inflatable member 224 of orienting element 204 extends away from longitudinal axis 222 of shaft assembly 202 in a second direction 22 that is generally opposite the first direction. Shaft assembly 202 defines a distal port 234, a proximal port (not shown in Figure 15) and a central lumen extending between the distal port and the proximal port.

15 Figure 16 is an additional stylized pictorial view of blood vessel 30 and orienting catheter 200 shown in the previous figure. In Figure 16, a distal portion of an occlusion catheter 300 can be seen residing in proximal lumen segment 36 of true lumen 34. Occlusion catheter 300 includes a balloon 302 carried by a shaft assembly 304. Shaft assembly 304 defines an aspiration lumen 308 ending at a distal aspiration port 306. With reference to Figure 16, it will
20 be appreciated that balloon 302 of occlusion catheter 300 is disposed at a location slightly proximal of occlusion 32. In some cases, occlusion catheter 300 may be positioned by advancing it over a guidewire. In other cases, it may be desirable to use orientation catheter 200 as a guide. When this is the case, a tracking element may be coupled to both orienting catheter 200 and occlusion catheter 300. The tracking element may be adapted and configured to slide in
25 distal and proximal axial directions along shaft assembly 202 of orienting catheter 200. The tracking element may be coupled to occlusion catheter 300 in a manner that precludes relative axial movement between shaft assembly 304 and the tracking element.

 Figure 17 is an additional stylized pictorial view of blood vessel 30 and occlusion catheter 300 shown in the previous figure. In Figure 17, balloon 302 of occlusion catheter 300 is
30 shown in an inflated state. In some useful embodiments, balloon 302 is adapted and dimensioned so as to occlude a blood vessel lumen when it assumes its inflated shape. In the embodiment of Figure 17, balloon 302 has isolated a target volume T by occluding proximal lumen segment 36. The target volume T includes a portion of proximal lumen segment 36

extending between balloon 302 and occlusion 32 in the embodiment of Figure 17. Target volume T also includes the intrawall space S occupied by orientation catheter 200.

With target volume T isolated, fluid may be withdrawn from the target volume T by drawing the fluid through distal aspiration port 306 and into aspiration lumen 308. Fluid may also be withdrawn from target volume T by drawing the fluid through central lumen 230 of orienting catheter 200. Withdrawing fluid from target volume T may reduce the pressure inside the target volume T (e.g., reduce the pressure inside the target volume T below ventral pressure PV) so that pressure inside distal lumen segment 38 presses the intima 44 of the blood vessel 30 against the orienting element 202 of orienting catheter 200. The pressure within the target volume T may be reduced to be less than the pressure within the distal lumen segment 38 (e.g., atrial pressure PA). Withdrawing fluid from the target volume may be particularly beneficial when the blood vessel wall has been dissected as one or more prolapsed guidewires, or other medical device, have passed through it. More particularly, withdrawing fluid from the target volume may facilitate the use of fluoroscopic imaging techniques when an elongated dissection is interfering with the flow of radiopaque imaging media into a lumen segment of the blood vessel. Additionally, withdrawing fluid from the intrawall space S may facilitate the piercing of intima 44 to complete a blood flow path extending between a proximal lumen segment and a distal lumen segment of the blood vessel.

Figure 18 is an additional stylized pictorial view of blood vessel 30 and orienting catheter 200 shown in the previous figure. For purposes of illustration, orienting catheter 200 is shown in cross-section in Figure 18. With reference to Figure 18, it will be appreciated that guidewire 999 has been withdrawn from a central lumen 230 of orienting catheter 200. Orienting catheter 200 comprises a shaft assembly 202 defining a first aperture 226 and a second aperture 228. In the embodiment of Figure 18, first aperture 226 extends away from central lumen 230 in a third direction 24. Second aperture 228 extends away from central lumen 230 in a fourth direction 26 that is illustrated using an arrow in Figure 18. Third direction 24 is also represented with an arrow in Figure 18. In the embodiment of Figure 18, third direction 24 and fourth direction 26 extend in generally opposite directions. In Figure 18, the arrows representing third direction 24 and fourth direction 26 are directed about 180 degrees away from one another.

Orienting catheter 200 includes an orienting element 204, such as an orienting balloon, that is carried by shaft assembly 202. Orienting element 204 is shown assuming an expanded shape in Figure 18. Orienting element 204 is also capable of assuming a collapsed shape. Orienting element 204 is dimensioned such that, when the orienting element assumes an

expanded shape within the blood vessel wall, the shaft assembly will assume an arbitrary one of two possible orientations relative to the blood vessel lumen. The two possible orientations comprise a first orientation and a second orientation. In the exemplary embodiment of Figure 18, first aperture 226 is positioned so as to open toward the blood vessel lumen when shaft assembly 202 is assuming the first orientation within the blood vessel wall. Second aperture 228 is positioned so as to open toward the blood vessel lumen when shaft assembly 202 is assuming the second orientation within the blood vessel wall. In the embodiment of Figure 18 orienting catheter 200 is oriented so that second aperture 228 opens toward intima 44 of blood vessel 30 and first aperture 226 opens away from intima 44. Therefore, it will be appreciated that orienting device is assuming the second orientation.

In the embodiment of Figure 18, first aperture 226 and second aperture 228 are longitudinally separated from one another, although other configurations are contemplated. Orienting catheter 200 includes a first radiopaque marker 240 that is located between first aperture 226 and second aperture 228. A second radiopaque marker 242 of orienting catheter 200 is located distally of second aperture 228.

In Figure 18, an occlusion 32 is shown blocking lumen 34 of blood vessel 30. Occlusion 32 prevents blood from flowing through blood vessel 30. Fluid communication between a proximal segment of blood vessel lumen 34 and a distal segment of blood vessel lumen 34 may be achieved by re-entering the lumen with a re-entry device. Orienting catheter 200 may be used to direct the re-entry device toward true lumen 34 to complete a blood flow path extending around occlusion 32.

Figure 19 is an additional stylized pictorial view of blood vessel 30 and orienting catheter 200 shown in the previous figure. In the embodiment of Figure 19, a re-entry device 100 has been advanced into central lumen 230 of orienting catheter 200. With reference to Figure 19, it will be appreciated that re-entry device 100 may include a bend 142. In the embodiment of Figure 19, re-entry device 100 is biased to assume a bent shape. Also in the embodiment of Figure 19, the wall of shaft assembly 202 is holding re-entry device 100 in a somewhat deflected state. When this is the case, re-entry device 100 can be inserted through second aperture 228 by positioning the distal end of re-entry device 100 over second aperture 228 and allowing bend 142 to assume its natural state (i.e., bent at a sharper angle). In the embodiment of Figure 19, rotating re-entry device 100 within central lumen 230 of orienting catheter 200 will cause the distal end of re-entry device 100 to enter second aperture 228.

A physician may use a fluoroscopic display for guidance when placing the distal end of the re-entry device 100 in general alignment with a selected aperture. When using fluoroscopic

guidance, re-entry device 100, first radiopaque marker 240, and second radiopaque marker 242 will all be brightly displayed by the fluoroscopy system. When the physician positions the distal end of re-entry device 100 slightly proximal of first radiopaque marker 240, the physician may infer that the distal end of re-entry device 100 is at a longitudinal position (i.e., a position along longitudinal axis 222) that is in general alignment with first aperture 226. The physician may then rotate re-entry device 100 so that the distal end of re-entry device 100 enters first aperture 226. The distal end of re-entry device 100 may then be advanced through first aperture 226. The physician may observe the direction that a distal portion of re-entry device 100 travels as it passes through first aperture 226. From these fluoroscopic observations, the physician can determine whether the distal end of the re-entry device 100 is directed toward the vascular lumen or directed away from the vascular lumen. If it is determined that the re-entry device 100 is directed toward the vascular lumen, then the re-entry device 100 can be advanced so that the distal end of re-entry device 100 travels through the intima to a position inside the lumen 34 of blood vessel 30. If it is determined that the re-entry device 100 is directed away from the vascular lumen, then the re-entry device 100 can be withdrawn from first aperture 226 so that the re-entry device 100 is again located within orienting catheter 200. At this point, the physician may determine second aperture 228 should be used for re-entry on this particular occasion.

When the physician positions the distal end of re-entry device 100 between first radiopaque marker 240 and second radiopaque marker 242, the physician may infer that the distal end of re-entry device 100 is at a longitudinal position (i.e., a position along longitudinal axis 222) that is in general alignment with second aperture 228. The physician may then rotate re-entry device 100 so that the distal end of re-entry device 100 enters second aperture 228. The distal end of re-entry device 100 may then be advanced through second aperture 228. The physician may observe the direction that a distal portion of re-entry device 100 travels as it passes through second aperture 228. From these fluoroscopic observations, the physician can confirm that the distal end of the re-entry device 100 is directed toward the vascular lumen 34. If it is confirmed that the re-entry device 100 is directed toward the vascular lumen 34, then the re-entry device 100 can be advanced so that the distal end of re-entry device 100 travels through the intima 44 to a position inside the lumen 34 of blood vessel 30. It is contemplated that other structures/configurations may be utilized to cause/allow the re-entry device 100 to pass from the orienting catheter 200 for re-entry into the vascular lumen 34.

Figure 20 is an additional stylized pictorial view showing re-entry device 100 and orienting catheter 200 shown in the previous figure. By comparing Figure 20 and the previous

figure, it will be appreciated that re-entry device 100 has been rotated so that a distal portion of re-entry device 100 has entered second aperture 228. With reference to Figure 20, it will be appreciated that re-entry device 100 may comprise a distal surface 108 and a probe 106 extending beyond distal surface 108. In the embodiment of Figure 20, probe 106 of re-entry device 100 is contacting intima 44 of blood vessel 30. Re-entry device 100 is shown extending distally through central lumen 230 and second aperture 228 in the embodiment of Figure 20. By advancing re-entry device 100 further in the distal direction D, re-entry device 100 can be advanced through second aperture 228 and through intima 44.

Figure 21 is an additional stylized pictorial view showing re-entry device 100 and orienting catheter 200 shown in the previous figure. In the embodiment of Figure 21, re-entry device 100 has been advanced further in distal direction D and probe 106 of re-entry device 100 has pierced the surface of intima 44. Probe 106 can be seen extending into intima 44 in Figure 21. Intima 44 may be weakened when pierced by probe 106 as shown in Figure 21. Probe 106 may also function to anchor the distal tip of re-entry device 100 to intima 44 so that the distal tip is less likely to slide along the intima 44 when pushing forces are applied to the proximal end of re-entry device 100. The anchoring and weakening functions described above may aid a physician in advancing re-entry device 100 through intima 44.

Figure 22 is an additional stylized pictorial view showing re-entry device 100 and orienting catheter 200 shown in the previous figure. In the embodiment of Figure 22, a distal portion of re-entry device 100 has been advanced through intima 44. With reference to Figure 22, it will be appreciated that distal surface 108 of re-entry device 100 is disposed in the lumen 34 of blood vessel 30. Probe 106 of re-entry device 100 can be seen extending beyond distal surface 108. Re-entry device 100 has pierced intima 44 creating a hole extending through the intima 44. A blood flow path extending around occlusion 32 is completed when re-entry device 100 pierces intima 44.

Figure 23 is a plan view showing a system 400 in accordance with the present detailed description. System 400 of Figure 23 may be useful, for example, when establishing a blood flow path between a proximal segment of a blood vessel and a distal segment of a blood vessel that are separated by an occlusion (e.g., the subject matter illustrated in the preceding series of figures). System 400 may also be used to facilitate visualization of a patient's vasculature using fluoroscopic techniques when conditions arise which interfere with the flow of radiopaque media.

Orienting catheter 200 of Figure 23 comprises a shaft assembly 202 and an orienting element 204, such as an orienting balloon, that is carried by shaft assembly 202. Orienting

element 204 is capable of assuming both a collapsed shape and an expanded shape. Orienting element 204 may be selectively placed in the collapsed shape, for example, while the orienting element 204 is being advanced past an occlusion. Orienting element 204 may be selectively placed in the expanded shape, for example, while the orienting catheter 200 is being used to
5 direct re-entry device 100 toward the lumen of a blood vessel. In Figure 23, orienting element 204 is shown assuming the expanded shape.

Orienting element 204 of orienting catheter 200 comprises a first portion 206 and a second portion 208. In the embodiment of Figure 23, first portion 206 of orienting element 204 comprises a first inflatable member 220. Second portion 208 of orienting element 204
10 comprises a second inflatable member 224 in the embodiment of Figure 23. First inflatable member 220 of orienting element 204 extends in a first direction 20 away from the longitudinal axis of shaft assembly 202. Second inflatable member 224 of orienting element 204 extends away from the longitudinal axis of shaft assembly 202 in a second direction 22. First direction 20 and second direction 22 are represented with arrows in Figure 23. With reference to Figure
15 23, it will be appreciated that second direction 22 is generally opposite first direction 20. In Figure 23, the arrows representing first direction 20 and second direction 22 are directed about 180 degrees away from one another.

Shaft assembly 202 of Figure 23 defines a first aperture 226 and a second aperture 228. In the embodiment of Figure 23, first aperture 226 extends away from central lumen 230 in a
20 third direction that is generally perpendicular to first direction 20 and second direction 22. Second aperture 228 extends away from central lumen 230 in a fourth direction that is generally perpendicular to first direction 20 and second direction 22. In the embodiment of Figure 23, the fourth direction is generally opposite to the third direction. In other words, the third direction and the fourth direction are directed about 180 degrees away from each other. The third
25 direction and the fourth direction are both generally orthogonal to the picture plane that the plan view of Figure 23 is displayed on. It is contemplated that in other embodiments the first and second apertures 226, 228 may have a different orientation.

A hub 236 is fixed to the proximal end of shaft assembly 202. Hub 236 includes an inflation port 238. Inflation port 238 fluidly communicates with the interior of first inflatable
30 member 220 and second inflatable member 224 via inflation lumens defined by shaft assembly 202. The inflatable members 220, 224 may be inflated by injecting an inflation media into inflation port 238. Examples of inflation media that may be suitable in some applications include saline, carbon dioxide, and nitrogen.

Orienting catheter 200 defines a proximal port 232, a distal port 234 and a central lumen 230 that extends between proximal port 232 and distal port 234. In the embodiment of Figure 23, proximal port 232 is defined by hub 236 and distal port 234 is defined by shaft assembly 202. In Figure 23, re-entry device 100 can be seen extending through proximal port 232, central lumen 230, and distal port 234. With reference to Figure 23, it will be appreciated that re-entry device 100 comprises a distal surface 108 and a probe 106 extending beyond distal surface 108. Re-entry device 100 may be inserted into proximal port 232, advanced along central lumen 230, and advanced through any one of distal port 234, first aperture 226 and second aperture 228.

System 400 of Figure 23 includes an occlusion catheter 300, an orienting catheter 200 and re-entry device 100. Occlusion catheter 300 includes a balloon 302 carried by a shaft assembly 304. A hub 320 is fixed to the proximal end of shaft assembly 304. Hub 320 defines an inflation port 322 and a proximal aspiration port 324. Shaft assembly 304 of occlusion catheter 300 defines an inflation lumen 328 and an aspiration lumen 308 that fluidly communicate with inflation port 322 and proximal aspiration port 324, respectively. Aspiration lumen 308 extends between proximal aspiration port 324 and a distal aspiration port 306. Inflation lumen 328 extends between inflation port 322 and the interior of balloon 302.

In Figure 23, balloon 302 is shown assuming an inflated shape. Balloon 302 can be selectively inflated by injecting an inflation fluid into balloon 302 via inflation port 322 and inflation lumen 328. In some useful embodiments, balloon 302 is adapted and dimensioned so as to occlude a blood vessel lumen when it assumes the inflated shape. Balloon 302 may be used to isolate a target volume by occluding the true lumen of the blood vessel. The target volume may include an intrawall space located between the intima and the adventitia of the blood vessel. The target volume may also include a portion of the lumen extending between the balloon and an occlusion that is blocking the lumen of the blood vessel. With the target volume isolated, fluid may be withdrawn from it by drawing the fluid through distal aspiration port 306 and aspiration lumen 308 of occlusion catheter 300. Fluid may also be withdrawn from target volume T by drawing the fluid through central lumen 230 of orienting catheter 200.

System 400 includes a tracking element 402 defining a tracking element lumen 404. Shaft assembly 202 of orienting catheter 200 can be seen extending through tracking element lumen 404 in Figure 23. Tracking element lumen 404 is configured so that tracking element 402 is free to slide in distal and proximal axial directions along shaft assembly 202 of orienting catheter 200. Occlusion catheter 300 is connected to tracking element 402 so that axial movement between tracking element 400 and occlusion catheter 300 is precluded.

Figure 24A is a plan view showing a system 400 in accordance with the present detailed description. Figure 24B is an enlarged plan view further illustrating a portion of system 400. Figure 24A and Figure 24B may be collectively referred to as Figure 24. System 400 of Figure 24 includes an occlusion catheter 300, an orienting catheter 200 and a re-entry device 100.

5 Orienting catheter 200 comprises an orienting element 204 carried by a shaft assembly 202. Occlusion catheter 300 comprises a balloon 302 carried by a shaft assembly 304.

Shaft assembly 202 of orienting catheter 200 defines a first aperture 226, a second aperture 228, a distal port 234 and a central lumen 230. Central lumen 230 extends between distal port 234 and a proximal port 232 is defined by a hub 236. In Figure 24, re-entry device 100 can be seen extending through proximal port 232, central lumen 230, and distal port 234. Re-entry device 100 may be inserted into proximal port 232, advanced along central lumen 230, and advanced through any one of distal port 234, first aperture 226 and second aperture 228. With reference to Figure 24, it will be appreciated that re-entry device 100 comprises a distal surface 108 and a probe 106 extending beyond distal surface 108.

15 Orienting element 204 of orienting catheter 200 comprises a first portion 206 and a second portion 208. In the embodiment of Figure 24, first portion 206 of orienting element 204 comprises a first inflatable member 220. Second portion 208 of orienting element 204 comprises a second inflatable member 224 in the embodiment of figure 24. Shaft assembly 202 defines inflation lumens that fluidly communicate with the interior of first inflatable member 220, the interior of second inflatable member 224, and inflation port 238 defined by hub 236. The inflatable members may be inflated by injecting an inflation media into inflation port 238.

A hub 320 is fixed to the proximal end of shaft assembly 304 of occlusion catheter 300. Hub 320 defines an inflation port 322 and a proximal aspiration port 324. Shaft assembly 304 of occlusion catheter 300 defines an inflation lumen 328 and an aspiration lumen 308 that fluidly 25 communicate with inflation port 322 and proximal aspiration port 324, respectively. Aspiration lumen 308 extends between proximal aspiration port 324 and a distal aspiration port 306. Inflation lumen 328 extends between inflation port 322 and the interior of balloon 302.

In Figure 24, balloon 302 is shown assuming a collapsed and folded state. Balloon 302 can be selectively inflated by injecting an inflation fluid into balloon 302 via inflation port 322 and inflation lumen 328. In some useful embodiments, balloon 302 is adapted and dimensioned 30 so as to occlude a blood vessel lumen when it assumes the inflated shape. Balloon 302 may be used to isolate a target volume by occluding a lumen segment of a blood vessel. The target volume may include an intrawall space located between the intima and the adventitia of the blood vessel. The target volume may also include a portion of the lumen segment extending

between the balloon 302 and an occlusion that is blocking the lumen of the blood vessel. With the target volume isolated, fluid may be withdrawn from it by drawing the fluid through distal aspiration port 306 and into aspiration lumen 308. Fluid may also be withdrawn from the target volume by drawing the fluid through central lumen 230 of orienting catheter 200 if desired.

5 System 400 includes a tracking element 402 defining a tracking element lumen 404. Shaft assembly 202 of orienting catheter 200 can be seen extending through tracking element lumen 404 in Figure 24. Tracking element lumen 404 is configured so that tracking element 402 is free to slide in distal and proximal axial directions along shaft assembly 202 of orienting catheter 200. Occlusion catheter 300 and tracking element 402 comprise a male coupling
10 element 408 and a female coupling element 406, respectively. Male coupling element 408 and female coupling element 406 are adapted and configured to cooperatively form a mechanical connection between occlusion catheter 300 and tracking element 402. In some useful
embodiments, this connection is adapted and configured so that axial movement between tracking element 400 and occlusion catheter 300 is precluded. In the embodiment of Figure 24,
15 male coupling element 408 includes a shoulder 420 having a proximal facing surface 424. Female coupling element 406 comprises two tangs 426 in the embodiment of Figure 24. In other embodiments, the female coupling element 406 and the male coupling element 408 may be reversed, with the female coupling element 406 provided on the occlusion catheter 300 and the male coupling element 408 provided on the tracking element 402.

20 Figure 25A is an additional plan view further illustrating system 400 shown in the previous figure. Figure 25B is an enlarged plan view further illustrating a portion of system 400. In the embodiment of Figure 25, male coupling element 408 of occlusion catheter 300 and female coupling element 406 of orienting catheter 200 are cooperating to form a connection 440. Connection 440 is adapted and configured so that axial movement between tracking element 400
25 and occlusion catheter 300 is precluded in the embodiment of Figure 25. A proximal edge of each tang 426 can be seen contacting the proximal-facing surface of the shoulder 420 in Figure 25B.

 Figure 26A is a plan view showing a system 400 in accordance with the present detailed description. Figure 26B is an enlarged plan view further illustrating a portion of system 400.
30 Figure 26A and Figure 26B may be collectively referred to as Figure 26. System 400 may be useful, for example, when establishing a blood flow path between a proximal segment of a blood vessel and a distal segment of a blood vessel that are separated by an occlusion (e.g., the subject matter illustrated in the preceding series of figures). System 400 may also be useful to facilitate

visualization of a patient's vasculature using fluoroscopic techniques when conditions arise which interfere with the flow of radiopaque media.

System 400 of Figure 26 includes an occlusion catheter 300, an orienting catheter 200 and re-entry device 100. Orienting catheter 200 of Figure 26 comprises a shaft assembly 202 and an orienting element 204 that is carried by shaft assembly 202. Orienting element 204 of
5 orienting catheter 200 comprises a first portion 206 and a second portion 208. In the embodiment of Figure 26, first portion 206 of orienting element 204 comprises a first inflatable member 220. Second portion 208 of orienting element 204 comprises a second inflatable member 224 in the embodiment of Figure 26. The inflatable members may be inflated by
10 injecting an inflation media into them via inflation lumens defined by shaft assembly 202. The interior of first inflatable member 220 and the interior of second inflatable member 224 fluidly communicate with an inflation port 238 defined by a hub 236.

Orienting catheter 200 defines a proximal port 232, a distal port 234 and a central lumen 230 that extends between proximal port 232 and distal port 234. In the embodiment of Figure
15 26, proximal port 232 is defined by hub 236 and distal port 234 is defined by shaft assembly 202. Shaft assembly 202 of orienting catheter 200 defines a first aperture 226 and a second aperture 228. In Figure 26, re-entry device 100 can be seen extending through proximal port 232, central lumen 230, and distal port 234. With reference to Figure 26, it will be appreciated that re-entry device 100 comprises a distal surface 108 and a probe 106 extending beyond distal
20 surface 108. Re-entry device 100 may be inserted into proximal port 232, advanced along central lumen 230, and advanced through any one of distal port 234, first aperture 226 and second aperture 228.

Occlusion catheter 300 of system 400 comprises a balloon 302 carried by a shaft assembly 304. A hub 320 is fixed to the proximal end of shaft assembly 304 of occlusion
25 catheter 300. Hub 320 defines an inflation port 322 and a proximal aspiration port 324. Shaft assembly 304 of occlusion catheter 300 defines an inflation lumen 328 and an aspiration lumen 308 that fluidly communicate with inflation port 322 and proximal aspiration port 324, respectively. Aspiration lumen 308 extends between proximal aspiration port 324 and a distal aspiration port 306. Inflation lumen 328 extends between inflation port 322 and the interior of
30 balloon 302.

In Figure 26, balloon 302 is shown assuming a collapsed and folded state. Balloon 302 can be selectively inflated by injecting an inflation fluid into balloon 302 via inflation port 322 and inflation lumen 328. In some useful embodiments, balloon 302 is adapted and dimensioned so as to occlude a blood vessel lumen when it assumes the inflated shape. Balloon 302 may be

used to isolate a target volume by occluding a lumen segment of a blood vessel. The target volume may include an intrawall space located between the intima and the adventitia of the blood vessel. The target volume may also include a portion of the lumen segment extending between the balloon and an occlusion that is blocking the lumen of the blood vessel. With the target volume isolated, fluid may be withdrawn from it by drawing the fluid through distal aspiration port 306 and into aspiration lumen 308. Fluid may also be withdrawn from the target volume by drawing the fluid through central lumen 230 of orienting catheter 200 if desired.

System 400 includes a tracking element 402 defining a tracking element lumen 404.

Shaft assembly 202 of orienting catheter 200 can be seen extending through tracking element lumen 404 in Figure 26. Tracking element lumen 404 is configured so that tracking element 402 is free to slide in distal and proximal axial directions along shaft assembly 202 of orienting catheter 200. Occlusion catheter 300 and tracking element 402 comprise a male coupling element 408 and a female coupling element 406, respectively. Male coupling element 408 and female coupling element 406 are adapted and configured to cooperatively form a mechanical connection between occlusion catheter 300 and tracking element 402. In some useful embodiments, this connection is adapted and configured so that axial movement between tracking element 400 and occlusion catheter 300 is precluded. In the embodiment of Figure 26, female coupling element 406 includes a shoulder 420 having a distal facing surface 422. Male coupling element 408 comprises two fingers 428 in the embodiment of Figure 26. In other embodiments, the female coupling element 406 and the male coupling element 408 may be reversed, with the female coupling element 406 provided on the occlusion catheter 300 and the male coupling element 408 provided on the tracking element 402.

Figure 27A is an additional plan view further illustrating system 400 shown in the previous figure. Figure 27B is an enlarged plan view further illustrating a portion of system 400. Male coupling element 408 of occlusion catheter 300 and female coupling element 406 of orienting catheter 200 are cooperating to form a connection 440 in the embodiment of Figure 27. In the embodiment of Figure 27, this connection is adapted and configured so that axial movement between tracking element 400 and occlusion catheter 300 is precluded. A proximal edge of each finger 428 can be seen contacting the distal-facing surface 422 of the shoulder in Figure 27B.

Figure 28A is a stylized pictorial view of a blood vessel 30 having a wall 40 including an adventitia 42, a media M, and an intima 44. In the embodiment of Figure 28A, an orienting element 202 of an orienting catheter 200 is disposed in an intrawall space S located between the intima 44 and the adventitia 42 of blood vessel 30. In the embodiment of Figure 28A, a portion

of intima 44 has become separated from the other layers of blood vessel wall 40. This situation may occur, for example, when a physician has passed one or more prolapsed guidewires between the intima and the adventitia.

Figure 28B is an additional stylized pictorial view of blood vessel 30 shown in the previous figure. By comparing Figure 28B with Figure 28A, it will be appreciated that the volume of intrawall space S has been reduced substantially. Intima 44 can be seen contacting orienting element 202 of orienting catheter 200 in Figure 28B. In some useful methods, the volume of an intrawall space S may be reduced by withdrawing fluid from the intrawall space. Fluid may be withdrawn from intrawall space S by drawing the fluid through central lumen 230 of orienting catheter 200. Fluid may also be withdrawn from intrawall space S by drawing the fluid through the aspiration lumen of an occlusion catheter 300 in accordance with this detailed description.

Withdrawing fluid from intrawall space S may reduce the pressure inside the intrawall space S to a pressure less than the pressure in the true lumen distal of the occlusion (e.g., below atrial pressure PA) so that pressure inside the true lumen distal of the occlusion presses the intima 44 of the blood vessel 30 against the orienting element 202 of the orienting catheter 200. In other words, the pressure on the intrawall side of the intima 44 may be less than the pressure on the true lumen side of the intima 44 distal of the occlusion. Withdrawing fluid from the intrawall space S may be particularly beneficial when the blood vessel wall has been dissected as one or more prolapsed guidewires have passed through it. More particularly, withdrawing fluid from the intrawall space S may facilitate the use of fluoroscopic imaging techniques when an elongated dissection is interfering with the flow of radiopaque imaging media into a lumen segment of the blood vessel. Additionally, withdrawing fluid from the intrawall space S may facilitate the piercing of intima 44 to complete a blood flow path extending between a proximal lumen segment and a distal lumen segment of the blood vessel.

From the foregoing, it will be apparent to those skilled in the art that the present disclosure provides, in exemplary non-limiting embodiments, devices and methods for the treatment of chronic total occlusions. Further, those skilled in the art will recognize that aspects of the present disclosure may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present disclosure as described in the appended claims.

CLAIMS

What is claimed is:

1. A system for treating a blood vessel including a blood vessel wall defining a blood vessel lumen, the blood vessel lumen being at least partially obstructed by an occlusion, the occlusion dividing the lumen into a proximal lumen segment and a distal lumen segment, the system comprising:
 - an orienting catheter including an orienting catheter shaft carrying an orienting element and a tracking element advanceable along the orienting catheter shaft;
 - an occlusion catheter comprising a balloon and a coupling element configured to engage a complementary coupling element of the tracking element to form a connection therebetween;
 - the occlusion catheter defining an inflation lumen disposed in fluid communication with an interior of the balloon so that the balloon can be selectively inflated by injecting an inflation fluid through the inflation lumen;
 - the balloon, when in an inflated state, being sized so as to occlude the blood vessel lumen to isolate a target volume defined by blood vessel tissues;
 - the occlusion catheter defining an aspiration lumen disposed in fluid communication with a distal port positioned so that fluid can be withdrawn from the target volume and into the aspiration lumen.
2. The system of claim 1, wherein the tracking element includes a tracking element lumen through which the orienting catheter shaft extends through.
3. The system of claim 2, wherein the tracking element lumen is dimensioned so that the tracking element is free to slide in proximal and distal axial directions along the orienting catheter shaft.
4. The system of claim 1, wherein the coupling element of the occlusion catheter is disposed distal of the balloon.
5. The system of claim 1, wherein the orienting element comprises a first inflatable member and a second inflatable member, the first inflatable member extending from the orienting

catheter shaft in a first direction, the second inflatable member extending from the orienting catheter shaft in a second direction, the second direction being substantially opposite the first direction.

6. The system of claim 5, wherein the first inflatable member, the second inflatable member, and the orienting catheter shaft are monolithic.

7. A method for treating a blood vessel including a blood vessel wall defining a blood vessel lumen, the blood vessel lumen being at least partially obstructed by an occlusion, the occlusion dividing the lumen into a proximal lumen segment and a distal lumen segment, the method comprising:

positioning an orienting element of an orienting catheter inside an intrawall space located distal of the occlusion from the proximal lumen segment, the intrawall space being located between an intima and an adventitia of the blood vessel wall;

positioning an occluding element of an occlusion catheter in the proximal lumen segment at a location near the occlusion, the occluding element comprising a balloon;

inflating the balloon of the occlusion catheter in the proximal lumen segment so as to isolate a target volume, the target volume including the intrawall space;

reducing the pressure inside the target volume;

deploying the orienting element in the intrawall space so that the orienting catheter assumes an orientation in which a port of the orienting catheter is directed toward the distal lumen segment; and

advancing a distal end of a reentry device from the port through the intima and into the distal lumen segment.

8. The method of claim 7, wherein:

the pressure inside the intrawall space is greater than the pressure in the distal lumen segment before the pressure inside the target volume is reduced; and

the pressure inside the intrawall space is less than the pressure in the distal lumen segment after the pressure inside the target volume is reduced.

9. The method of claim 7, wherein reducing the pressure inside the target volume comprises placing a vacuum source in fluid communication with the target volume via a lumen defined by the orienting catheter or via a lumen defined by the occlusion catheter.

10. The method of claim 7, wherein reducing the pressure inside the target volume comprises placing a source of relatively low pressure in fluid communication with the target volume via a lumen defined by the orienting catheter or via a lumen defined by the occlusion catheter.

11. The method of claim 7, wherein reducing the pressure inside the target volume comprises placing a lumen of the occlusion catheter or a lumen of the orienting catheter in fluid communication with the target volume.

12. The method of claim 7, wherein reducing the pressure inside the target volume comprises withdrawing fluid from the target volume via a lumen defined by the orienting catheter or via a lumen defined by the occlusion catheter.

13. The method of claim 7, wherein:
the orienting catheter comprises a central lumen and a first port in fluid communication with the central lumen; and
deploying the orienting element causes the orienting catheter to assume an arbitrary one of two possible orientations relative to the distal lumen segment, the two possible orientations comprising a first orientation in which the first port is directed toward the distal lumen segment and a second orientation in which the first port is directed about 180 degrees away from the distal lumen segment.

14. The method of claim 7, wherein:
the orienting catheter comprises a central lumen, a first port and a second port, the first and second ports both being in fluid communication with the central lumen; and
deploying the orienting element while the intima is pressing thereagainst causes the orienting catheter to assume an arbitrary one of two possible orientations relative to the distal lumen segment, the two possible orientations comprising a first orientation in which the first port is

directed toward the distal lumen segment and a second orientation in which the second port is directed toward the distal lumen segment.

15. The method of claim 7, wherein the pressure in the distal lumen segment presses the intima against the orienting element of the orienting catheter while the pressure inside the intrawall space is less than the pressure in the distal lumen segment.

16. The method of claim 7, wherein:
the occlusion catheter comprises a tracking element carried by a shaft; and
the method comprises forming a sliding connection between the occlusion catheter and the orienting catheter with the tracking element.

17. The method of claim 7, wherein:
the occlusion catheter comprises a tracking element carried by a shaft; and
the method comprises advancing the tracking element in an axial direction along the orienting catheter while the occlusion catheter remains outside of and positioned along side the orienting catheter.

18. The method of claim 7, further comprising:
advancing the distal end of a crossing device between the occlusion and the adventitia of the blood vessel wall; and
advancing the distal end of the crossing device distally beyond the occlusion to form a tunnel between the intima and the adventitia.

19. The method of claim 7, wherein:
a portion of the distal lumen segment adjacent to the target volume is not visible using fluoroscopic techniques before the pressure inside the target volume is reduced; and
the portion of the distal lumen segment adjacent to the target volume is visible using fluoroscopic techniques after the pressure inside the target volume is reduced.

20. A method for treating a blood vessel including a blood vessel wall defining a blood vessel lumen, the blood vessel lumen being at least partially obstructed by an occlusion, the

occlusion dividing the lumen into a proximal lumen segment and a distal lumen segment, the method comprising:

positioning an orienting element of an orienting catheter inside an intrawall space located distal of the occlusion from the proximal lumen segment, the intrawall space being located between an intima and an adventitia of the blood vessel wall;

positioning an occluding element of an occlusion catheter in the proximal lumen segment at a location near the occlusion, the occluding element comprising a balloon;

inflating the balloon of the occlusion catheter in the proximal lumen segment so as to isolate a target volume, the target volume including the intrawall space;

reducing the volume of the target volume so that the intima presses against the orienting element of the orienting catheter;

deploying the orienting element in the intrawall space so that the orienting catheter assumes an orientation in which a port of the orienting catheter is directed toward the distal lumen segment; and

advancing the distal end of a reentry device from the port through the intima and into the distal lumen segment.

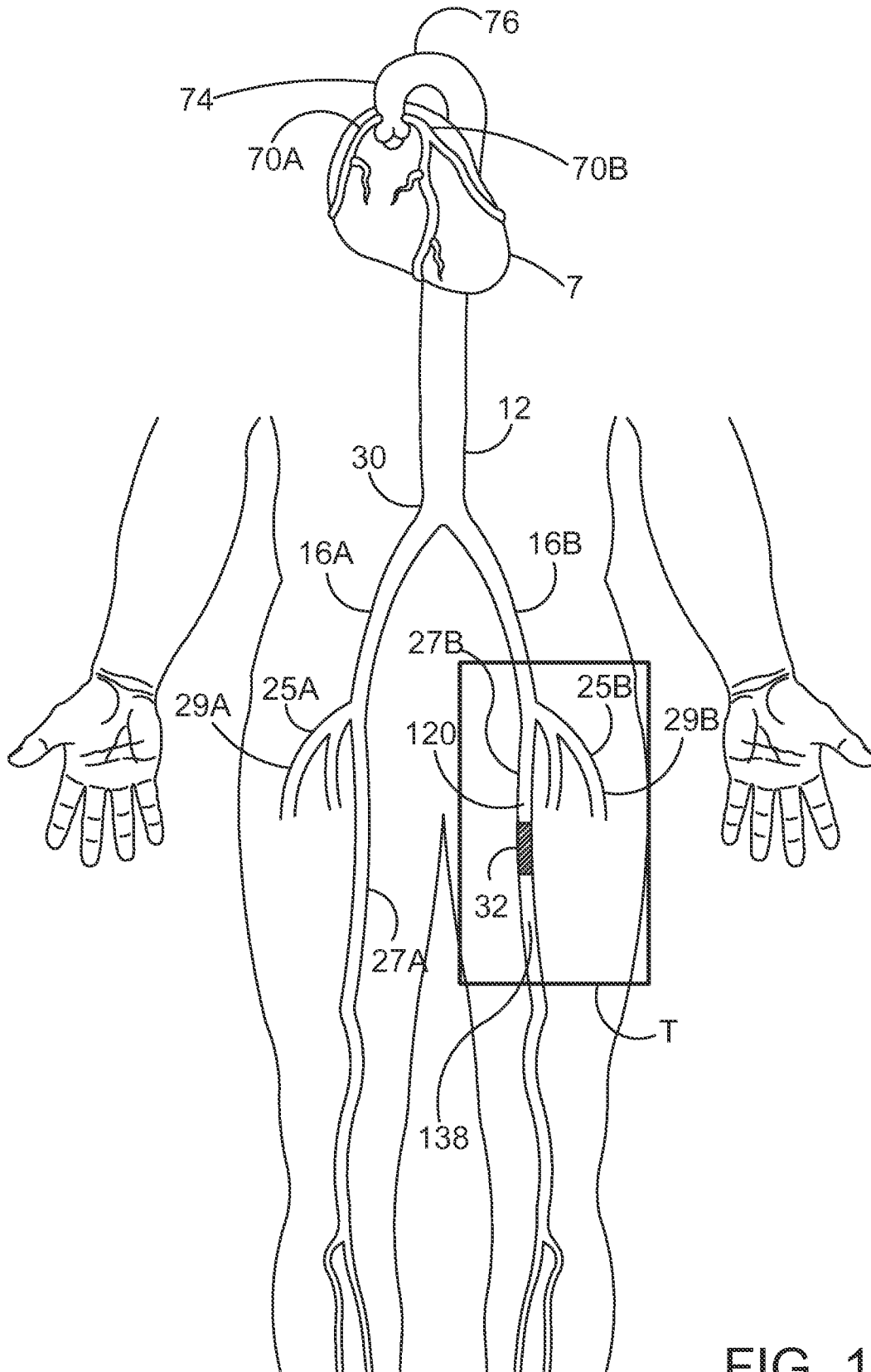
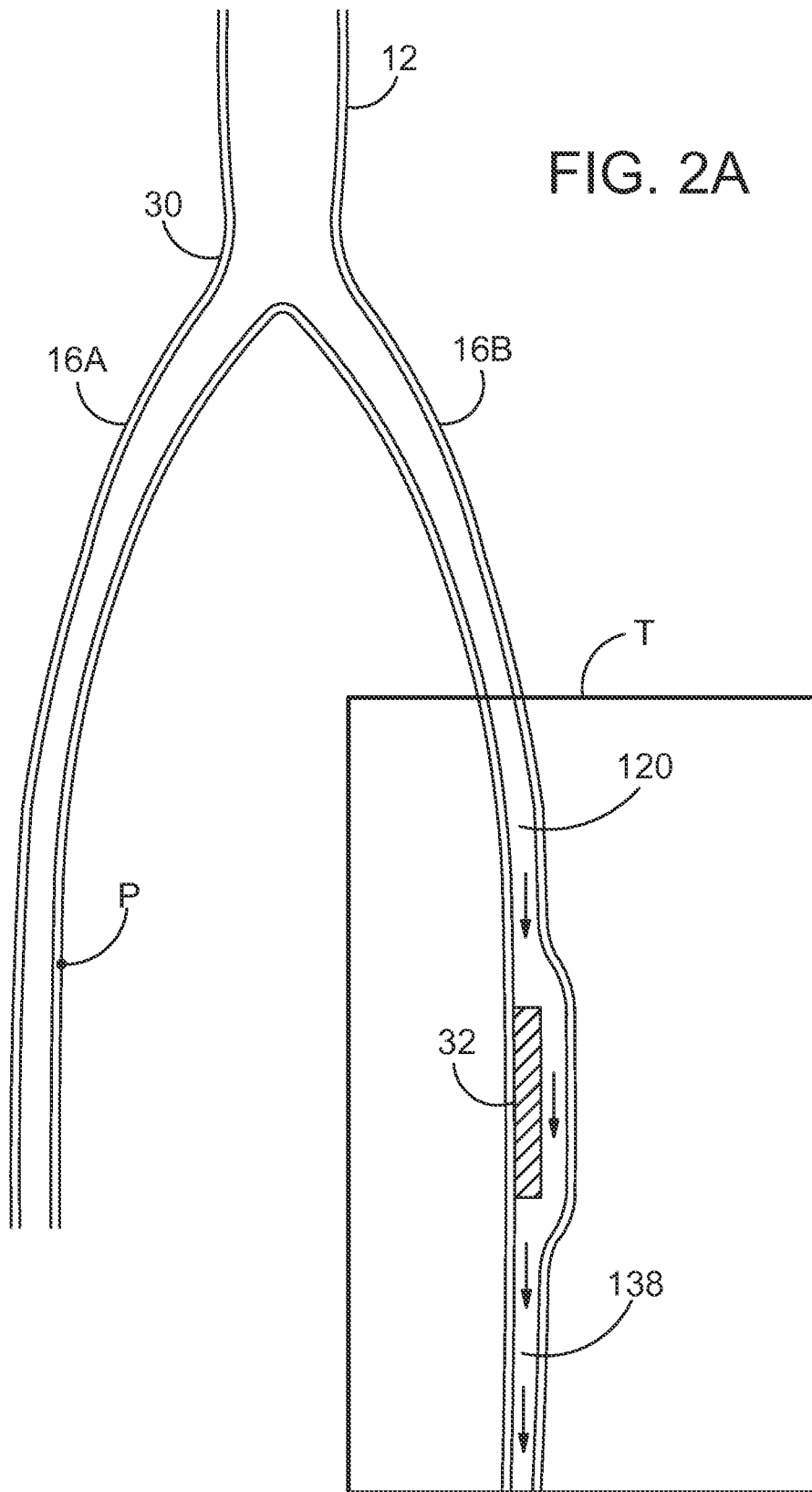


FIG. 1



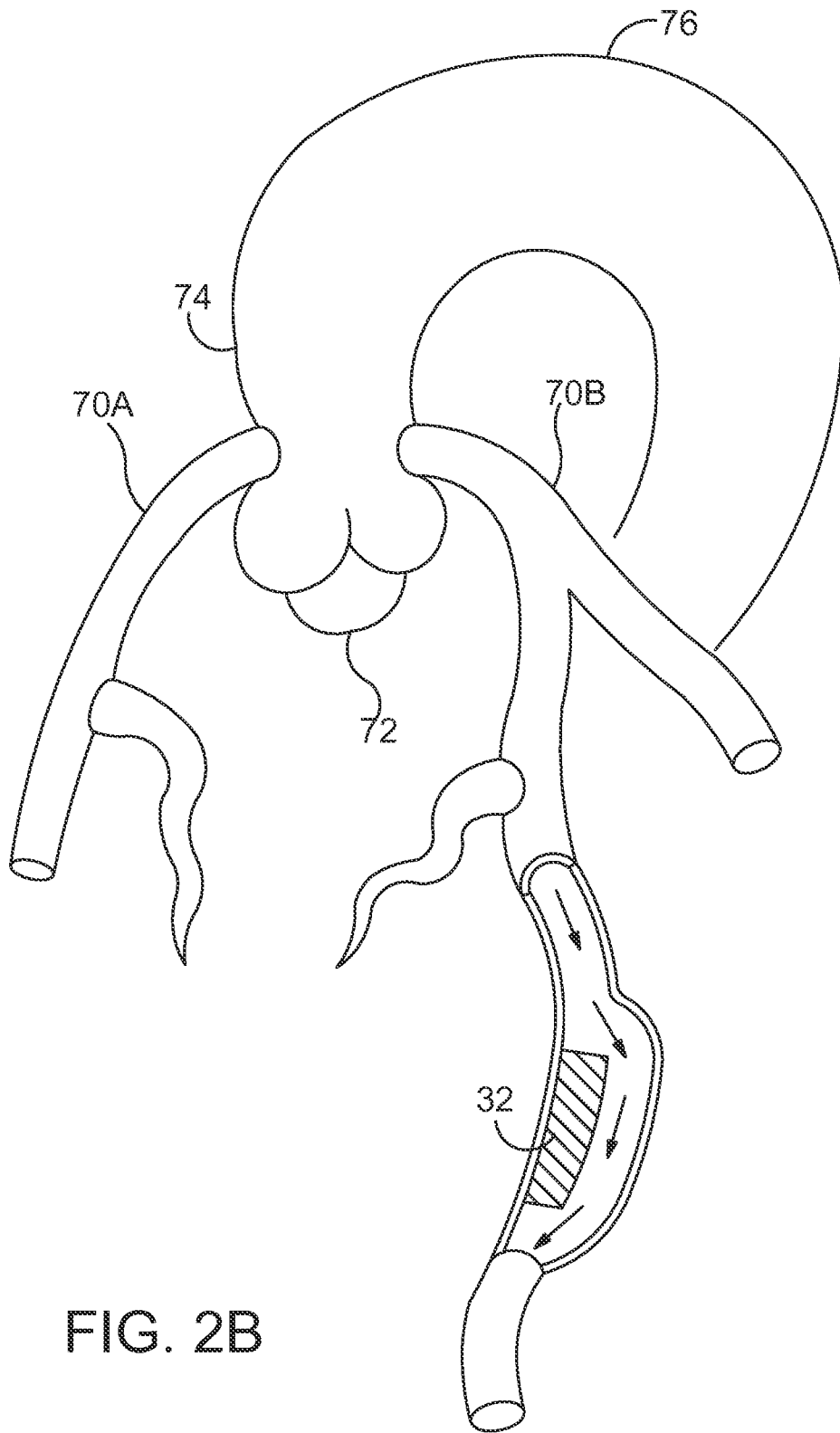


FIG. 2B

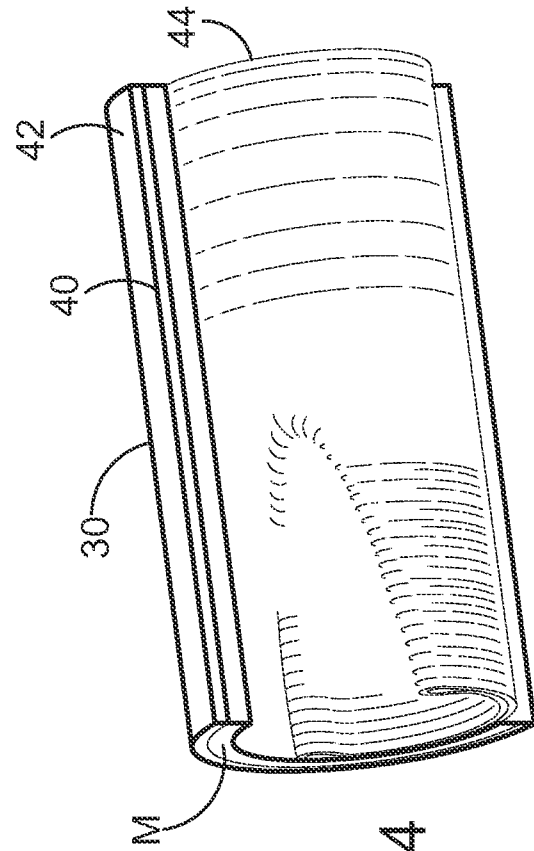
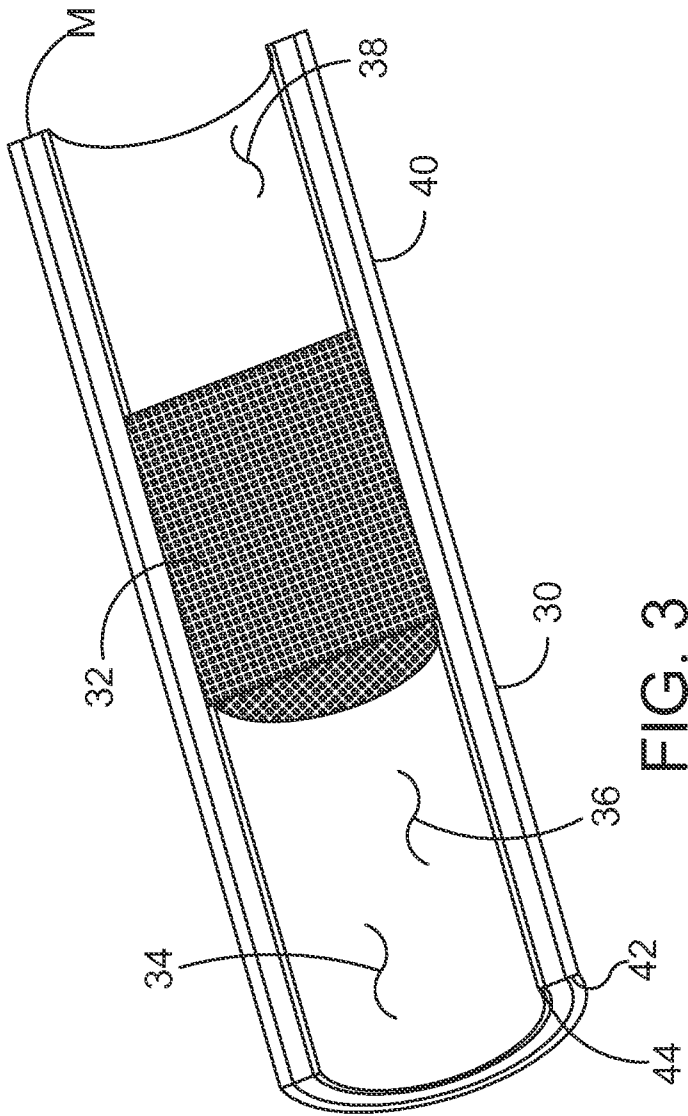


FIG. 4

FIG. 3

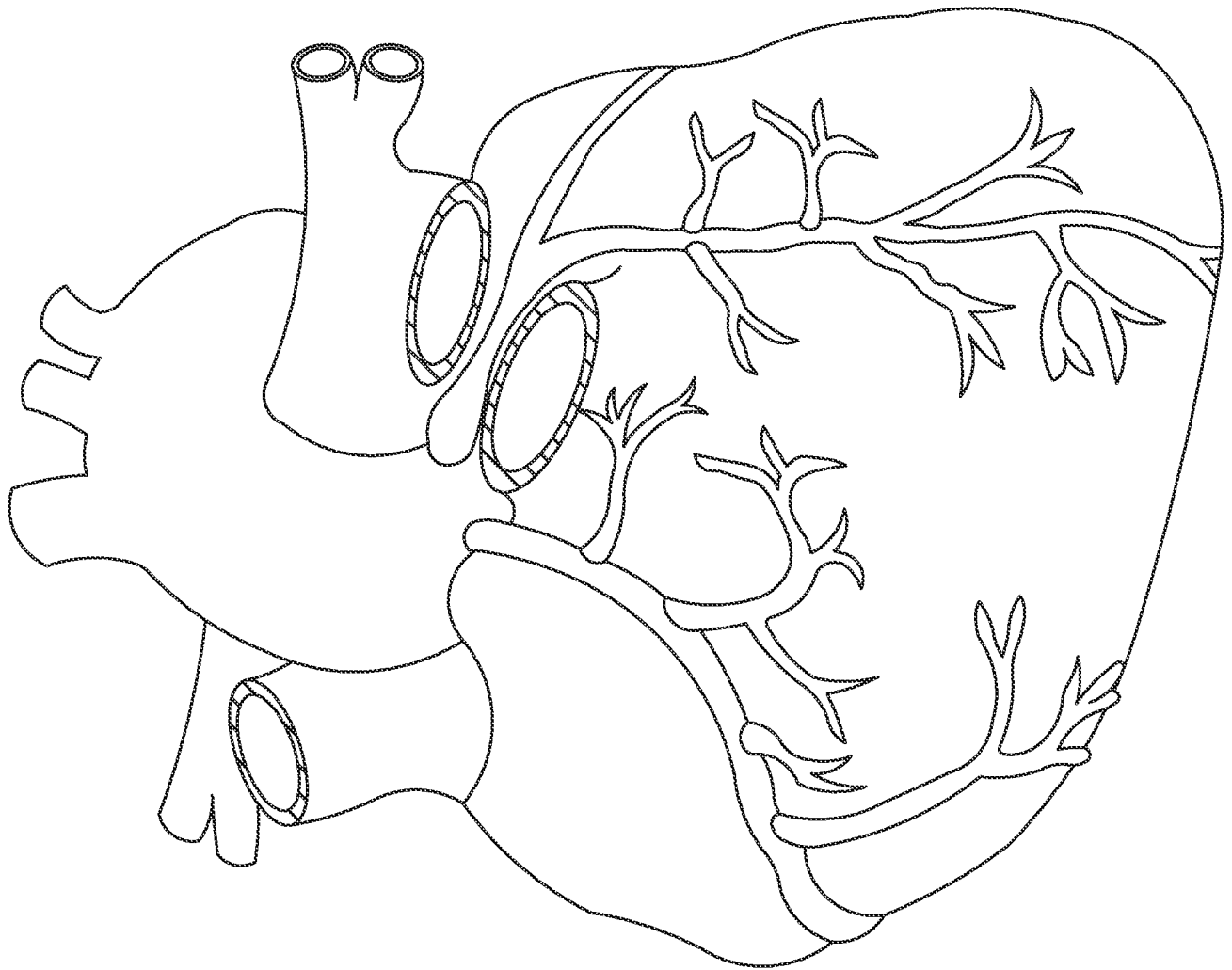


FIG. 5

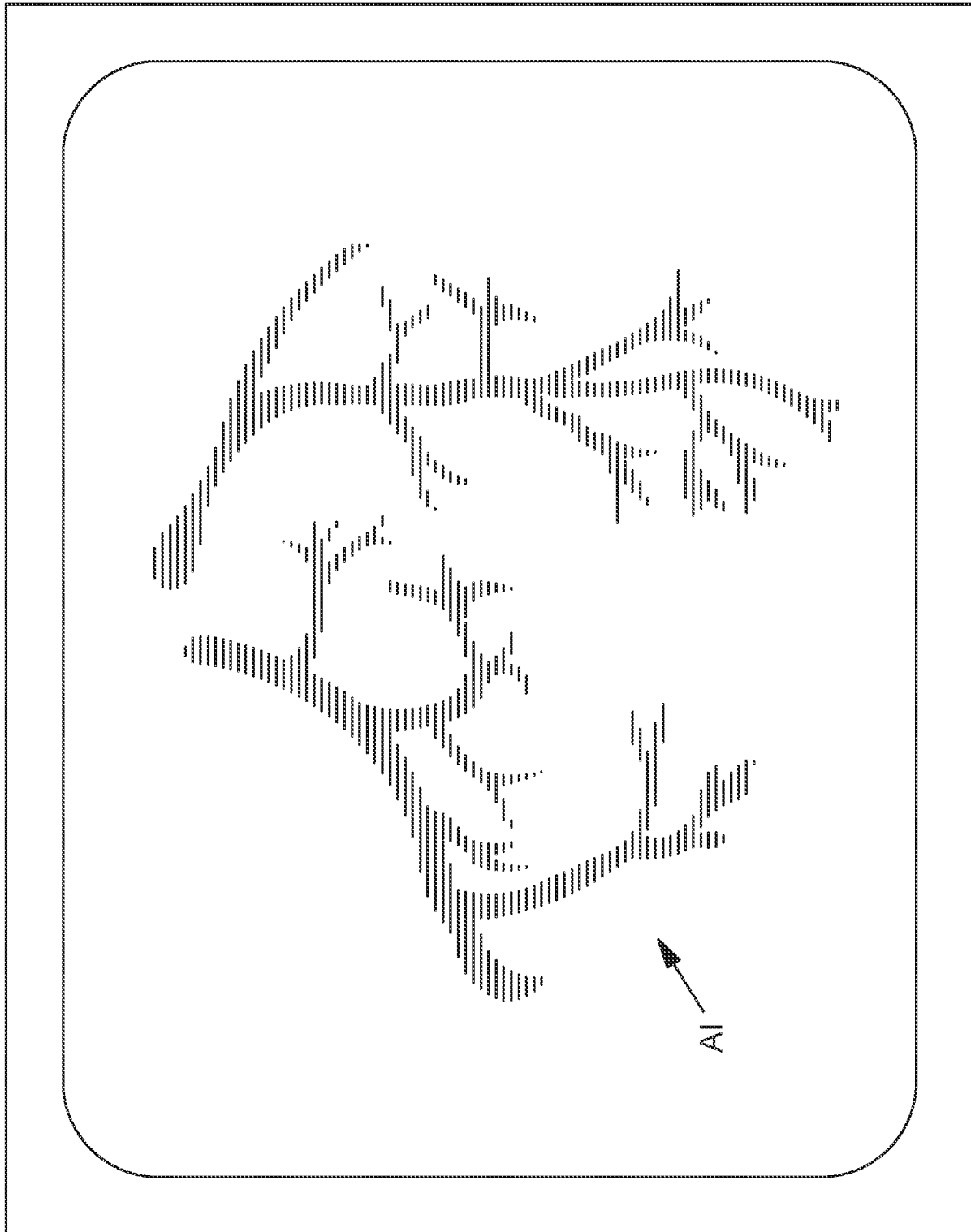


FIG. 6

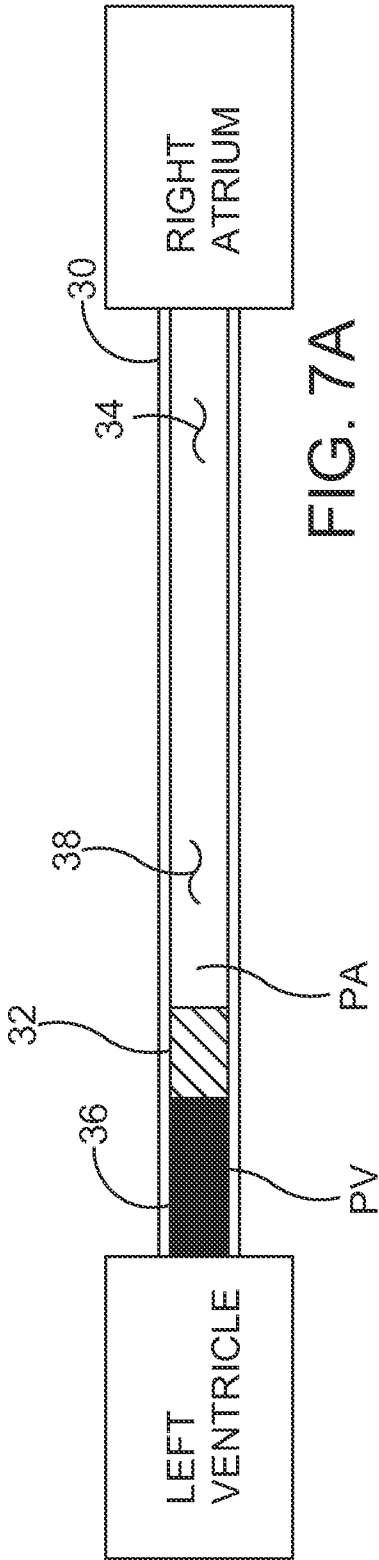


FIG. 7A

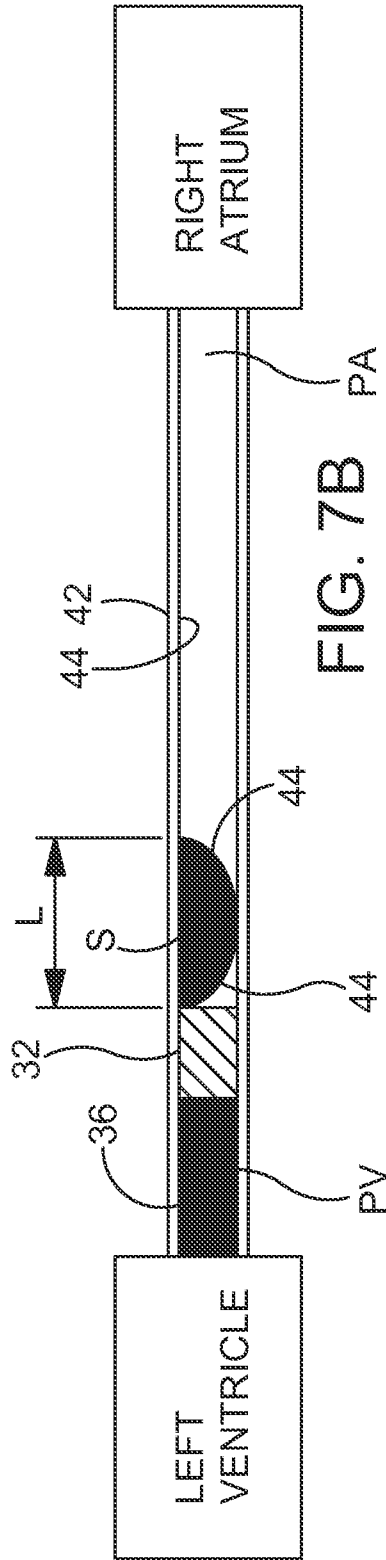


FIG. 7B

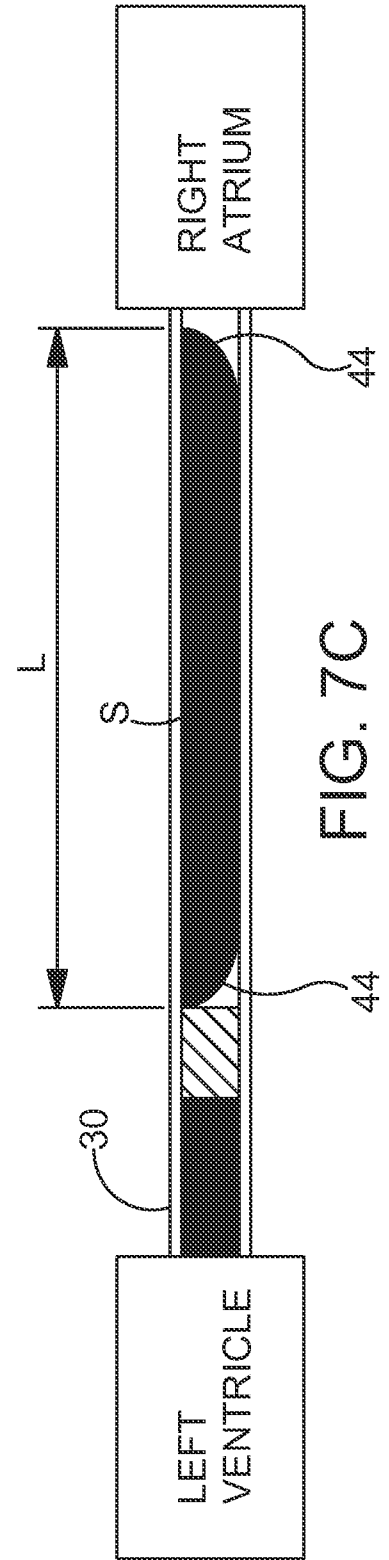


FIG. 7C

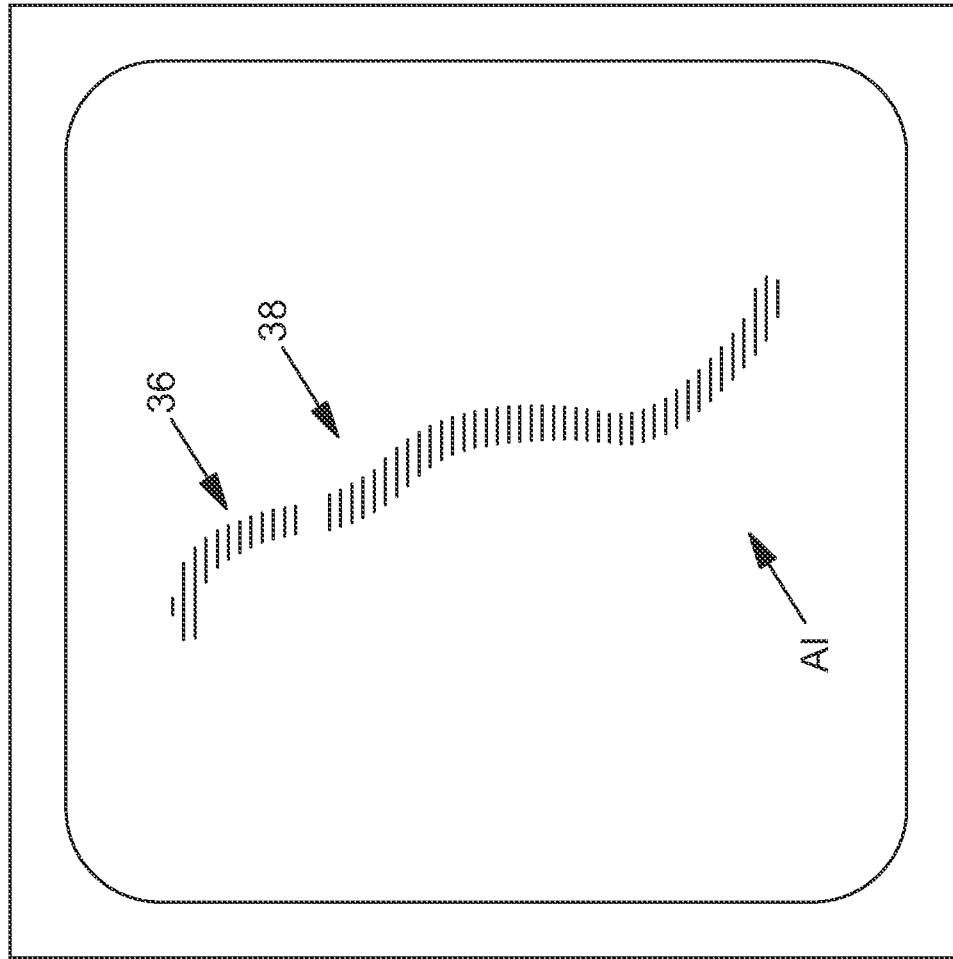


FIG. 8B

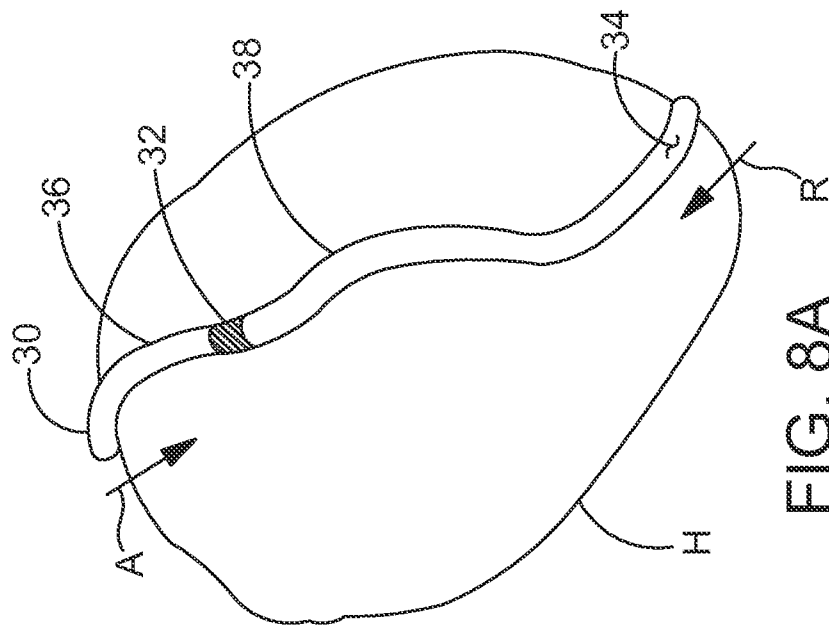


FIG. 8A

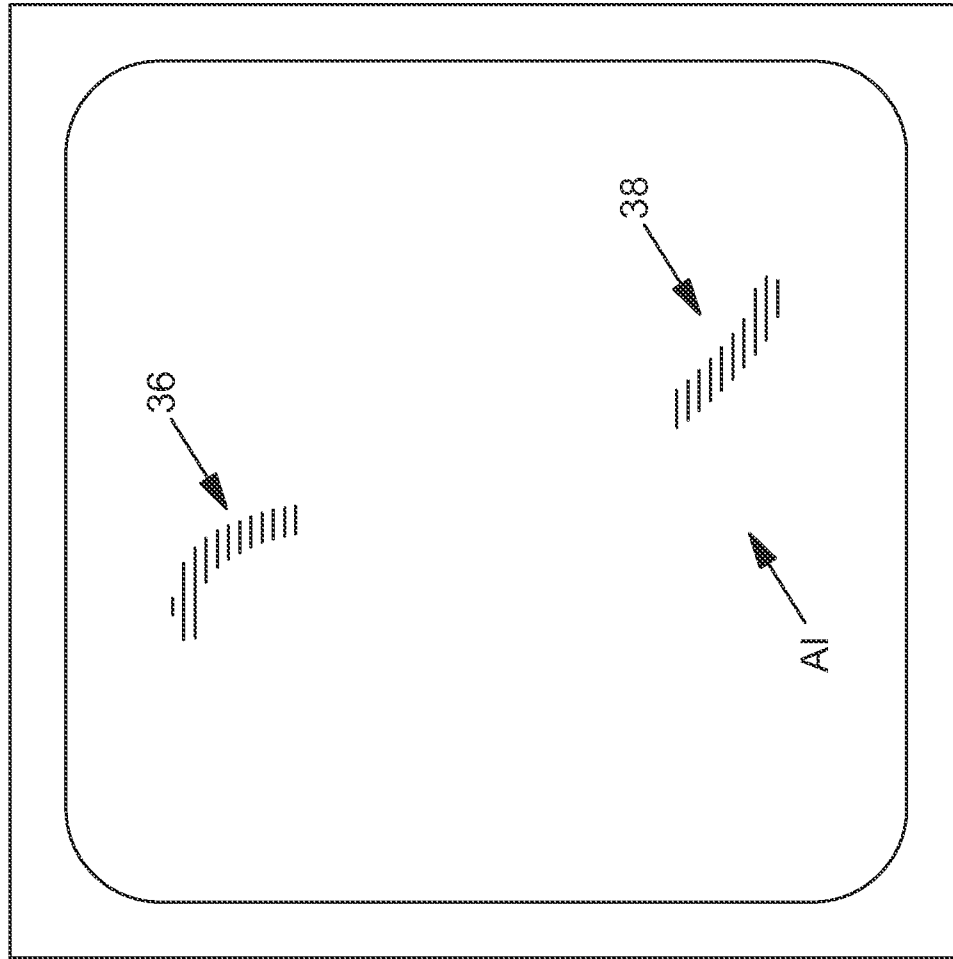


FIG. 8D

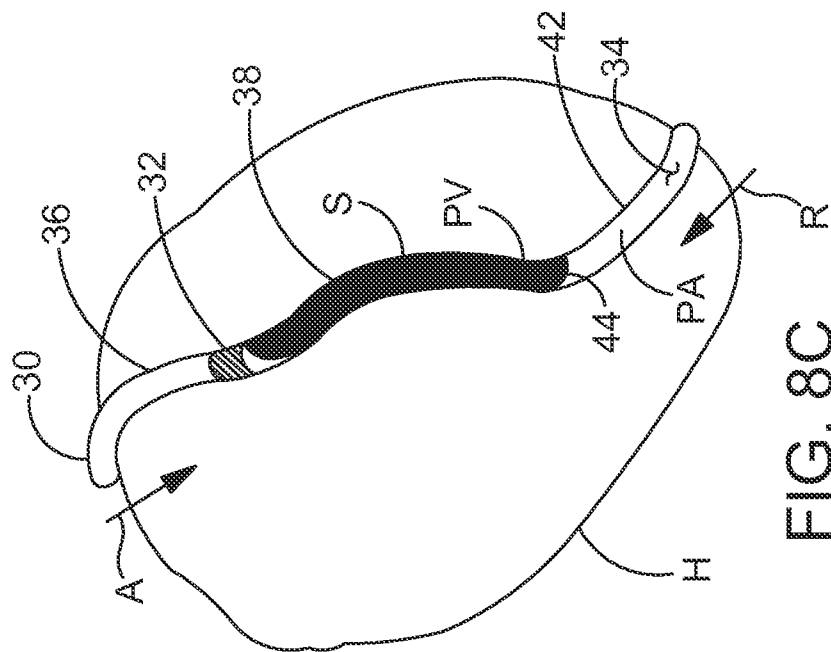
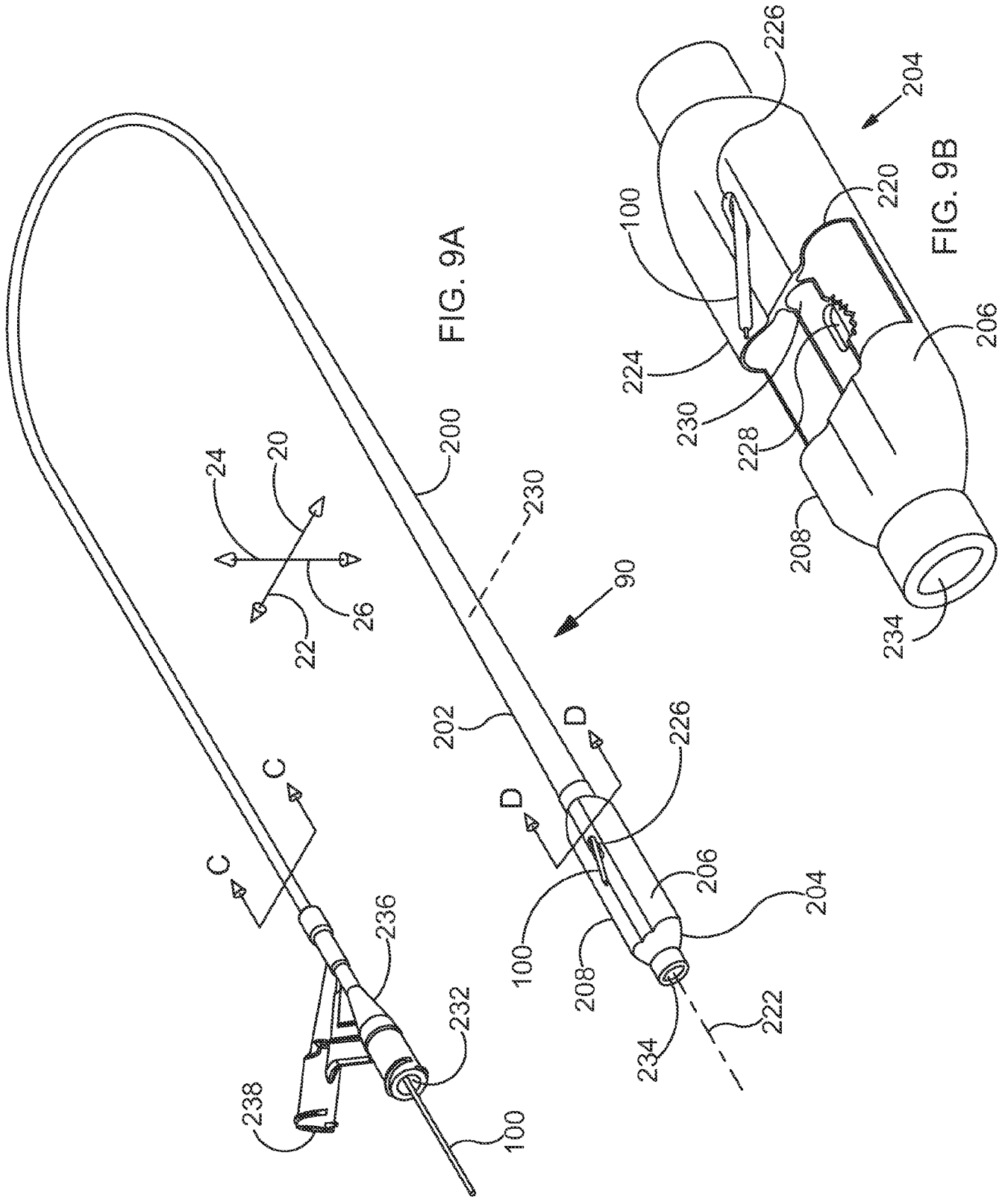


FIG. 8C



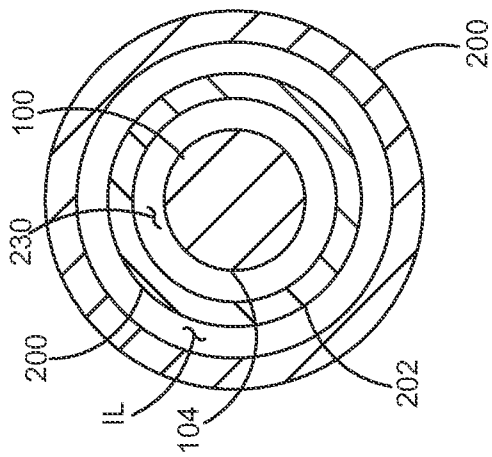


FIG. 9C

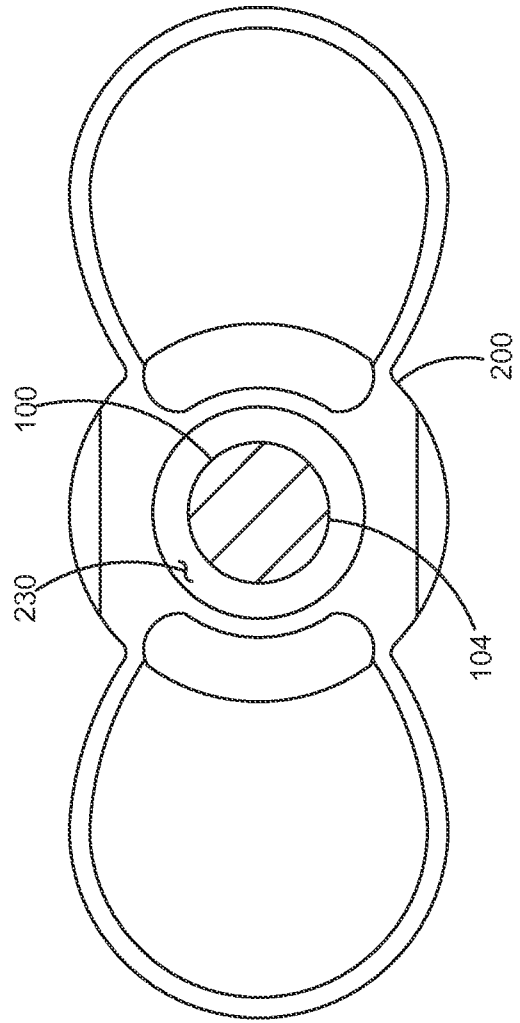
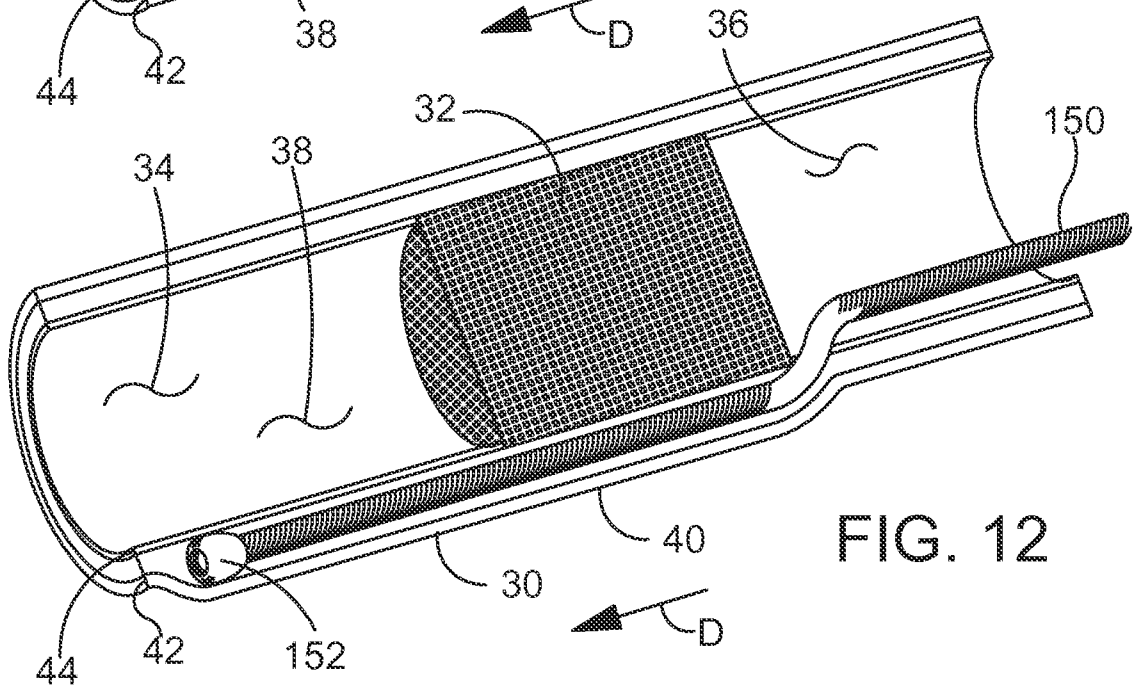
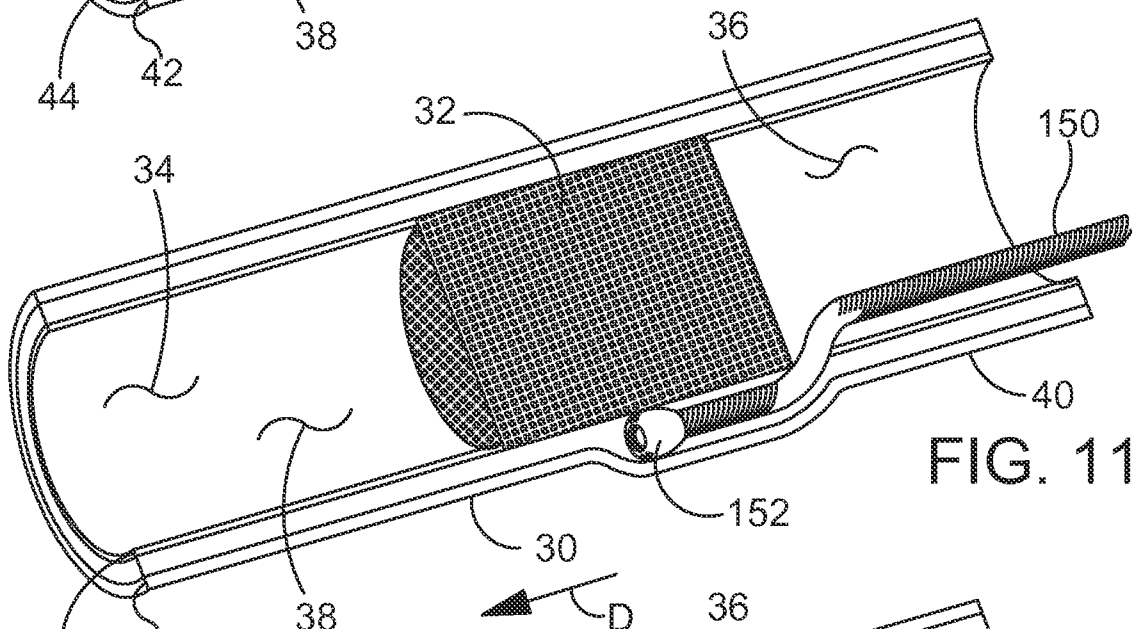
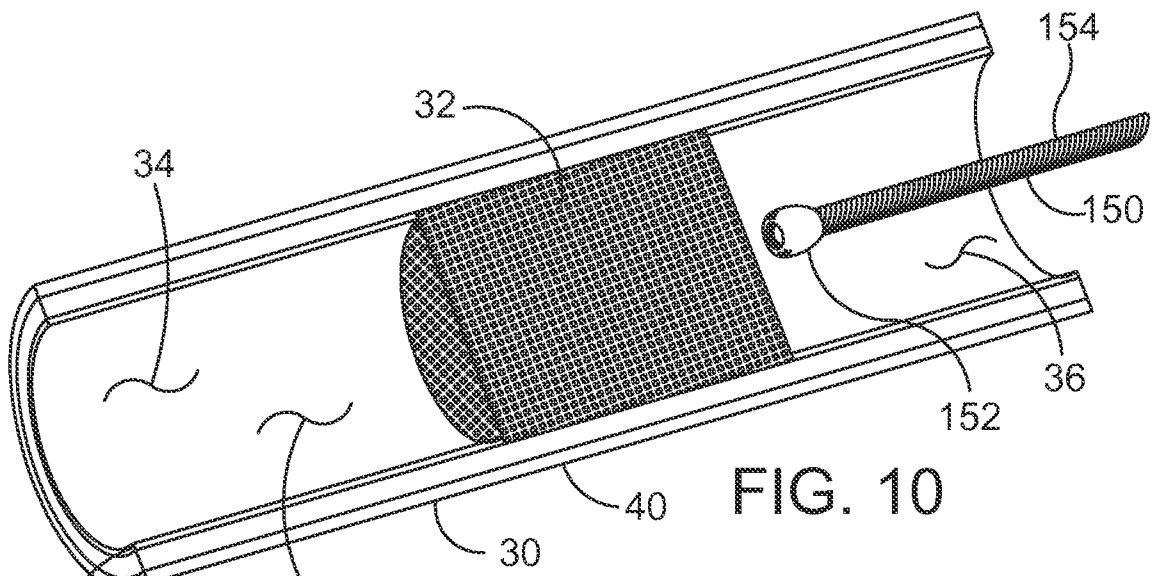


FIG. 9D



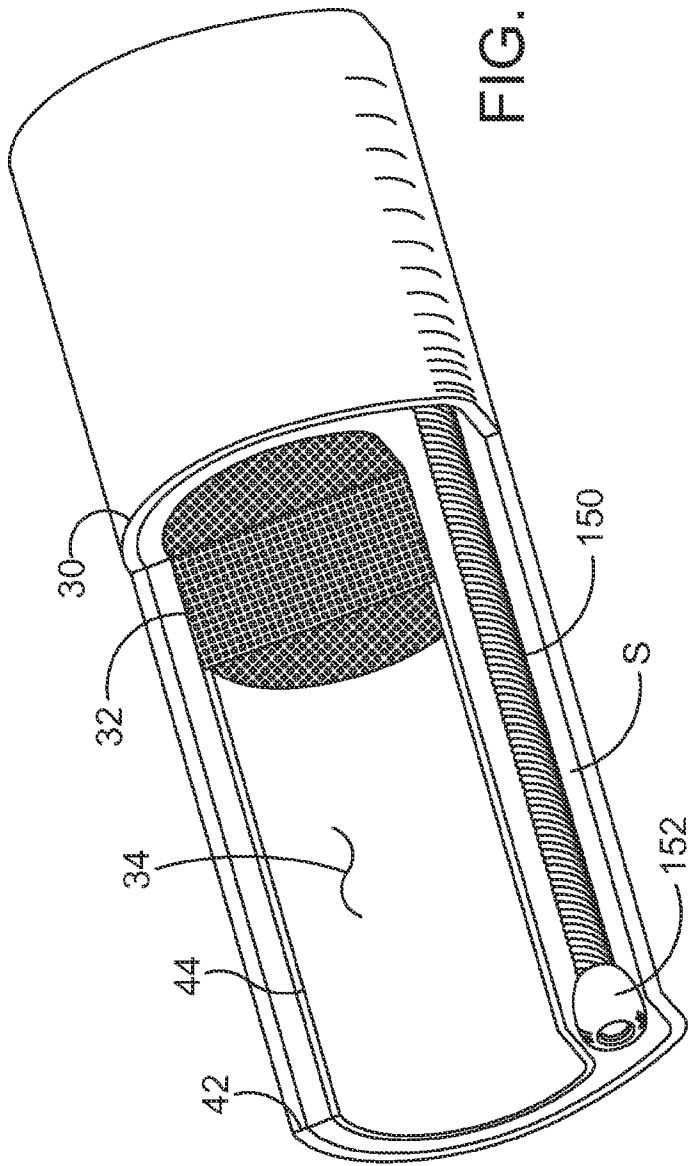


FIG. 13

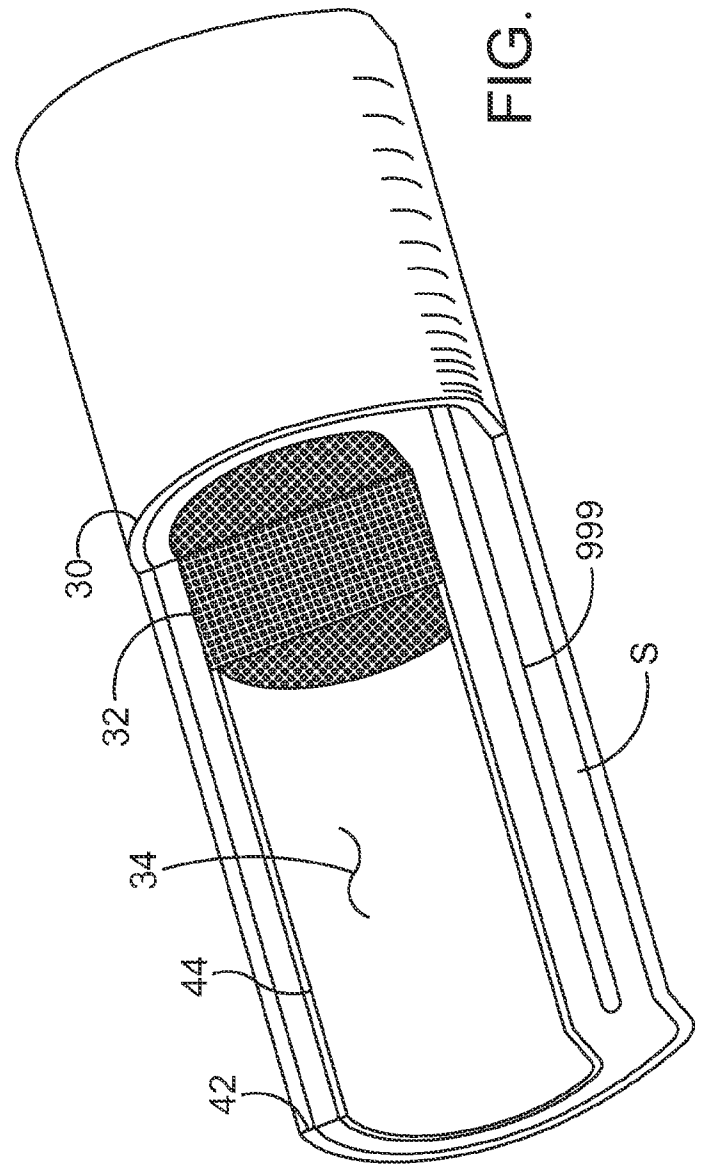
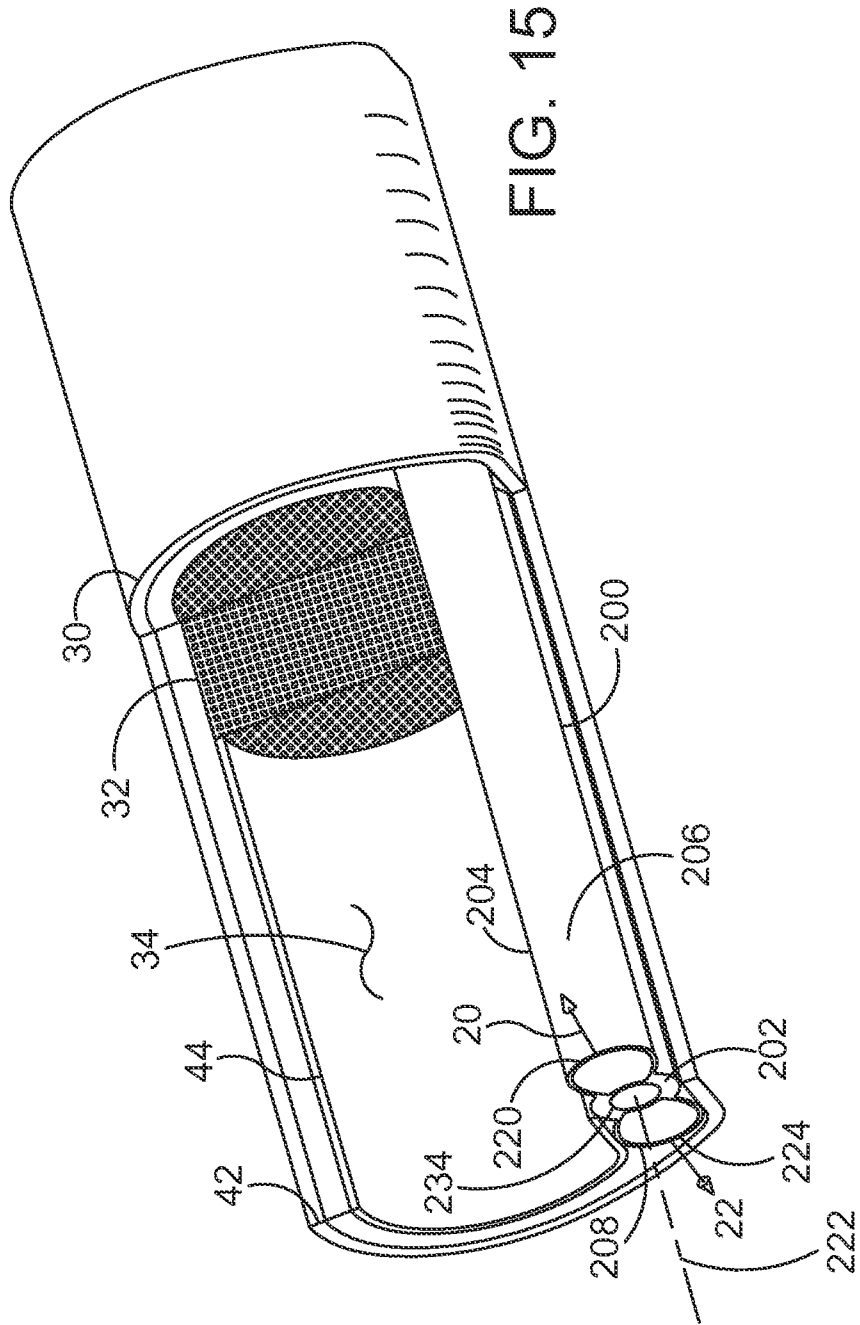


FIG. 14



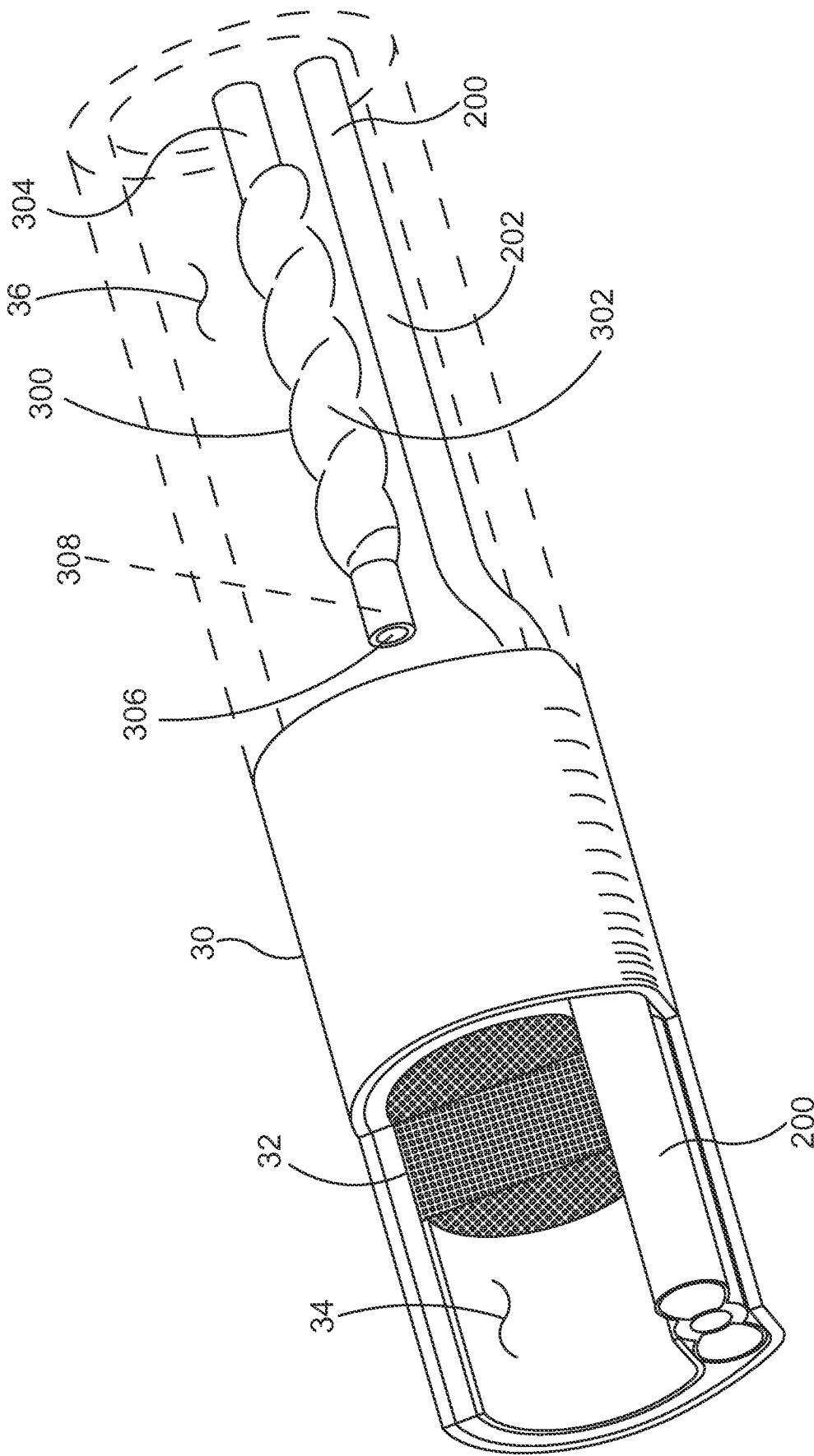


FIG. 16

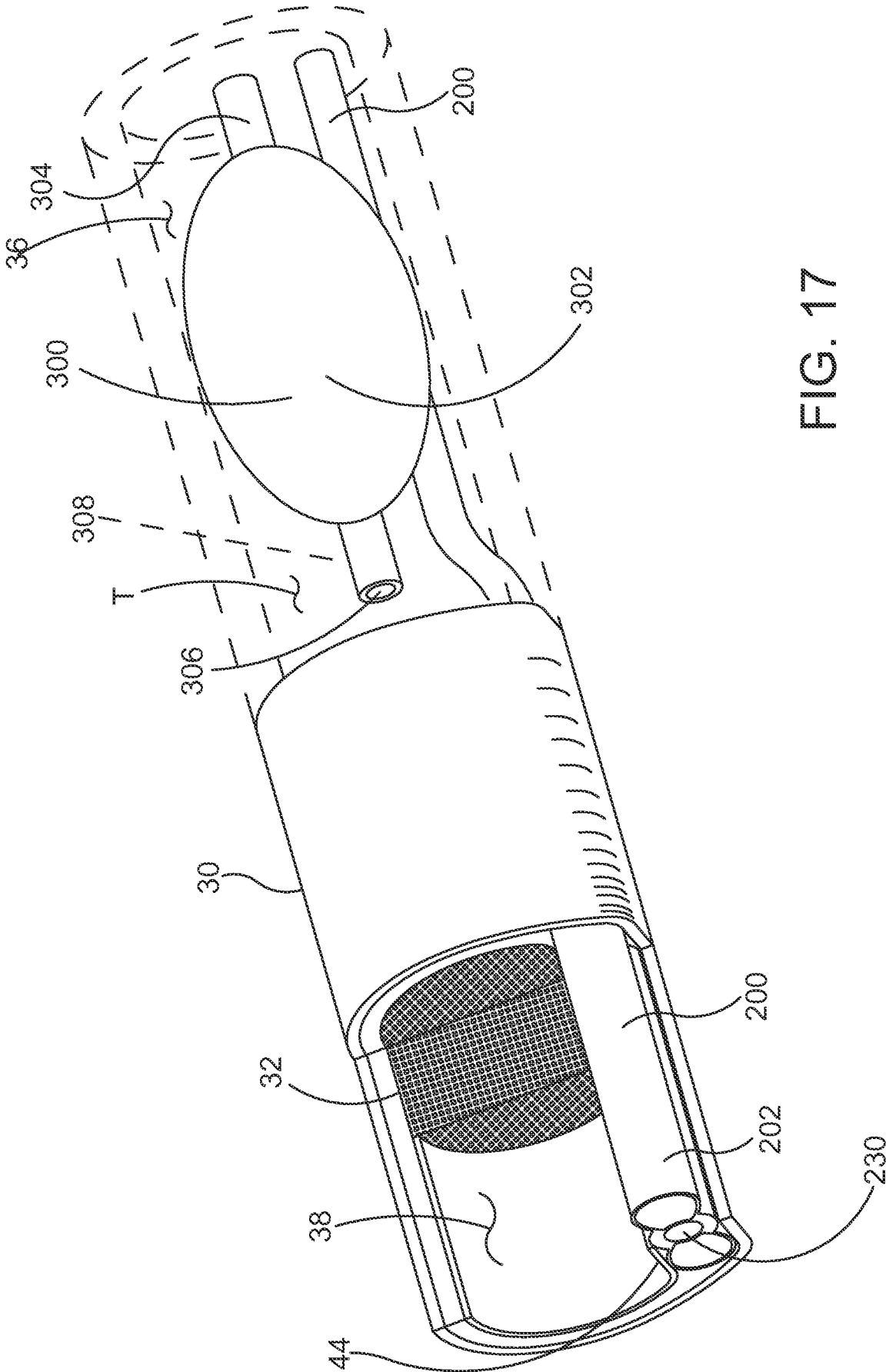


FIG. 17

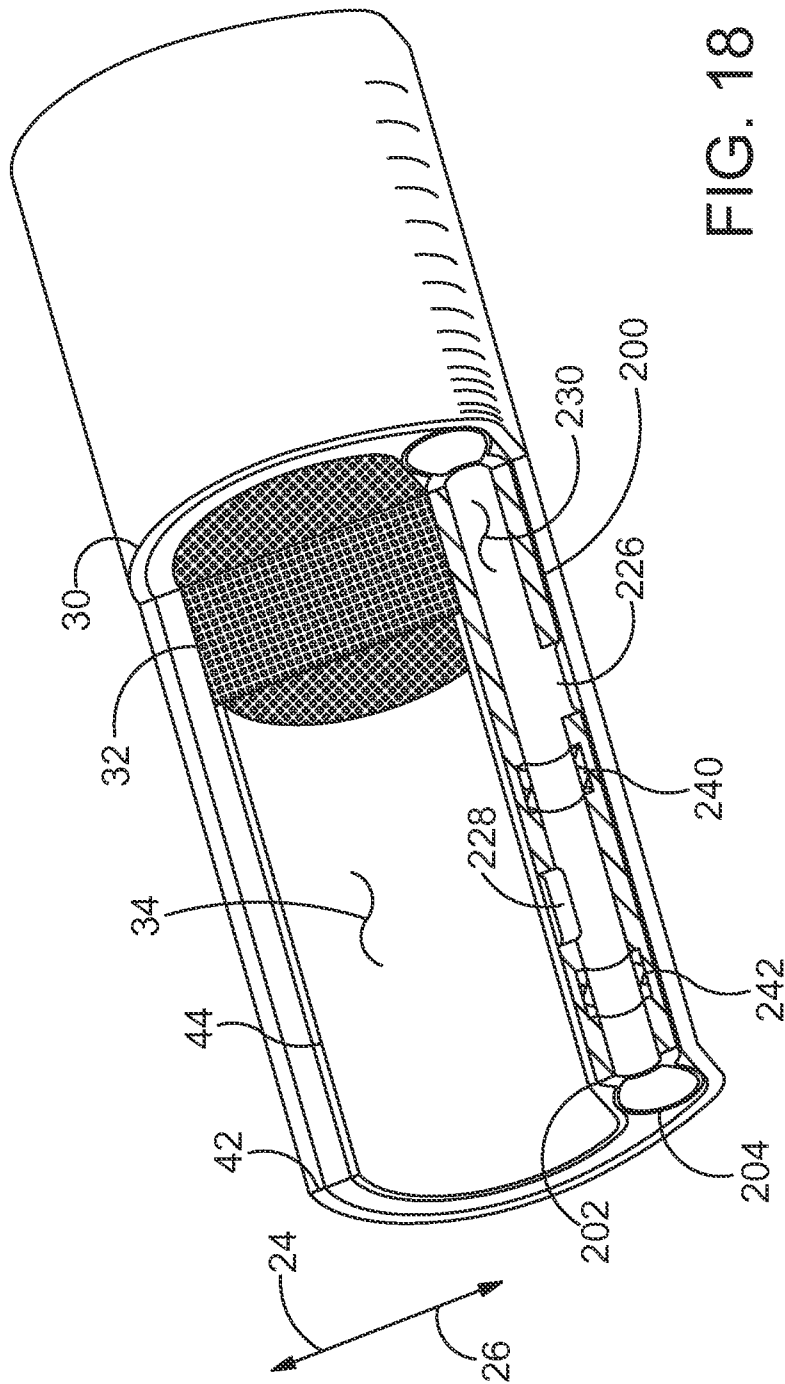


FIG. 18

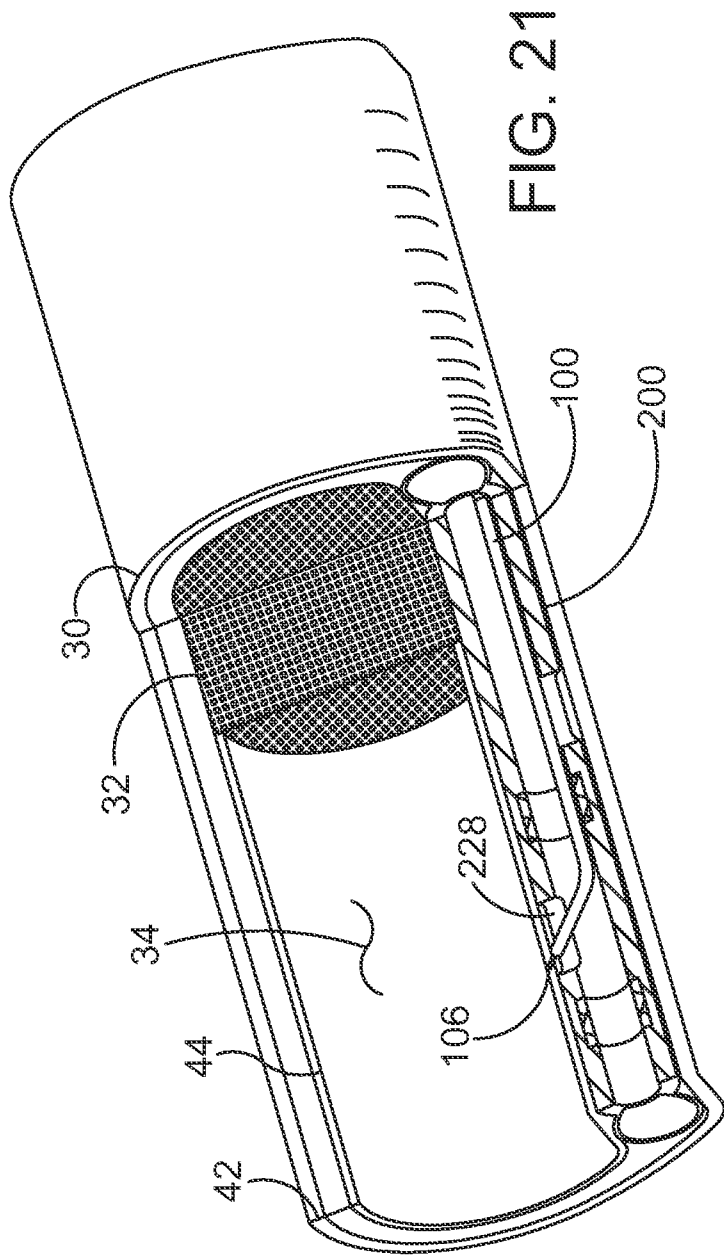


FIG. 21

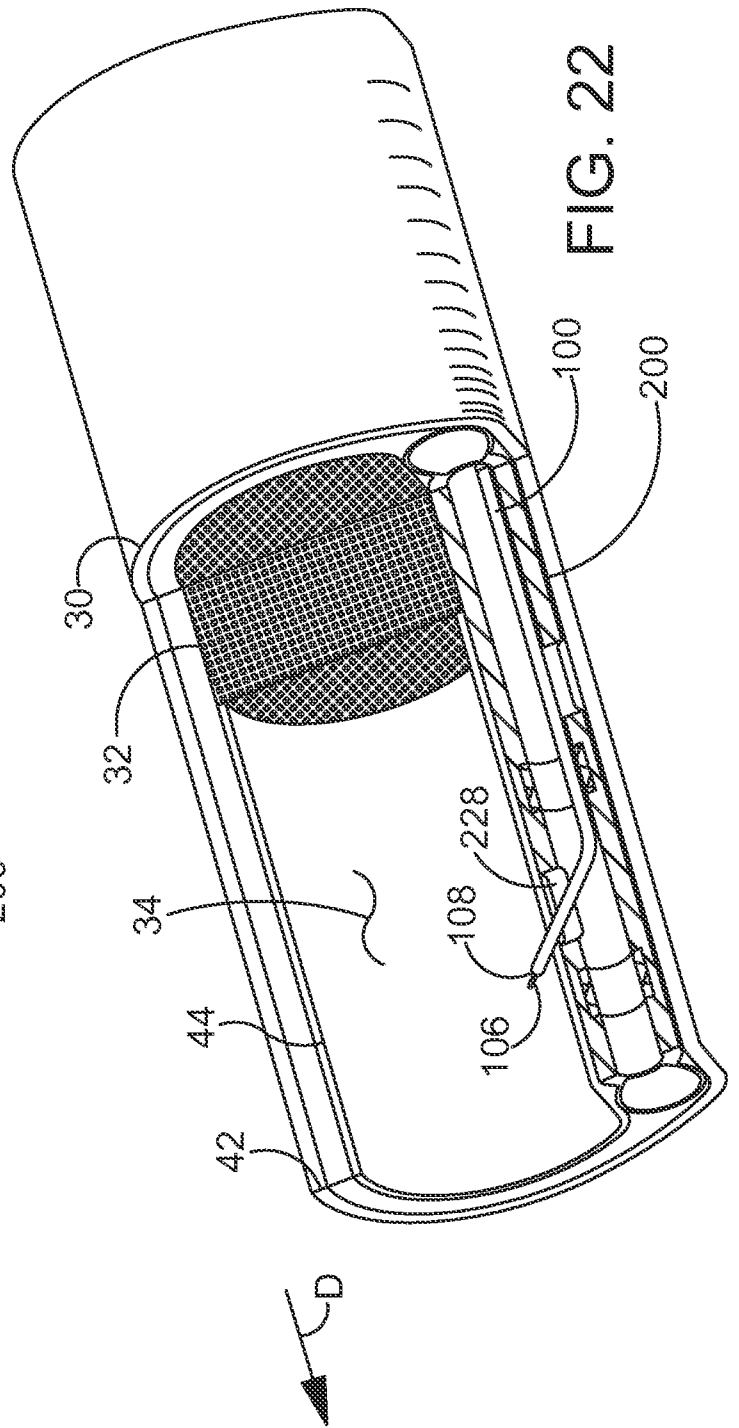


FIG. 22

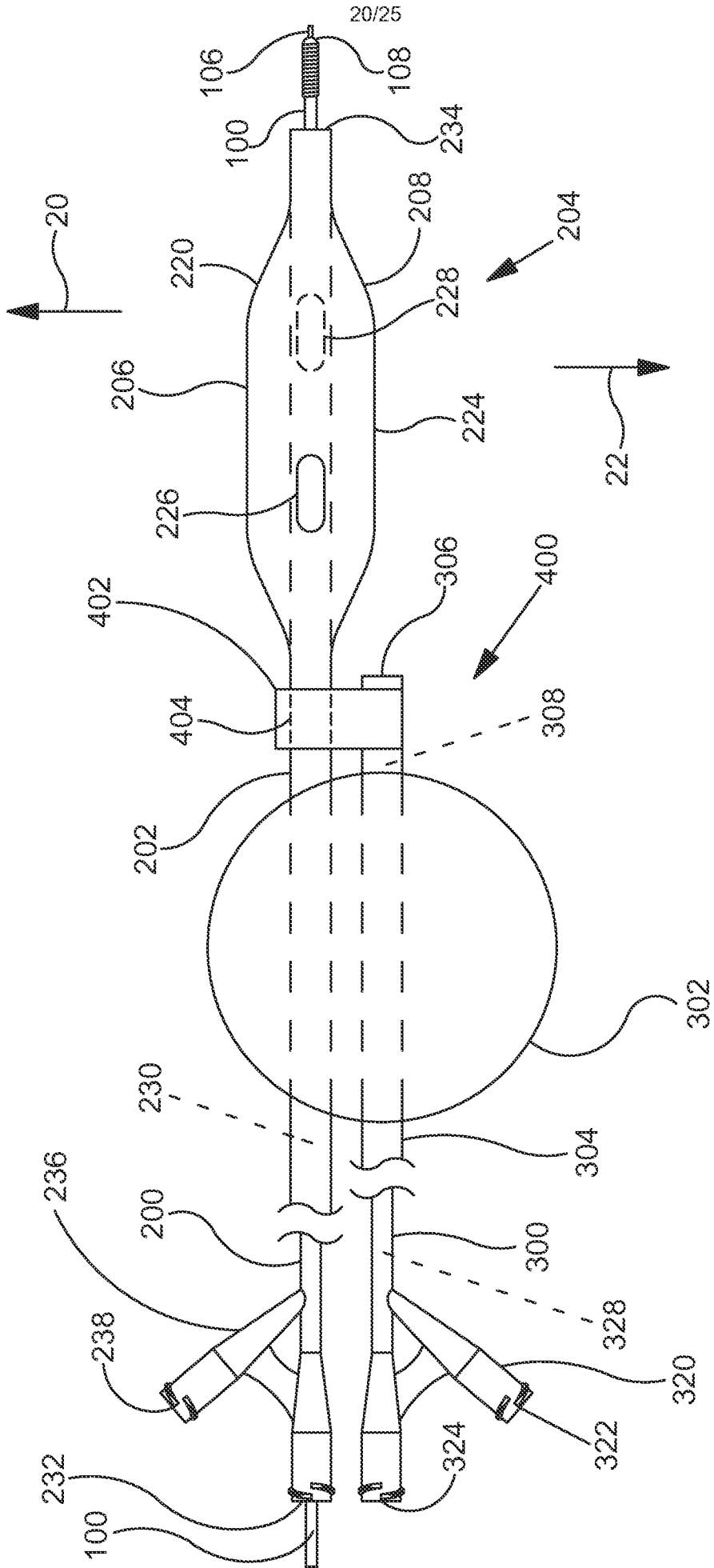
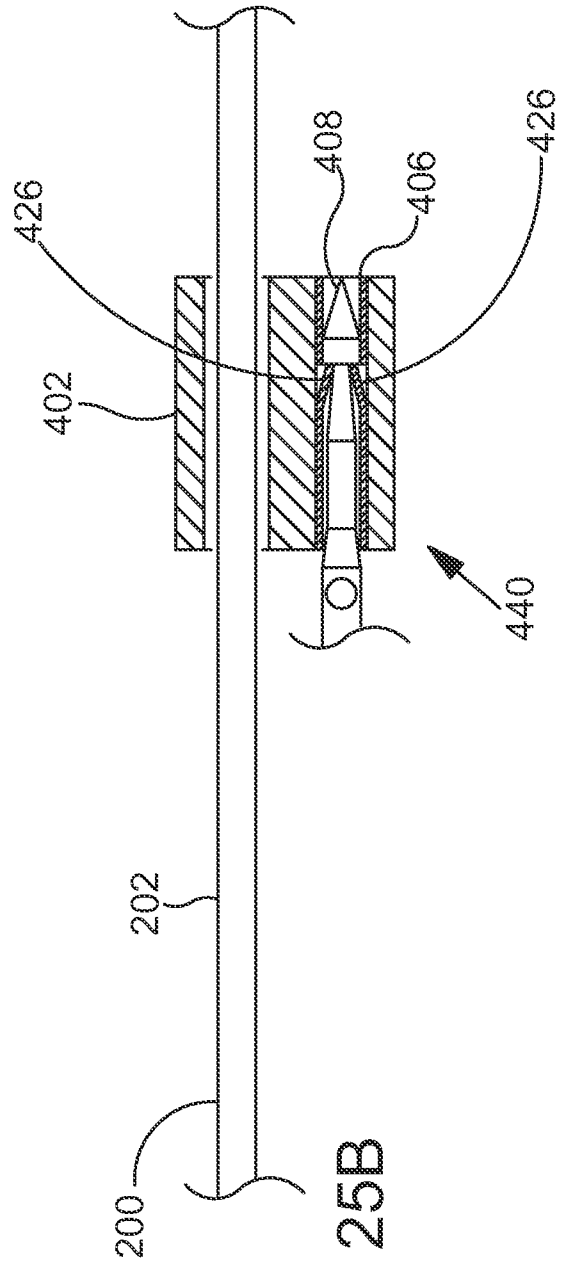
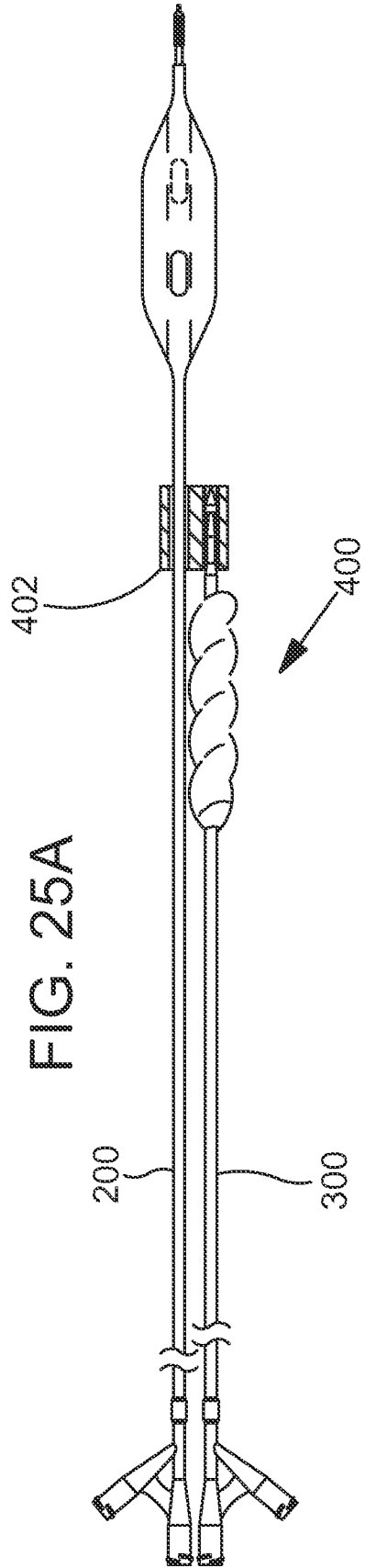
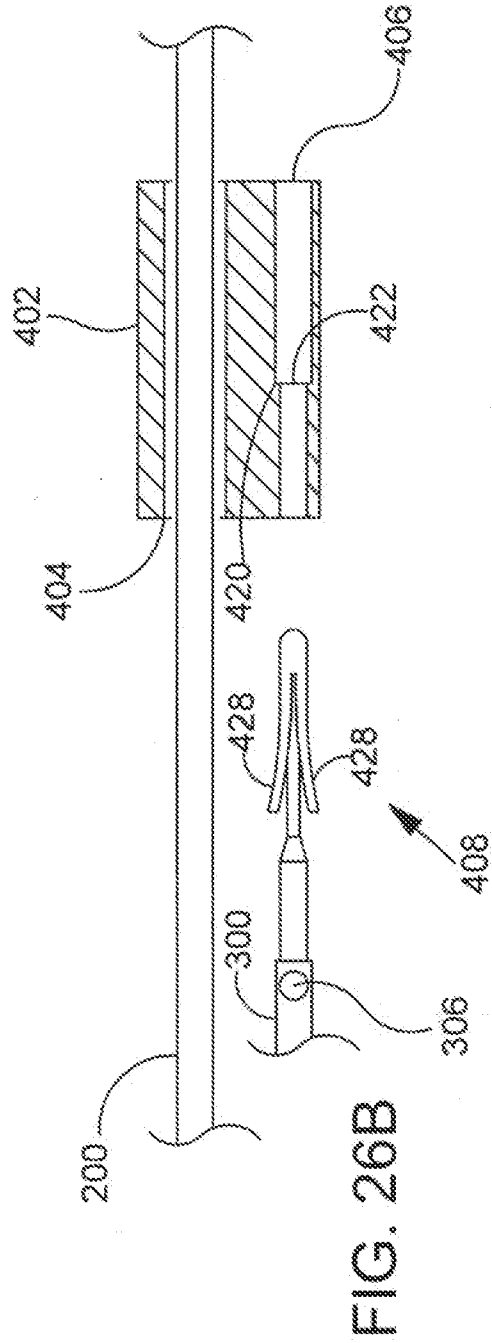
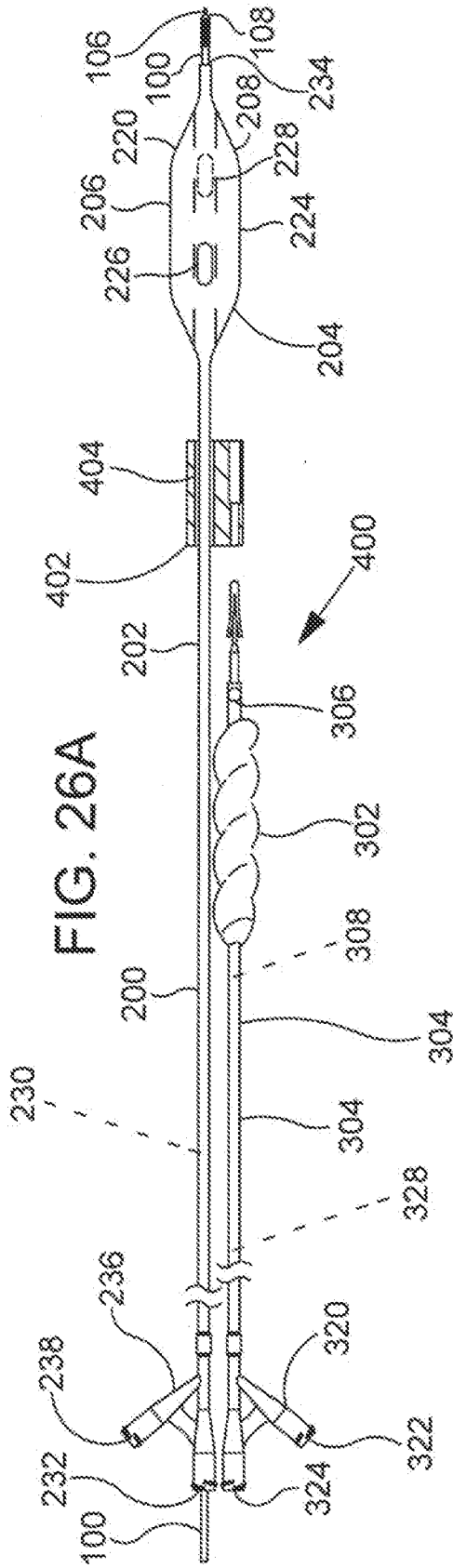
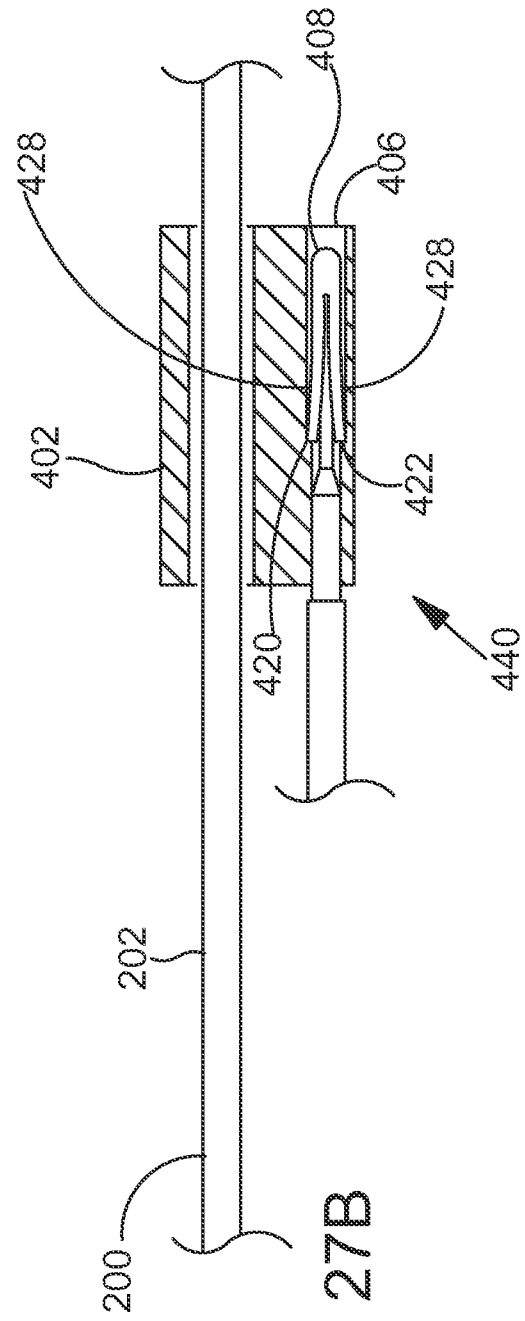
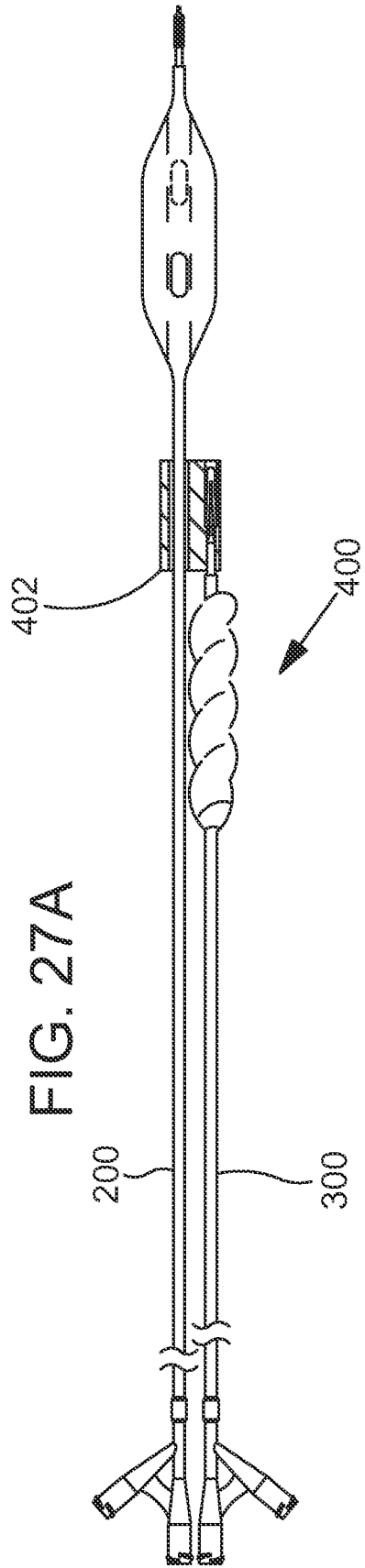


FIG. 23







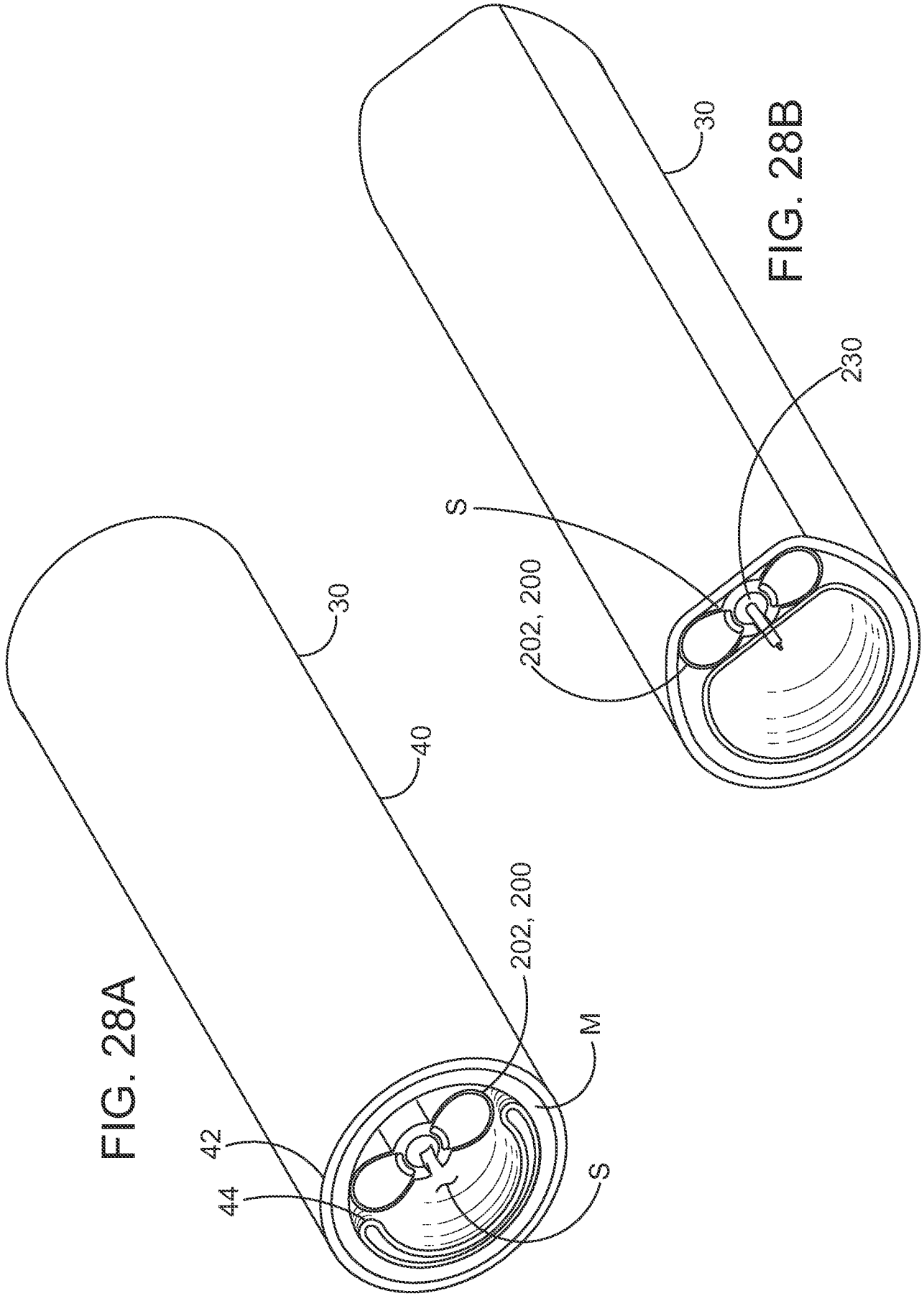


FIG. 28A

FIG. 28B