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(54) Title: INFLATABLE MEDICAL DEVICES

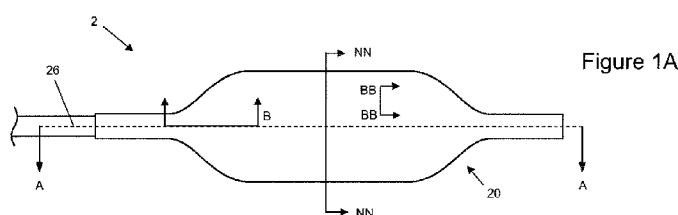


Figure 1A

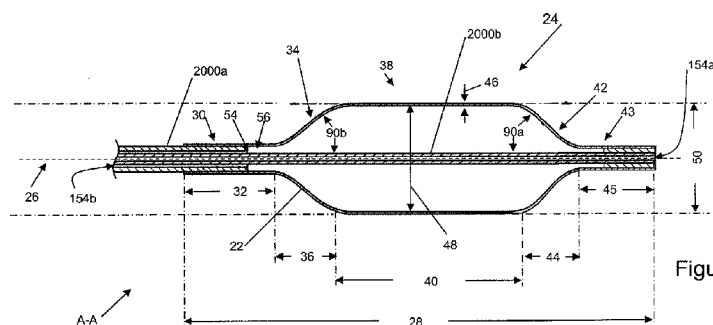


Figure 1B

(57) Abstract: Inflatable medical devices and methods for making and using the same are disclosed. The devices can be medical invasive balloons, such as those used for transcatheter heart valve implantation, such as balloons used for transcatheter aortic-valve implantation. The balloons can have high strength, fiber-reinforced walls.

INFLATABLE MEDICAL DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Application No. 61/761,138, filed February 5, 2013, and titled "INFLATABLE MEDICAL DEVICES," the entirety of which is incorporated by reference herein.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

1. Technical Field

[0003] Inflatable medical devices and methods for making and using the same are disclosed. More narrowly, medical invasive balloons, such as those used for transcatheter heart valve implantation are disclosed. For example, those balloons used for transcatheter aortic-valve implantation.

2. Description of Related Art

[0004] Inflatable structures, such as balloons, are widely used in medical procedures. A balloon is inserted, typically on the end of a catheter, until the balloon reaches the area of interest. Adding pressure to the balloon causes the balloon to inflate. In one variation of use, the balloon creates a space inside the body when the balloon inflates.

[0005] Balloons may be used in the heart valves, including during Balloon Aortic Valvuloplasty (BAV) and Transcatheter Aortic Valve Implantation (TAVI). The balloons can be used to open a stenosed aortic valve. A stenosed valve may have hard calcific lesions which may tend to tear or puncture a balloon. Additionally, a precise inflated balloon diameter may be desired for increased safety and control.

[0006] Balloons may be used to move plaque away from the center of a vascular lumen toward the vasculature walls, such as during an angioplasty or a peripheral vasculature procedure. During this procedure, a balloon tipped catheter is placed in a vascular obstruction. As the balloon is inflated, the vessel constriction is dilated, resulting in improved blood flow.

[0007] Two basic types of balloons are utilized: One is a high pressure, low-compliance balloon. The other is a lower pressure, high-compliance balloon.

[0008] High-compliance medical balloons are often composed of urethane, latex, silicone, PVC, Pebax, and other elastomers. As the pressure in a high-compliant balloon is increased, the balloon dimensions expand. Once the pressure is reduced, the high-compliance medical balloon may return to its original shape, or near its original shape. High-compliance medical balloons can easily expand several times in volume between zero inflation pressure and burst.

[0009] Traditional high-compliance medical balloons can be inadequate for many reasons. High-compliance, or highly elastic medical balloons typically cannot reach high pressures because their walls have a low tensile strength and their walls thin out as the balloon expands. In some instances, high-compliance medical balloons provide insufficient force to complete a procedure. Exceeding the rated pressure of a high-compliance medical balloon creates an excessive risk of balloon failure which can lead to serious complications for the patient.

[0010] High-compliance medical balloons also have poor shape control. As a high-compliance medical balloon expands, it may assume a shape dictated mostly by the particulars of the environment inside the patient rather than the clinical goals. In some cases, this can be contrary to what the medical practitioner desires. Many medical procedures are predicated on forming a particular balloon shape reliably.

[0011] High-compliance medical balloons often suffer from poor puncture and tear resistance.

[0012] Low-compliance, high pressure medical balloons substantially retain their shape under comparatively high pressures. PET (polyethylene terephthalate) is the most common material for use in high pressure low-compliance balloons. PET is commonly used for high-performance angioplasty balloons. PET is stronger than other polymers, can be molded into a variety of shapes and can be made very thin (e.g., 5 μm to 50 μm (0.0002 in. to 0.002 in.)), thus giving these balloons a low profile.

[0013] Balloons made from PET walls are fragile and prone to tears. When pressed against a hard or sharp surface in the body, such as stenosis, PET balloons have poor puncture resistance. PET is very stiff so balloons made from PET may be difficult to pack or fold into a small diameter and may have poor trackability (i.e., the ability to slide and bend over a guidewire deployed through a tortuous vessel).

[0014] Balloons made from PET, while stronger than most other balloons made from homogenous polymers, may still not be strong enough to hold pressures sufficient to complete certain medical procedures. Additionally, with a large balloon diameter (For example, 20 mm or greater), a PET balloon still has excessive compliance for procedures such as BAV and TAVI.

[00015] PET, like most low compliance balloons, is usually blow-molded. The blow molding process makes it difficult or impossible to create certain shapes. Blow molding can result in wall thicknesses in the balloon that do not match the material thicknesses to the expected load.

[00016] Nylon balloons are an alternative material for low-compliance, high pressure balloons. These balloons are typically weaker than PET balloons and so can contain less pressure. Nylon readily absorbs water, which can have an adverse affect on Nylon's material properties in some circumstances. Nylon has improved puncture resistance over PET and is more flexible than PET.

[00017] A balloon is desired that can sustain high pressures, provide precise shape control and be highly resistant to tear and puncture.

SUMMARY

[00018] A method of aligning a fluoroscope for valvuloplasty comprises inserting a balloon having a plurality of radiopaque markers thereon into an aortic root; imaging the balloon with a fluoroscope; using the image to determine that the radiopaque markers on the balloon are not properly aligned, wherein having the radiopaque markers not properly aligned indicates that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane of the aortic valve; and adjusting a position of the fluoroscope until the radiopaque markers on the balloon are properly aligned such that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane of the aortic valve. The radiopaque markers may comprise radiopaque rings around the balloon, and the step of using the image to determine that the radiopaque markers on the balloon are not properly aligned may comprise identifying elliptical features in the image corresponding to the radiopaque rings.

[00019] An inflatable medical device comprises a balloon; and a radiopaque marker on the balloon, the radiopaque marker configured to provide a signal in a fluoroscopic image indicative of the orientation of the balloon relative to the fluoroscope taking the image. The radiopaque marker may comprise a radiopaque ring around the circumference of the balloon.

[00020] An inflatable medical device comprises a balloon having a constant diameter section, proximal and distal tapered sections, and proximal and distal stem sections, and a first layer over the balloon comprising a fiber extending circumferentially around the balloon, the fiber having a pitch in the proximal and distal tapered sections that is greater than a pitch of the fiber in the constant diameter and proximal and distal stem sections.

[00021] An inflatable medical device comprises a leak resistant bladder, the leak resistant bladder comprising a plurality of sublayers of a vapor deposited material, the sublayers of vapor deposited material configured to slide relative to one another; and a layer of fiber over the leak resistant bladder. The vapor deposited material may comprise parylene. The plurality of

sublayers of vapor deposited material may include an adhesion retardant (such as for example fluorine) therebetween. The bladder may be less than 20 microns thick, and each sublayer of vapor deposited material may be less than 5 microns thick.

[00022] An inflatable medical device comprises a balloon having at least one layer of fibers, and a leak resistant outer layer, the leak resistant outer layer comprising a plurality of sublayers of a vapor deposited material. The vapor deposited material may comprise parylene. The plurality of sublayers of vapor deposited material may include an adhesion retardant (such as for example fluorine) therebetween. The bladder may be less than 20 microns thick, and each sublayer of vapor deposited material may be less than 5 microns thick.

[00023] A method of making an inflatable medical device comprises vapor depositing a plurality of sublayers onto a solid mandrel to form a leak resistant bladder; applying at least one layer of fiber over the bladder; and vapor depositing a plurality of sublayers over the at least one fiber layer to form a leak resistant outer layer.

[00024] A method of making an inflatable medical device comprises rotating a mandrel about a longitudinal axis; running a single fiber tow in a first direction along the longitudinal axis onto the rotating mandrel so as to create a positive transverse wind, the positive transverse wind forming an angle of approximately 40 to 60 degrees with the longitudinal axis; and running the fiber tow in a second direction opposite to the first direction along the longitudinal axis onto the rotating mandrel so as to create a negative transverse wind, the negative transverse wind forming an angle of approximately -40 to -60 degrees with the longitudinal axis.

[00025] An inflatable medical device comprises a balloon having a constant diameter section, proximal and distal tapered sections, and proximal and distal stem sections; and a panel covering the balloon, wherein the panel comprises a plurality of fibers extending substantially parallel with a longitudinal axis of the balloon, and wherein the panel comprises a rectangular section and a plurality of triangular or trapezoidal sections, the rectangular section substantially covering the constant diameter section of the balloon, and the triangular or trapezoidal sections substantially covering the proximal and distal tapered sections and the proximal and distal stem sections. The triangular or trapezoidal sections may overlap in the proximal and distal tapered sections of the balloon. The proximal and distal tapered sections may have a stiffness that is greater than the stiffness of the constant diameter section.

[00026] An inflatable medical device comprises a balloon having a constant diameter section, proximal and distal tapered sections, and proximal and distal stem sections, and a panel covering the balloon, wherein the panel comprises a plurality of fibers extending substantially parallel to a longitudinal axis of the balloon, the panel further comprising a plurality of fiber separation areas within the constant diameter section, the fiber separation areas arranged in a

pattern such that no adjacent fibers have the same length. At least some of the fiber separation areas extend through the fibers at an angle greater than 0 degrees and less than 90 degrees relative to the circumferential axis of the balloon. The angle may be between 10 and 45 degrees, and may be approximately 25 degrees. At least some of the fiber separation areas may extend through the fibers parallel with the circumferential axis of the balloon.

[00027] An inflatable medical device for performing a valvuloplasty in an aortic root, comprises a balloon adapted for positioning in the aortic root, and a radiopaque marker on the balloon, the radiopaque marker configured to provide a fluoroscopic image indicative of the orientation of the balloon relative to a fluoroscope taking the image.

[00028] The balloon may comprise a constant diameter section having a diameter of less than about 30 millimeters, said constant diameter section including the radiopaque marker. The balloon may include a plurality of radiopaque markers on the balloon, which may be spaced in the circumferential direction. The radiopaque markers comprise a plurality of groups of radiopaque markers spaced in the circumferential direction, each group of radiopaque markers also being spaced in the longitudinal direction. The radiopaque markers may comprise three substantially identical bands spaced in the longitudinal direction, including a first radiopaque marker is positioned at each end of the constant diameter section and a second radiopaque marker is between the first radiopaque markers. The radiopaque marker or each of the plurality of radiopaque markers extends a distance of between about 0.0002 inches and 0.032 inches in the longitudinal direction. The radiopaque marker or each of the plurality of markers comprises a wire. The wire may be round or flat. The radiopaque marker or each of the radiopaque markers comprises an annular band. The radiopaque marker or markers may comprise gold. The balloon may comprise at least one fiber, the fiber being arranged so as to form a gap for the radiopaque marker. The balloon may comprise at least one fiber layer including the radiopaque mark. The radiopaque marker may comprise a continuous spiral, and may be embedded in a wall of the balloon.

[00029] A method of manufacturing a balloon, comprises providing a metal radiopaque marker in a wall of the balloon. The providing step may comprise embedding a metal wire in the balloon wall. The providing step may comprise providing the metal radiopaque marker as part of a fiber layer forming the wall of the balloon. The providing step may comprise embedding a gold wire in the balloon wall. The providing step may comprise embedding a plurality of wires in the wall of the balloon.

[00030] A method of aligning a fluoroscope for valvuloplasty may comprise imaging the balloon as described herein with a fluoroscope, and using the image to determine that the radiopaque marker on the balloon is not properly aligned. Having the radiopaque marker not

properly aligned indicates that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane of an external structure, in which case the method may include adjusting a position of the fluoroscope until the radiopaque marker on the balloon is properly aligned such that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane. The radiopaque marker comprises a radiopaque ring around the balloon, and the method may include using the image to determine that the radiopaque marker on the balloon is not properly aligned comprises identifying elliptical features in the image corresponding to the radiopaque ring.

[00031] A further method relates to use in connection with performing a valvuloplasty on an aortic valve, comprising: inserting the balloon herein into the aortic root, inflating the balloon, imaging the balloon with a fluoroscope, and using the image to determine a profile of the aortic root.

[00032] A further aspect relates to an inflatable medical device, comprising: a balloon including a balloon wall fully encasing at least one metal wire extending around the balloon in a circumferential direction. The wire may comprise a band, and the balloon may comprise a constant diameter portion further including a plurality of spaced wires. The wire or wires may each extend a distance of between about 0.0002 inches and 0.032 inches in a longitudinal direction of the balloon, and may be round or flat. The wire or wires may comprise gold, the balloon further includes at least one fiber layer, and the metal wire forms a part of the fiber layer. The at least one fiber may be arranged to form a gap for receiving the metal wire.

[00033] An inflatable medical device comprises a balloon having a longitudinal direction and a circumferential direction, and a plurality of radiopaque markers on the balloon, the plurality of radiopaque markers comprising at least one group of at least two radiopaque markers elongated in the circumferential direction and spaced from each other in the circumferential direction. The device may further include a plurality of groups of radiopaque markers spaced in the circumferential direction, each group of markers also being spaced in the longitudinal direction. Each radiopaque marker comprises a wire, and each radiopaque marker may comprise metal (such as gold). Each radiopaque marker may be embedded in a wall of the balloon, and may form part of a fiber layer forming a wall of the balloon.

[00034] A method of determining the proper orientation of a fluoroscope, comprises imaging a radiopaque marker on a balloon, the radiopaque marker configured to provide a fluoroscopic image indicative of the orientation of the balloon relative to a fluoroscope taking the image. The method may further include the step of inserting the balloon into the vasculature prior to the imaging step.

[00035] Any balloon described herein may be connected to a catheter shaft including an inflation lumen for delivering the inflation fluid for inflating the balloon. A guidewire lumen may also be provided.

BRIEF DESCRIPTION OF THE DRAWINGS

[00036] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the claimed inventions will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

- [00037] Figure 1A illustrates a variation of the device.
- [00038] Figure 1B illustrates a variation of cross section A-A of Figure 1.
- [00039] Figure 2A illustrates a variation of the device.
- [00040] Figure 2B illustrates a variation of cross section QQ-QQ of Figure 2.
- [00041] Figures 3A, 3B, 3C, and 3D are cross-sectional views of a length of variations of the device.
- [00042] Figure 4A illustrates a variation of the device.
- [00043] Figures 4B and 4C are variations of cross-section H-H of Figure 4A.
- [00044] Figure 5 illustrates a variation of the device.
- [00045] Figure 6A illustrates a variation of the device.
- [00046] Figures 6B and 6C are variations of cross-section D-D of Figure 5A.
- [00047] Figures 7A, 7B and 7C show close-up cross section views of variations of the seam.
- [00048] Figure 8A illustrates a variation of the device.
- [00049] Figure 8B is a variation of cross section E-E of the device of Figure 8A.
- [00050] Figure 8C is a variation of cross section F-F of the device of Figure 8A.
- [00051] Figure 8D is a variation of cross section G-G of the device of Figure 8A.
- [00052] Figures 8E and 8F illustrate variations of the device.
- [00053] Figure 9A illustrates a variation of the device in a deflated state.
- [00054] Figure 9B illustrates a variation of the device in an inflated state.
- [00055] Figures 9C, 9C', 9D, 9E, 9F, 9G, and 9H illustrate variations of the device.
- [00056] Figures 9I and 9J are cross-sectional views of a portion of the wall of variations of the device.
- [00057] Figures 9K and 9L illustrate variations of the device.
- [00058] Figure 10A illustrates a variation of the device in a deflated state.
- [00059] Figure 10B illustrates a variation of the device in an inflated state.
- [00060] Figure 11A illustrates a variation of the device.

- [00061] Figure 11B is a variation of cross section R-R of the device of Figure 11A.
- [00062] Figure 12A illustrates a variation of the device.
- [00063] Figure 12B is a variation of cross section S-S of the device of Figure 12A.
- [00064] Figure 13A illustrates a variation of the device.
- [00065] Figures 13B and 13C are variations of cross section T-T of the device of Figure 13A.
- [00066] Figure 14A illustrates a variation of the device.
- [00067] Figure 14B is a variation of cross section i-i of the device of Figure 14A.
- [00068] Figures 15A and 15B are variations of the device
- [00069] Figure 16A illustrates a variation of the device.
- [00070] Figures 16B and 16C are variations of cross section V-V of the device of Figure 16A.
- [00071] Figure 17A illustrates a variation of the device.
- [00072] Figure 17B is a variation of a cross section of the device of Figure 17A
- [00073] Figure 18A illustrates a variation of the device.
- [00074] Figures 18B, 18C and 18D are variations of cross-section X-X and Y-Y of Figure 18A.
- [00075] Figure 19A illustrates a variation of the device.
- [00076] Figures 19B, 19C are variations of cross-section Z-Z and AA-AA respectively of Figure 19A.
- [00077] Figure 20 illustrates a variation of the device.
- [00078] Figures 21A and 21B illustrate a variation of the device in deflated and inflated configurations, respectively.
- [00079] Figures 22A and 22B illustrate a variation of the device in deflated and inflated configurations, respectively.
- [00080] Figures 23A-23E are partial see-through views of variations of the device.
- [00081] Figures 24A, 24B, 24C and 24D illustrate variations of the device.
- [00082] Figure 25 illustrates a variation of the device.
- [00083] Figures 26A through 26O are sectional views through variations of cross section BB-BB of Figure 1.
- [00084] Figures 27 through 29 are tables listing film materials, reinforcement materials, and adhesive and matrix materials, respectively.
- [00085] Figure 30A illustrates a variation of a tool for manufacturing a variation of the inflatable device.
- [00086] Figure 30B is a variation of cross-sectional view CC-CC of Figure 30A.
- [00087] Figure 31 is a chart of material characteristics for variations of mandrel materials.

- [00088] Figures 32A through 32E illustrate a variation of a method for manufacturing the device.
- [00089] Figures 32F and 32G are transverse cross-sectional views of variations of a bladder.
- [00090] Figures 33A through 33D illustrate a method for manufacturing the device.
- [00091] Figures 34A through 34I illustrate a method for manufacturing the device.
- [00092] Figure 35 illustrates a variation of a panel.
- [00093] Figure 36 illustrates a variation of a method for manufacturing the device.
- [00094] Figure 37 illustrates a variation of a method for manufacturing the device.
- [00095] Figures 38A through 38E are transverse cross-sections of variations of fiber tows in various configurations during a method of manufacturing.
- [00096] Figures 39A through 39H illustrate a method of making a panel.
- [00097] Figures 40 through 44 illustrate variations of a panel.
- [00098] Figures 45A through 45D illustrate a method for manufacturing the device
- [00099] Figure 46 illustrates a method for manufacturing the device.
- [00100] Figure 47A illustrates a method for manufacturing the device.
- [00101] Figures 47B through 47G are cross-sectional views of variations of a layer.
- [00102] Figures 47E through 47H are cross-sectional views of variations of multiple layers.
- [00103] Figures 48A through 48D illustrate details of the manufacturing process in Figure 47A
- [00104] Figures 49A and 49B illustrate a method for manufacturing the device
- [00105] Figures 50A and 50B illustrate variations of a panel.
- [00106] Figures 51A through 51F illustrate a method for manufacturing the device
- [00107] Figure 52 illustrates a method for manufacturing the device.
- [00108] Figures 53A and 53B illustrate a method for manufacturing the device
- [00109] Figure 54 illustrates a variation of a method for removing the mandrel.
- [00110] Figures 55A through 55C illustrate a method for manufacturing the device
- [00111] Figure 56A illustrates a variation of the device in an inflated state before being pleated.
- [00112] Figure 56B illustrates a method of adding pleats or folds to a variation of the device.
- [00113] Figure 56C illustrates a variation of the device in a deflated, pleated state.
- [00114] Figure 57A illustrates a cross-section of a variation of the balloon wall.
- [00115] Figure 57B illustrates a cross-section of a variation of the balloon contracted inside of a delivery tube.
- [00116] Figure 58 is a graph of compliance of the variation of the balloon compared with a typical compliant balloon.

[000117] Figures 59 and 60 illustrate variations of a deployment tool with the device.

[000118] Figure 61 illustrates a cross section of a human heart.

[000119] Figures 62A and 62B illustrate a variation of the device in deflated and inflated configurations, respectively.

[000120] Figures 63A through 63F illustrate a variation of a method for using the device.

[000121] Figures 64A through 64F illustrate a variation of a method for using the device.

[000122] Figures 65A through 65C illustrate a variation of a method for using the device.

[000123] Figure 66A illustrates a variation of a panel having a rectangular portion and a plurality of triangular sections extending therefrom.

[000124] Figure 66B illustrates a variation of a panel having a rectangular portion and a plurality of trapezoidal sections extending therefrom.

[000125] Figure 66C illustrates the process of laying the pattern of Figure 66A onto a mandrel.

[000126] Figure 66D illustrates the process of laying the pattern of Figure 66B onto a mandrel.

[000127] Figure 67A illustrates a variation of a panel having a rectangular portion with a plurality of fiber separations therein and a plurality of triangular sections extending from the rectangular portion.

[000128] Figure 67B is a close-up of a portion of the fiber separations of Figure 67A.

[000129] Figure 67C illustrates a variation of a panel having a rectangular portion with a plurality of fiber separation therein and a plurality of trapezoidal sections extending from the rectangular portion.

[000130] Figure 67D shows a pattern of fiber separation areas over an exemplary dotted-line matrix.

[000131] Figure 67E is a close-up of a portion of Figure 67D.

[000132] Figure 67F shows the lengths of fibers extending between tapered edges of a panel serration.

[000133] Figure 67G shows the lengths of fibers extending between blunt edges of a panel serration.

[000134] Figure 68A is a transparent zero degree image of a balloon having radiopaque rings, such as an image gathered with an x-ray at zero degrees relative to the axes of the balloon.

[000135] Figure 68B is a transparent angled image of the balloon of Figure 68A, such as an image gathered with an x-ray at an angle relative to the axes of the balloon.

[000136] Figure 69A illustrates a transparent zero degree image of a balloon having radiopaque parallel markers, such as an image gathered with an x-ray at zero degrees relative to the axes of the balloon.

[000137] Figure 69B is a transparent angled image of the balloon of Figure 69A, such as an image gathered with an x-ray at an angle relative to the axes of the balloon.

[000138] Figure 70A is a fluoroscopic image of a balloon having radiopaque spiral markers that is well refolded.

[000139] Figure 70B is a fluoroscopic image of the balloon of Figure 70A that is not well refolded.

[000140] Figure 71A and 71B illustrate the exemplary placement of a radiopaque marker within the layers of a balloon.

[000141] Figure 72 illustrates the positioning of the hoop wind over a balloon to leave space for radiopaque markers.

[000142] Figure 73 illustrates a balloon having thicker hoop winds, or higher pitch, in the proximal and distal tapers of the balloon than in the constant diameter section.

[000143] Figure 74 is a cross-sectional view of a mandrel with a bladder thereon that is composed of multiple vapor deposited sublayers.

[000144] Figure 75A is a view of a tube having a helical wind.

[000145] Figure 75B is a view of the tube of Figure 75A rotated 90 degrees in the direction indicated by the arrow in Figure 75A.

[000146] Figure 75C is a view of the tube of Figure 75A rotated 180 degrees in the direction indicated by the arrow in Figure 75A.

[000147] Figure 75D is a view of the tube of Figure 75A rotated 270 degrees in the direction indicated by the arrow in Figure 75A.

DETAILED DESCRIPTION

[000148] Figures 1A and 1B illustrate that a medical inflatable device 2 can have a balloon 20 and a hollow shaft 2000. An inflation system (shown herein) can be attached to the hollow shaft to deliver a fluid pressure through the hollow shaft 2000 and to the balloon 20. The balloon 20 can be resilient (i.e., elastic) or non-compliant (i.e., inelastic). The balloon 20 can have a balloon longitudinal axis 26. The balloon 20 can have a balloon wall 22. The balloon wall 22 can define a cavity having a balloon volume 24. The balloon 20 can be a tube or a sheath. The tube or sheath can be a tubular structure that can be positioned over a medical device, such as an endoscope, vasculoscope, colonoscope, arthroscope, or combinations thereof. A tube can be a cylinder with a roughly equal inside and outside diameter. The balloon 20 can have a closed end (as shown in Figure 2). The balloon 20 can have openings on either end (as shown in Figure 1).

[000149] Figure 1B illustrates that the balloon 20 can have a balloon length 28. The balloon length 28 can be from about 1.0 meter (39 in.) to about 5 mm (0.2 in.), more narrowly from about 200 mm (7.87 in.) to about 10mm (0.4 in.), yet more narrowly from about 120mm (4.72

in.) to about 50mm(1.97 in) The balloon 20 can have a balloon proximal stem 30 having a balloon proximal stem length 32. The proximal stem length 32 can be from about 3.0 mm (0.12 in.) to about 15 mm (0.60 in.), for example about 10 mm (0.40 in.). The balloon 20 can have a balloon proximal taper 34 having a balloon proximal taper length 36. The balloon proximal taper length 36 can be from about 0 mm (0 in.) to about 25 mm (0.98 in.), more narrowly from about 10 mm (0.40 in.) to about 22 mm (0.87 in.), yet more narrowly from about 16 mm (0.63 in.) to about 20 mm (0.79 in.).

[000150] The balloon 20 can have a constant-diameter section 38 having a constant-diameter section length 40. The constant-diameter section 38 can be the length between the balloon proximal taper 34 and a balloon distal taper 42. The constant-diameter section length 40 can be from about 0 mm (0 in) to about 55 mm (2.17 in), more narrowly from about 30 mm (1.18 in) to about 50 mm (1.97 in). The constant-diameter section 38 is referred to herein as "constant-diameter" for illustrative purposes, and the constant-diameter section 38 can have a constant or variable diameter along the length of the constant-diameter section 38. In the case of a substantially variable diameter along the constant-diameter section, the constant-diameter section 38 is defined as the portion of the balloon between the cross sections of maximum balloon diameter.

[000151] The balloon 20 can have a balloon distal taper 42 having a balloon distal taper length 44. The balloon distal taper length 44 can be from about 0 mm (0 in) to about 25 mm (0.98 in), more narrowly from about 10 mm (0.4 in) to about 22 mm (0.87mm), yet more narrowly from about 16 mm(0.63 in) to about 20 mm (0.79 in). The balloon 20 can have a balloon distal stem 43 having a balloon distal stem length 45. The distal stem length 45 can be from about 3 mm (0.12 in) to about 15 mm (0.6 in), more narrowly about 10 mm (0.4 in).

[000152] The balloon 20 can have an inner lumen 154a and an outer lumen 154b. Inner lumen 154a may be formed by second hollow shaft 2000b. Inner lumen 154a may provide a lumen thru the entire balloon 20. Inner lumen 154a may allow a guidewire to pass thru the interior of the balloon. Outer lumen 154b may connect to balloon volume 24 and allow fluid into the balloon volume 24. Placing fluid into balloon volume 24 may cause the balloon to inflate. Outer lumen 154b may be formed between the inner wall of first hollow shaft 2000a and the outer wall of second hollow shaft 2000b.

[000153] The proximal taper angle 90b and the distal taper angle 90a can be from about 0 to about 90°, more narrowly about 50° to about 20°, yet more narrowly about 45° to about 30°, for example about 40° or about 35° or about 30° or about 25° or about 20°. The proximal taper angle 90b and the distal taper angle 90a do not need to be substantially the same.

[000154] The balloon 20 can have one or more balloon fluid ports 56. The first hollow shaft 2000a can have a hollow shaft distal port 54. One of the balloon fluid ports 56 can attach to the hollow shaft distal port 54.

[000155] The balloon 20 can have a wall thickness 46. The wall thickness 46 can be less than about 25 μm (1 mil). The wall thickness 46 can be from about 25 μm (0.98 mil) to about 250 μm (9.8 mil), more narrowly from about 50 μm (2 mil) to about 150 μm (5.9 mil), more narrowly from about 35 μm (1.4mil) to about 75 μm (3mil), for example about 50 μm (2 mil), about 65 μm (2.6 mil), about 75 μm (3 mil), or about 100 μm (4 mil).

[000156] The balloon 20 can have a balloon inner diameter 48 and a balloon outer diameter 50. The balloon outer diameter 50 can be measured perpendicular to the balloon longitudinal axis 26 at the widest point along the length of the balloon 20. The balloon outer diameter 50 can be from about 2 mm (0.08in) to about 50 mm (2in.) for example about 3 mm (0.12 in.), about 6 mm (0.24 in.), about 10 mm (0.4in), about 17 mm (0.67 in.), about 20 mm (0.79 in), about 22 mm (0.87 in), about 26 mm (1.02in), or about 30 mm (1.18in).

[000157] The balloon proximal stem 30 may have a diameter of 2 mm (0.08 in) to about 50 mm (2 in.), more narrowly 2 mm (0.08 in) to about 5 mm (0.20 in), for example about 2mm (0.08 in), about 3 mm (0.12 in) or about 4 mm (0.16 in).

[000158] The balloon 20 can have an unsupported burst pressure. The unsupported burst pressure is the pressure at which the balloon ruptures when inflated without any external constraint on the walls at about 1 atm external pressure and about 20 °C temperature. The unsupported burst pressure can be greater than about 150 psi (1,034 kPa). For example, the unsupported burst pressure can be from about 200 psi (1,379kPa) to about 1,500 psi (10,343 kPa). More narrowly, the burst pressure can be from about 200 psi (1,379 kPa) to about 500 psi (3,448kPa). For example, the burst pressure can be about 200 psi (1,379 kPa), 250 psi (1,724 kPa), about 300 psi (2,069 kPa), about 350 psi (2,413 kPa) about 400 psi (2,758 kPa), or about 500 psi (3,448 kPa).

[000159] Figures 2A and 2B illustrate that the balloon 20 can have balloon length 28. The balloon 20 can have a balloon proximal stem 30 having a balloon proximal stem length 32. The proximal stem length 32 can be from about 5 mm (0.20in) to about 15 mm (0.59 in). The balloon can have a balloon proximal taper 34 having a balloon proximal taper length 36. The balloon proximal taper length 36 can be from about 0 mm (0 in) to about 20 mm (0.79 in), more narrowly from about 0 mm (0 in) to about 15 mm (0.59 in), yet more narrowly from about 5 mm (0.20 in) to about 10 mm (0.39 in). The balloon 20 can have a constant-diameter section 38 having a constant-diameter section length 40. The constant-diameter section length 40 can be from about 0 mm (0 in) to about 15 mm (0.59 in), more narrowly from about 0 mm (0 in) to

about 10 mm (0.39 in). The balloon 20 can have a balloon distal taper 42 at the terminal distal end 68 or tip of the balloon 20. The distal taper 42 can have a distal taper length 44. The distal taper length 44 can be from about 0 mm (0 in) to about 14 mm (0.55 in), more narrowly from about 2 mm (0.08 in) to about 9 mm (0.35 in).

[000160] The proximal and/or distal tapers 34 and/or 42 can be concave, convex and/or s-curves. For example, the proximal and/or distal tapers 34 and/or 42 can have continuously varying angles with respect to the balloon longitudinal axis 26.

[000161] The balloon 20 can have one, two, three or more balloon fluid ports 56. The balloon 20 can have no through lumen. For example, the balloon 20 can have no longitudinal through-lumen extending through the proximal terminal end 70 nor through the distal terminal end 68.

[000162] The balloon 20 can have a balloon inner diameter 48 and a balloon outer diameter 50. The balloon outer diameter 50 can be measured perpendicular to the balloon longitudinal axis 26 at the widest point along the length of the balloon 20.

[000163] The balloon 20 can have a radius (i.e., half the diameter), for example about 8.5 mm (0.33 in), and a distal taper length, for example about 8.5 mm (0.33 in). The ratio of the distal end length to the radius can be from about 2:1 to about 0:1, more narrowly about 1:1 to about 0.25:1.

[000164] The balloon 20 can have an unsupported burst pressure. The unsupported burst pressure is the pressure at which the balloon ruptures when inflated without any external constraint on the walls at about 1 atm external pressure and about 20 °C temperature. The unsupported burst pressure can be greater than about 150 psi. For example, the unsupported burst pressure can be from about 1,400 kPa (200 psi) to about 10,000 MPa (1,500 psi). More narrowly, the burst pressure can be from about 3,500 kPa (500 psi) to about 6,000 kPa (900 psi). For example, the burst pressure can be about 3,500 kPa (500 psi), about 5,200 kPa (750 psi), about 7,000 (1,000 psi), about 10,000 kPa (1,500 psi), or higher than 10,000 kPa (1500 psi).

[000165] The balloon 20 can be non-compliant or inelastic. The balloon 20 can have a failure strain of less than about 0.30, more narrowly less than about 0.20, more narrowly less than about 0.10, yet more narrowly less than about 0.05. A non-compliant balloon can have a failure strain of less than about 0.30.

[000166] The failure strain of the balloon 20 is the difference between the balloon outer diameter 50 when the balloon 20 is inflated to 100% of the burst pressure and the balloon outer diameter 50 when the balloon 20 is inflated to 5% of the burst pressure (i.e., to expand from a deflated state without stretching the wall material) divided by the 100% pressure diameter.

[000167] For example, the burst pressure of the balloon 20 can be greater than about 3,500 kPa (500 psi) and have an outer diameter 50 of about 17 mm and a wall thickness 46 of less than about 100µm with a failure strain of less than about 0.10, for example less than about 0.05.

[000168] Also for example, the burst pressure of the balloon 20 can be greater than about 200 psi (1,379 kPa) and have an outer diameter 50 of about 24 mm and a wall thickness 46 of less than about 75 µm with a failure strain of less than about 0.10, for example less than about 0.05.

[000169] The reinforced balloon wall 22 may have a high tear strength as compared to traditional polymers. Tear strength can correlate to puncture strength and toughness. For example, in a Mod Mil-C-21189 10.2.4 tear test, a specimen is created. That specimen has a width, a height, and thickness. A slit is made in the sample parallel to the width, mid-way along its height. The slit is then pulled to initiate tear at the corners of the slit. The Mod Mil-C-21189 10.2.4 tear test gives resultant data in tensile pounds force (lbf). For the test to be meaningful as a comparison between two material samples, the tear test should be done on a thickness-comparable basis. A nylon 12 balloon material at about 0.0055 in (140 µm) thickness failed the tear test at a mean tensile load of 25 lbf (111 newtons). A variation of the balloon wall 22 of about 0.005 in. (127 µm) wall thickness 46 can fail the same tear test performed on the nylon 12 balloon at a mean tensile value of 134 lbf (596 newtons).

[000170] In an ASTM D-3039 tensile test, a nylon 12 material at 0.0055 in. (140 µm) thickness, failed at a mean tensile load of 22 lbf (98 newtons). The balloon wall 22 of about 0.005 in. (127 µm) wall thickness 46 can fail the same tensile test performed on the nylon 12 material at a mean tensile value of 222 lbf (988 newtons).

[000171] The balloon wall 22 can have a high puncture strength. For example, when a balloon 20 is inflated to about 60 psi (414 kPa) and a 1 mm (0.040 in) gauge pin is driven into the balloon 20 at about 1mm/sec (0.04 in/sec), the pin may need to exert more than 6 lbf (27 newtons) to puncture the balloon wall 22. A typical non-compliant polymer medical balloon may fail at about 3 lbf (13 newtons).

[000172] Figure 3A illustrates that the balloon 20 can have a constant wall thicknesses 46 along the length of the balloon 20. A wall proximal stem thickness 46a can be substantially equal to a wall constant-diameter section thickness 46c and the wall proximal taper thickness 46b.

[000173] Figure 3B illustrates that the balloon 20 can have a varying, such as increasing and/or decreasing, wall thicknesses 46 along the length of the balloon 20. Figure 3B illustrates that the wall constant-diameter section thickness 46c can be substantially greater than the wall proximal stem thickness 46a. The wall proximal taper thickness 46b can be less than the wall constant-diameter section thickness 46c and greater than the wall proximal stem thickness 46a.

[000174] Figure 3C illustrates that the wall proximal stem thickness 46a can be substantially greater than the wall constant-diameter section thickness 46c. The wall proximal taper thickness 46b can be less than the wall proximal stem thickness 46a and greater than the wall constant-diameter section thickness 46c.

[000175] Figure 3D illustrates that balloon 20 may terminate at the proximal end of the proximal taper 34. The balloon 20 may have no proximal stem 30. First hollow shaft 2000a may have a flare 2004 that attaches to inner wall of proximal taper 34.

[000176] Figure 4A illustrates that the balloon 20 can have a first balloon external seam 67a and a second balloon external seam 67b. Any or all seams 67 can extend partially, completely, not at all, or a combination thereof, through the depth of the wall thickness 46. The balloon external seams 67a and 67b can be longitudinal seams (i.e., oriented in a longitudinal direction with respect to the balloon 20, parallel or at an angle to the longitudinal axis 26 of the balloon 20). The balloon external seams 67a and 67b can extend from a first lateral side of the balloon 20 at the proximal terminal end 70 of the balloon 20, along the first lateral side of the balloon to the balloon distal stem 43. A balloon seam may be between 75% and 150% as long as the balloon length 28, more narrowly between 85% and 125% as long as the balloon length 28. A balloon seam may be between 180% and 300% as long as the balloon length 28, more narrowly between 190% and 260%.

[000177] Figures 4B and 4C illustrate that the balloon wall 22 can have one or more layers 72. Each layer 72 can be a homogenous or heterogeneous discrete element distinguished from other layers by radial distance along the thickness of the balloon wall 22. A layer 72 may comprise film, reinforcement material or adhesive or combinations thereof, for example, the materials listed in Figures 27, 28 and 29. The balloon 20 can have a leak-proof bladder 52. The bladder 52 can be defined by one or more leak-proof layers within the balloon wall 22. The bladder 52 can be fluid-tight, such as air-tight or saline tight, or can be a fluid-porous bladder. The bladder 52 can be made of a urethane, a nylon, any material listed infra (eg. the materials listed in Figure 29), or combinations thereof. The bladder 52 can be made from the radial inner-most layer 72b (as shown in Figures 4B and 4C) of the balloon wall 22. A bladder 52 may comprise film, reinforcement material or adhesive or combinations thereof (for example, the materials listed in Figures 27, 28 and 29).

[000178] The bladder 52 can be fixedly or removably attached to the hollow shaft 2000, for example at the inside and/or outside diameter of hollow shaft 2000. The hollow shaft 2000 can be a flexible or rigid catheter. The hollow shaft 2000 can deliver pressurized fluid to the balloon volume 24.

[000179] The balloon wall 22 can be made from panels 76. The panels 76 can, for example, be cut or formed pieces of film and/or resin with or without other materials such as fibers. The layers 72 can each be made from one or more panels 76. The panels 76 can each contain one or more layers 72, or multiple panels 76 (e.g., of the same material) can be formed into a single layer 72, for example by melting panels 76 of the same material into an indiscrete, integral homogenous layer during the method of making the device. A panel 76 or a panel 74 or a panel 196 may comprise film, reinforcement material or adhesive or combinations thereof (for example, the materials listed in Figures 27, 28 and 29).

[000180] The outer layer 72a of the balloon wall 22 can have an outer layer first panel 76a and an outer layer second panel 76b. The outer layer first panel 76a can cover from about 90° to about 270° of the balloon, as measured in a transverse plane from the balloon longitudinal axis 26, for example about 185° of the balloon 20. The outer layer second panel 76b can cover from about 90° to about 270°, as measured along the balloon longitudinal axis 26, for example about 185°.

[000181] The balloon wall 22 can have one or more seams 66 and/or 67 and/or 69 attaching panels 76 to other panels 76 in the same layers or to itself. The seams 66 and/or 67 and/or 69 can be an abutment or overlap of one or two panels 76 and/or panels 196 and/or panels 74. The seams 66 and/or 67 and/or 69 can be linear, curved, circular, equatorial or combinations thereof.

[000182] Figure 4B illustrates that the balloon external seams 67a and 67b can be overlaid seams, lap joints, or combinations thereof. The balloon external seams 67a and 67b can be flush against the side (i.e., having a substantially constant radius with respect to the balloon longitudinal axis 26) of the outer layer first panel 76a or outer layer second panel 76b. The outer layer first panel 76a can be radially outside of the outer layer second panel 76b where the outer layer first panel 76a overlaps the layer second panel 76b. The outer panels 76 may have an overlap length 59. The overlap length 59 can be from about 0 mm (0 in.) (e.g., an abutment seam) to about 3 mm (0.12 in.), more narrowly from about 1 mm (0.04 in.) to about 2 mm (0.08 in.). The outer layer first panel 76a can be bonded or adhered (e.g., with an adhesive) to the outer layer second panel 76b. The adhesive can be an epoxy or a thermally weldable material, such as a thermoplastic urethane.

[000183] The inner layer 72b can have balloon internal seams 69a and 69b. The balloon inner seams 69a and 69b can join an inner layer first panel 74a and an inner layer second panel 74b. The inner seams 69a and 69b can have a similar structure to those described here for the balloon outer seams 67a and 67b.

[000184] Figure 4C illustrates that the outer layer first panel 76a can be fused, solvated to, glued, adhered to, welded to, or a combination thereof, with the outer layer second panel 76b at

the outer seams 67A and 67B. An adhesive 208 may be placed between the first panel 76a and the second panel 76b at the inner seams 69a and 69b and the outer seams 67a and 67b.

[000185] Figure 5 illustrates that the balloon 20 can have a single balloon external seam 66a. The seam 66a can extend partially, completely, or not at all through the depth of the wall thickness 46. The balloon external seam 66a can be a longitudinal seam. The balloon external seam 66a can extend from a first lateral side of the balloon 20 at the proximal terminal end 70 of the balloon 20, along the first lateral side of the balloon to the balloon distal terminal end 68. The balloon external seam 66a can wrap around the balloon distal terminal end 68a, extending around the distal end of the balloon 20 and returning on the second lateral side of the balloon 20.

[000186] The inner layer 72b can have a balloon inner seam 66b. The balloon inner seam 66b can join an inner layer first panel 74a and an inner layer second panel 74b. The inner seam 66b can have a similar structure to those described here for the balloon outer seam 66a.

[000187] Sections C-C can be identical to variations of Sections H-H, except the outer seams 67 would be the single balloon external seam 66a and the inner seams 69 would be the inner seam 66b.

[000188] Figure 6A illustrates that the balloon external seam 66a can be a flange joint. The outer layer first panel 76a can have a seam first flange 80a around the perimeter of the outer layer first panel 76a. The outer layer second panel 76b can have a seam second flange 80b around the perimeter of the outer layer second panel 76b. The seam first flange 80a can attach to the seam second flange 80b at the balloon external seam 66a. The flange 80 can extend radially away from the balloon longitudinal axis 26. The balloon external seam 66a can be reinforced, for example with a metal foil, a wire or a polymer or combinations thereof. The balloon external seam 66a can be used to cut tissue during use in a biological target site or through tissue during delivery to the target site.

[000189] Figure 6B illustrates that the seam first flange 80a can be bonded or adhered to the seam second flange 80b in the flange joint. Figure 6C illustrates that the layer first panel 76a can be fused, solvated to, glued, adhered to, welded to, or a combination thereof, with the layer second panel 76b in the flange joint. An adhesive 208 may be placed between the first panel 76a and the second panel 76b at the seams inner seam 66b and the outer seam 66a.

[000190] Figure 7A illustrates that the balloon wall 22 can have a flange seam 66. The panels 76a and 76b can have seam areas 780. The seam areas 780 can be located at the terminal edges and/or areas near the terminal edges of panels 76a and 76b in a plane in which the panels 76a and 76b lie. The seams 66 and/or 67 and/or 69 can join seam areas 780 of first panels 76 to seam areas of adjacent second panels 76 in the same layer or adjacent layers to the first panels 76a.

[000191] Figure 7B illustrates that the balloon wall can have an abutment seam 66. The seam areas 780 can be perpendicular to the plane of the panels 76a and 76b.

[000192] Figure 7C illustrates that the balloon wall can have a lap joint or overlap seam 66. The seam areas 780 can be parallel to the plane of the panels 76a and 76b.

[000193] Figure 8A illustrates that the balloon external seam 66a can be a lateral or latitudinal seam. The balloon external seam 66a can be in a plane perpendicular or substantially perpendicular to the balloon longitudinal axis 26. The balloon 20 can have one or more balloon external seams 66a and/or 67.

[000194] The outer layer first panel 76a can be at the distal end of the balloon 20. The outer layer second panel 76b can be at the proximal end of the balloon 20. The outer layer second panel 76b can overlay the outer layer first panel 76a at the balloon external seam 66a.

[000195] Figure 8B illustrates that the outer layer first panel 76a can overlay the outer layer second panel 76b at the balloon external seam 66a.

[000196] Figure 8C illustrates that the balloon wall 22 at a first length along the balloon 20 can have a first layer and a second layer. The first layer can be a radially inner layer 72b, as measured from the balloon longitudinal axis 26. The second layer can be a radially outer layer 72a. Any of the layers 72 can have a laminate of fiber and resin (e.g., that can be elements of one or more panels 76 in the respective layers 72). The resin can be an adhesive. The fiber and resin laminate can be a matrix of the fiber in the resin.

[000197] Figure 8D illustrates that the balloon wall 22 at a second length along the balloon 20 can have first, second and third layers. The second layer can be a first middle layer 72c between the inner and outer layers 72b and 72a, respectively. Any combination of the layers can be leak-proof, reinforced with one or more fibers, resistant and releasable from MMA, or combinations thereof. The first middle layer 72c can be reinforced with a fiber. The outer layer 72a can be MMA-resistant and/or MMA-releasing.

[000198] An MMA-resistant material can substantially maintain material strength and thickness when exposed to MMA bone cement in any stage of the MMA bone cement from mixing to curing. An MMA-releasable material can form no substantial bond with MMA.

[000199] Figure 8E illustrates that the balloon external seam 66A can be positioned at the proximal taper 34 of the balloon 20. The balloon external seams 66a and/or 67 can be in the constant-diameter section 38, the distal taper 42, the proximal taper 34, the proximal stem 30, or combinations thereof.

[000200] Figure 8F illustrates that balloon external seam 66a can lie in a plane at a non-perpendicular angle to the balloon longitudinal axis 26. The plane in which the balloon external seam 66a lies can form a seam angle 82 with the balloon longitudinal axis 26. The seam angle

82 can be from about 0° (i.e., a longitudinal seam) to about 90° (i.e., a latitudinal seam). More narrowly, the seam angle 82 can be from about 30° to about 60°. For example, the seam angle 82 can be about 0°, about 30°, about 45°, about 60°, or about 90°.

[000201] Figure 9A illustrates that the balloon 20 can be pleated to form flutes 84, for example four, five or six flutes 84, such as first flute 84a and second flute 84b. The flutes 84 can be made from accordion pleats, box pleats, cartridge pleats, fluted pleats, honeycomb pleats, knife pleats, rolled pleats, or combinations thereof. The pleating can be heat and/or pressure formed and/or the reinforcement fibers and/or panels can be oriented to form the flutes 84. The balloon 20 can be in a deflated configuration when the flutes 84 are shown.

[000202] Figure 9B illustrates that the balloon 20 in an inflated configuration can push the pleated flutes 84 radially outward to form a substantially smooth outer surface of the balloon wall 22. The balloon 20 can have reinforcement fibers 86. Longitudinal reinforcement fibers 86b can be substantially parallel with the balloon longitudinal axis 26. Latitudinal reinforcement fibers 86a can be substantially perpendicular to the balloon longitudinal axis 26. Latitudinal reinforcement fibers 86a can be multiple fibers or a continuously wound single fiber. The balloon 20 may have a load path 750.

[000203] The angle between fibers 86a and 86b may be approximately perpendicular and may not change between inflation and deflation.

[000204] Figures 9C illustrates that latitudinal reinforcement fibers 86a can be applied in a wavy or curvy pattern (e.g., a sinusoidal configuration). Figure 9C' shows a close-up of the latitudinal reinforcement fiber 86a. The wave pattern can have a first wave amplitude width 754 of less than about 10 mm (0.39 in), more narrowly less than about 5 mm (0.20 in), more narrowly less than about 2 mm (0.08 in). The wave pattern may have wave period width 758 of less than about 10 mm (0.39 in), more narrowly less than about 5 mm (0.20 in), more narrowly less than about 2 mm (0.08 in). When pressure is applied to the balloon 20 in 9C, the fibers 86a can straighten to resemble the configuration of the fibers 86a in Figure 9B.

[000205] During heating and consolidation of the balloon 20 during manufacture (for example, the process shown in Figures 55A, 55B and 55C), the fibers 86a may transform to a straighter configuration (e.g., the wave period width 758 may increase and the first wave amplitude width 754 may decrease). The balloon 20 can expand in the hoop direction without placing the fibers 86a in significant stress, for example, stress in excess of 10% of the yield stress.

[000206] Figure 9D illustrates that longitudinal reinforcement fibers 86b can be applied to the balloon 20 in a wavy or curvy pattern similar to the pattern of fiber 86A shown in Figure 9C and 9C'. Similarly, as described supra, during heating and consolidation of the balloon 20 during manufacture, the fibers 86b may transform to a straighter configuration.

[000207] The latitudinal and longitudinal reinforcement fibers 86a and 86b on a single balloon 20 can both have wavy configurations.

[000208] When inflated, the balloon 20 may have a biphasic compliance: a first compliance curve and a second compliance curve. The first compliance curve may be generated as the balloon 20 is first pressurized and be the result of the straightening of fibers 86a and/or 86b in the balloon wall 22. The second compliance curve may be generated by the straining under tension of fibers 86a and/or 86b which are then in a substantially straight (e.g., not curvy) configuration.

[000209] For example, when the balloon volume 24 is initially inflated to a transition pressure of, for example, about 90 psi (610 kPa), the diametrical compliance of the balloon may average a first compliance of about 0.1% strain per psi (0.1% per 6.9 kPa). Therefore, when the balloon volume 24 is inflated to a transition pressure of 90 psi (610 kPa), the balloon outer diameter 50 may have grown 9%. At pressures beyond the transition pressure of 90 psi (610 kPa), the compliance of the balloon may average a second compliance of about 0.015% per psi (0.015% per 6.9kPa). Therefore, when the balloon volume 24 is inflated to, for example, about 180 psi (1220 kPa), the balloon outer diameter 50 may have grown 1.35% between about 90psi(610 kPa) and about 180psi psi (1220 kPa).

[000210] The transition pressure can be from about 15 psi (101 kPa) to about 1000 psi (6890 kPa), more narrowly from about 15 psi (101 kPa) to about 250 psi (1723 kPa), still more narrowly from about 15 psi (101 kPa) to about 90 psi (610 kPa). The first compliance can be from about 0.025% per psi (0.025% per 6.9 kPa) to about 1% per psi (1% per 6.9kPa), more narrowly from about 0.05% per psi (0.05% per 6.9 kPa) to about 0.3% per psi (0.3% per 6.9 kPa). The second compliance can be from about 0.005% per psi (0.005% per 6.9 kPa) to about 0.05% (0.05% per 6.9 kPa), more narrowly from 0.01% per psi (0.01% per 6.9 kPa) to about 0.025% per psi (0.025% per 6.9 kPa).

[000211] The balloon 20 can have uniphasic compliance. For example, the balloon 20 may have no first compliance. The balloon 20 may have no second compliance. The balloon 20 may have no transition pressure.

[000212] Figure 9E illustrates that first and second longitudinal reinforcement fibers 86b and 87b, respectively, can be substantially parallel with the balloon longitudinal axis 26. The longitudinal reinforcement fibers 86b and 87b can longitudinally overlap (i.e., have concurrent longitudinal locations along the balloon 20) in reinforcement fiber overlap area 612. The reinforcement fiber overlap area 612 may form a hoop-shaped area that partially or completely encircles the constant-diameter section 38. The fibers 86B and 87B may have fiber lengths less than about 80% of the balloon length 28 more narrowly less than about 75% as long, more

narrowly less than about 70% as long, still more narrowly less than about 65% as long, still more narrowly less than about 60% as long as the balloon length 28. Second or latitudinal reinforcement fibers 86a can be substantially perpendicular to the balloon longitudinal axis 26.

[000213] Figure 9F illustrates that the reinforcement fiber overlap area 612 may form a spiral or helical-shaped area that partially or completely encircles the constant-diameter section 38.

[000214] Figure 9G illustrates that the fibers 86b and 87b can be separated by fiber separation areas 614. Fiber separation areas 614 may be substantially rectangular and may have a fiber separation width 613 and fiber separation length 611. The fiber separation area 614 may separate fibers 86b and 87b by a fiber separation length 611 of about 2 mm (0.079 in.), more narrowly less than about 1 mm (0.039 in.), still more narrowly less than about 0.25 mm (0.01 in.). The fiber separation areas 614 may be distributed on the balloon surface such that no area 614 longitudinally substantially overlaps any other area on the balloon 20. The fiber separation areas 614 may be distributed such that latitudinally adjacent fiber separation areas 614 do not have any longitudinal overlap. The fiber separations 614 may be positioned along the length of the balloon 20 in a pattern sufficient to prevent any fiber from reaching from a first terminal longitudinal end of the balloon 20 to a second terminal longitudinal end of the balloon 20. As shown in Figure 9G, the balloon 20 may have the panel 196 shown in Figures 40B, 40C or 41B. Fibers 86b and 87b may have fiber lengths 88 less than about 80% as long as the balloon length 28, more narrowly less than about 75% as long, more narrowly less than about 70% as long, still more narrowly less than about 65% as long, still more narrowly less than about 60% as long as the balloon length 28.

[000215] Figure 9H illustrates that the balloon 20 can have angled reinforcement fibers 85a and 85b. First angled reinforcement fiber 85a and/or second angled reinforcement fiber 85b can be at an angle with respect to the balloon longitudinal axis 26. For instance, first angled reinforcement fiber 85a and/or second angled reinforcement fiber 85b can be from about 10° to about 60°. For instance, the fiber 85a and/or 85b can be at about 10°, about 15°, about 20° or about 25° to the balloon longitudinal axis 26. The fiber 85a can be at about 50°, about 55° or about 60° with respect to the balloon longitudinal axis 26. Fiber 85b can have an equal but opposite angle to fiber 85a. For example, fiber 85a can be at +20 degrees and fiber 85b can be at about -20° to the balloon longitudinal axis 26. The balloon 20 can have one or more latitudinal reinforcement fibers 85c and/or longitudinal reinforcement fibers (e.g., 86b and/or 87b, not shown in Figure 9H) with one or more angled reinforcement fibers 85.

[000216] When inflated, the balloon 20 shown in Figure 9H may have a biphasic diametrical compliance: a first compliance curve and a second compliance curve. For example, the balloon 20 may have a first angled reinforcement fiber 85a that forms an angle of about 20° with the

balloon longitudinal axis 26 and a second angled reinforcement fiber 85b that forms an angle of about -20° with the balloon longitudinal axis 26. The first diametrical compliance curve may be generated as the balloon 20 is first pressurized and be the result of the absolute value of the angle that the fibers 85 make with the balloon longitudinal axis 26 increasing. For instance the angles may change from about 20° to about 39° , or from about -20° to about -39° . The balloon length 26 may decrease and the balloon outer diameter 50 may increase, both in proportion to the pressure contained in balloon volume 24. The second diametrical compliance curve may be generated by the straining under tension of fibers 85a and/or 85b as the pressure in balloon volume 24 is further increased. The first diametrical compliance curve may be more compliant than the second diametrical compliance curve.

[000217] Moreover, referring to Figure 9H, in some embodiments, a balloon 20 can have angled reinforcement fibers 85a and 85b that are formed from a single continuous fiber tow. In some embodiments, the tow is cut at the end of balloon to leave a plurality of individual fibers that run from one end of the balloon to the other, while in other embodiments, the tow is kept fully intact. Fiber 85b can have an equal but opposite angle to fiber 85a. The angled reinforcements fibers 85a and 85b can be at an angle relative to the balloon longitudinal axis.

[000218] In some embodiments, the angle of the reinforcement fibers 85a, 85b can be fairly constant in the constant diameter section 38. For example, the angle can be approximately 30 to 89 degrees, such as 40 to 70 degrees, such as 50 to 60 degrees, such as approximately 54 degrees in the central constant diameter section 38. Having an angle of approximately 54 degrees can advantageously balance the hoop and traverse stresses in the constant diameter section to keep the balloon diameter and length approximately fixed when the balloon is inflated. In some embodiments, the angles of the reinforcement fibers 85a, 85b in the proximal and distal tapers 34, 42 can be steeper than the angles in the constant diameter section 38. Moreover, in some embodiments, the angle of the reinforcement fibers 85a, 85b can vary more than once and/or continuously within the proximal and distal stems and/or the proximal and distal tapers 34, 42.

[000219] Figures 9I and 9J illustrate that the balloon wall 22 can have a first load path 750a, second load path 750b a third load path 750c, or combinations thereof. The load path 750 may be a portion of the balloon wall 22. The load path 750 can have a load path width 762 and a load path length 766. For instance, the load path 750 may be bounded by the thickness of a layer of longitudinal fiber 86b, have a load path length 766 about as long as the constant-diameter length 40 and have a load path width 762 that encompasses one or a plurality of filaments 274 or reinforcement fibers 86 or combinations thereof. The load path length 766 may be about parallel with the longitudinal axis 26 of the balloon 20. A load path 750 may have one or more

continuous fibers, one or more cut or separated fibers, or combinations thereof. Load path width 762 may be about equal to fiber separation width 613

[000220] Figure 9I shows that load paths 750a, 750b and 750c may each contain a continuous fiber 86b. When balloon 20 is inflated, the fibers 86b in the load paths 750 may carry a tensile load along the longitudinal axis 26.

[000221] Figure 9J shows that load paths 750a, 750b and 750c may each contain a first longitudinal reinforcement fiber 86b and a second longitudinal reinforcement 87b. The first longitudinal reinforcement fiber 86b can be separated by the fiber separation area 614 from the second longitudinal reinforcement 87b in the same load path 750. The tensile load in the respective load path 750 can be transferred by shear loading, as shown by arrows 770, from one load path to one or more adjacent load paths, for example, from the second load path 750b to the adjacent first and/or third load paths 750a and/or 750c, respectively; also for example from the first and/or third load paths 750a and/or 750c, respectively, to the second load path 750b.

[000222] When the balloon 20 is inflated, the reinforcement fibers 86b and 87b in the load paths may not carry a tensile load to between the two fibers 86b and 87b, for example, because the fiber separation area 614 is in the respective load path 750. The reinforcement fiber 86b or 87b may transfer the respective fiber's tensile load via one or more shear loads 770 to adjacent "receiving" reinforcement fibers 86b and 87b in adjacent load paths 750. The shear transferring of the tensile load can tension the adjacent receiving reinforcement fibers 86b and 87b. For instance, first shear load 770A may transfer tension from reinforcement fiber 87b'' to reinforcement fiber 86b' over shear load length 772a. Similarly, second shear load 770b may transfer tension from reinforcement fiber 87b''' to reinforcement fiber 86b''' over shear load length 772b.

[000223] About 20% or more of the longitudinal reinforcement fibers 86b may transmit their tensile loads as shear loads 770, more narrowly about 40% or more, still more narrowly about 60% or more, still more narrowly about 80% or more.

[000224] Figure 9K illustrates that the reinforcement fiber 86 can be a single continuous fiber wound (e.g., in a hoop wind) around the balloon 20. The reinforcement fibers 86 can have a fiber density of about 100 winds per inch (i.e., the pitch of the wind). The pitch can vary across the length of the balloon 20. The balloon 20 can have a proximal pitch zone 618a, a middle pitch zone 618b, a distal pitch zone 618c, or combinations thereof. The reinforcement fiber(s) 86 in the pitch zones 618a, 618b, and 618c can have the same or different pitches. For instance, the pitch of the fiber 86 in zone 618b may be less than the pitches in zones 618a and 618c. The pitches in zones 618a and 618c may be substantially equivalent. For example, the pitch in zones 618a and 618c may be about 128 winds per inch, while the pitch in zone 618b may be about 100

winds per inch. A lower pitch in one zone, such as middle zone 618b with respect to the other zones, such as the proximal and distal zones 618a and 618c, may force the balloon wall 22 to fail (if failure of the balloon wall occurs 22 at all) in the respective zone 618b before failure of the balloon wall 22 were to occur in the other zones 618a and 618c. In the example above, zone 618b may burst during failure of the balloon 20 before zones 618a and 618c burst. The pitch zones with a lower pitch, such as middle zone 618b, may be more compliant than zones with a higher pitch, such as the proximal and distal pitch zones 618a and 618c. The balloon 20 can inflate more in the zone with the lower pitch, such as middle pitch zone 618b, relative to the zones with the higher pitch, such as the proximal and distal pitch zones 618a and 618c. One pitch zone (e.g., pitch zone 618b) may have a 10% lower pitch than the remainder of the balloon wall 22 (e.g., pitch zones 618a and 618c), more narrowly a 20% lower pitch.

[000225] Figure 73 illustrates that the reinforcement or hoop fiber can have a higher pitch towards the distal and proximal ends of the balloon than in the constant diameter section 38. Thus, in one embodiment, the balloon can have two or more sections of different pitch, such as approximately four section of different pitch. For example, referring to Figure 73, the constant diameter section 38 can have a pitch of 118 (i.e., 118 turns of the tow per inch), sections 1223a,b within the proximal and distal tapers 34, 42 can have a pitch of 138, sections 1225a,b in the outer portion of the proximal and distal tapers 34, 42 can have a pitch of 157, and sections 1227a,b at the transition between the proximal and distal tapers 34, 42 and the proximal and distal stems 30, 43 can have a pitch of 177. Thus, the pitch can increase towards the ends of the balloon. Further, in some embodiments, the pitch of the reinforcement fiber 86 can vary continuously within the tapers 34, 42. Having the reinforcement fiber wound at a higher pitch in the proximal and distal tapers 34, 42 and/or the stems 40, 43 can result in an increased number of hoop winds in the proximal and distal tapers 34, 42, thereby advantageously making the proximal and distal tapers 34, 42 and/or the stems 40, 43 stiffer relative to the rest of the balloon. This enhanced stiffness can advantageously prevent the balloon from folding or inverting in on itself at the tapers 34,42 or the stems 30, 43 during use.

[000226] Figure 9L illustrates that the balloon 20 can have a proximal latitudinal reinforcement band 616a and a distal latitudinal reinforcement band 616b. The pitch in the latitudinal reinforcement bands 616 may be higher or lower than the pitch of the latitudinal reinforcement fiber 86a in the remainder of the balloon. For instance, the pitch in the bands 616 may be at least 10% higher than the pitch in the remainder of the balloon, more narrowly 20% higher. Proximal latitudinal reinforcement band 616a may begin at the proximal end of the constant-diameter section 38 and end in the balloon proximal taper 34. For instance, band 616a may cover 50% or 25% or 10% of taper 34. Similarly, distal latitudinal reinforcement band 616b may begin at the

distal end of the constant-diameter section 38 and end in the balloon distal taper 42. For instance, band 616b may cover 50% or 25% or 10% of taper 42. The hoop strength of the balloon wall 22 in bands 616 may be increased over the hoop strength in the remainder of the balloon wall 22. The additional strength may minimize or stop balloon rupture propagation. For instance, if the balloon 20 were inflated and subsequently suffered a break in constant-diameter section 38 in latitudinal reinforcement fiber 86a, a rupture might form that was substantially parallel to the longitudinal axis. The resulting rupture may propagate into balloon proximal taper 34 or balloon distal taper 42. However, bands 616 may server to stop the propagation of the rupture because of their increased strength in the hoop or latitudinal direction.

[000227] A balloon 20 may be designed to burst in a certain mode. For instance, hoop fiber pitch may be chosen such that as pressure is increased in balloon volume 24, the balloon 20 will break fibers 86a before breaking fibers 86b.

[000228] Figure 10A illustrates that the balloon 10 can be pleated to form flutes 84, for example four, five or six flutes 84, such as first flute 84a, second flute 84b. The flutes 84 can be made from accordion pleats, box pleats, cartridge pleats, fluted pleats, honeycomb pleats, knife pleats, rolled pleats, or combinations thereof. The pleating can be heat and/or pressure formed and/or the reinforcement fibers and/or panels can be oriented to form the flutes 84. The balloon 20 can be in a deflated configuration when the flutes 84 are shown.

[000229] Figure 10B illustrates that the balloon 20 in an inflated configuration can push the pleated flutes out to form a substantially smooth outer surface of the balloon wall 22. The balloon 20 can have reinforcement fibers 86. Longitudinal reinforcement fibers 86b can be parallel with the balloon longitudinal axis 26. Latitudinal reinforcement fibers 86a can be perpendicular to the balloon longitudinal axis 26.

[000230] Figures 11A and 11B illustrates the distal end of the balloon outer wall 22b can be folded around (“everted”) and attached to the outside of the second hollow shaft 2000b. The proximal end of the balloon outer wall 22b can be folded around (“everted”) and attached to the outside of the first hollow shaft 2000a.

[000231] Figures 12A and 12B illustrate that from the proximal end to the distal end, the balloon 20 can have a proximal taper 34, a first step 134a, a second step 134b, a third step 134c, and a distal taper 42, or combinations thereof. The first step 134a can have a first step outer radius 136a. The second step 134b can have a second step outer radius 136b. The third step 134c can have a third step outer radius 136c. The first step outer radius 136a can be greater than or less than (as shown) the second step outer radius 136b. The second step outer radius 136b can be greater than or less than (as shown) the third step outer radius 136c. The first step outer radius 136a can be greater than or less than (as shown) the third step outer radius 136c.

[000232] During use, the increasing radii steps 134 can be used to measure the target site. The steps 136 may also be used to dilate a target site in a patient. The dilation may be done in succession, first using a step 134 (for example, 134a), next using a step 134 with a larger radius (for example, 134b). For example, the balloon can sequentially dilate a stenotic vessel or valve with increasing known radii (e.g., instead of purely by feel) of dilation.

[000233] Figures 13A and 13B illustrate that the first step radius 136a and the third step radius 136c can be substantially equal. The second step radius 136b can be less than the first step radius and the third step radius.

[000234] Figure 13C illustrates that a radially expandable implant 156 can be removably attached to the balloon wall 22. For example, a stent, a percutaneous aortic heart valve, a replacement heart valve annulus, or combinations thereof, can be balloon-expandable and deformed into the second step before insertion of the balloon into the target site.

[000235] Figures 14A and 14B illustrate that the balloon 20 can have a peanut configuration with a smaller diameter step 134b between two larger steps 134a and 134c.

[000236] Figure 15A illustrates that the balloon proximal stem 30, proximal taper 34, constant-diameter section 38, distal taper 42, or combinations thereof can be curved. The balloon longitudinal axis can be straight or have a balloon radius of curvature 102. The balloon radius of curvature 102 can be from about 2mm (0.08in) to about 50 mm(1.97in), for example about 5 mm (0.20in), about 8 mm(0.31in), about 15mm(0.59in) or about 30 mm(1.18in).

[000237] Figure 15B illustrates that the balloon can have a C-shaped configuration. The balloon 20 can trace out an arc (e.g., a portion of a circle). The arc can form an angle of 180 degrees or less, more narrowly 30-120 degrees. The arc can form an angle of 30 degrees, 45 degrees, 60 degrees, 90 degrees or 120 degrees.

[000238] Figures 16A and 16B illustrate that the balloon 20 can have a toroidal or annular shape. A fluid conduit 176 can extend from the hollow shaft 2000 to the balloon 20. The fluid conduit 176 can delivery fluid pressure to inflate and deflate the balloon 20. The balloon 20 can have an inner wall 22a and an outer wall 22b. The inner wall 22a can be radially inside the outer wall 22b. The inner wall 22a and/or the outer wall 22b can comprise a fiber 86 and/or a panel 196. The balloon 20 can have an annular lumen 160 passing through the radial center of the balloon 20. The annular lumen 160 can open to an annular lumen distal port 162a and an annular lumen proximal port 162b.

[000239] The distal end of the annular lumen 160 can be attached to one or more distal tensioners 164a. The distal tensioners 164a can be elastic or inelastic wires, fibers or threads. The distal tensioners 164a can be fixed at distal tensioner first ends evenly or unevenly angularly distributed around the distal end of the balloon 20. The distal tensioners 164a can attach at distal

tensioner second ends to a distal tension anchoring wrap 166a. The distal tension anchoring wrap 166a can be fixed to the hollow shaft 2000.

[000240] The proximal end of the annular lumen 160 can be attached to one or more proximal tensioners 164b. The proximal tensioners 164b can be elastic or inelastic wires, fibers or threads. The proximal tensioners 164b can be fixed at proximal tensioner first ends evenly or unevenly angularly distributed around the proximal end of the balloon. The proximal tensioners 164b can attach at proximal tensioner second ends to a proximal tension anchoring wrap 166b. The proximal tension anchoring wrap 166b can be fixed to a tensioning collar 168.

[000241] The second step can form a waist. The waist can have additional hoop wrapped fibers. The waist can be substantially non-compliant. The waist can be from about 0 mm (0 in) to about 12 mm in the balloon longitudinal direction, more narrowly from about 3 mm to about 9 mm. The waist diameter can be from about 2 mm (0.08in) to about 35 mm, for example about 3 mm, about 6 mm, about 20 mm, or about 23 mm.

[000242] The tensioning collar 168 can be slidably attached to the hollow shaft 2000. The tensioning collar 168 can translate longitudinally, as shown by arrows in Figure 16B, along the shaft. The tensioning collar can be pulled and/or pushed by a control line 170 or rod. Before deployment of the inflatable device and after deployment but before removal of the inflatable device, the balloon can be deflated and contracted against the hollow shaft. For example, the control line can be pulled to retract the proximal end of the balloon. For example, the balloon can fold and contract against the hollow shaft. The balloon may be pleated such that, when the tensioning collar is pulled or when a vacuum is applied to the inflatable device, the balloon contracts into a small, packed form (not shown).

[000243] The balloon can have a distal segment 172a and a proximal segment 172b. The distal segment 172a and the proximal segment 172b can be annular or toroidal. The annular or toroidal planes can be perpendicular to the balloon longitudinal axis 26. The distal segment 172a can be longitudinally adjacent to the proximal segment 172b. The distal segment 172a can be directly bonded to the proximal segment 172b or joined to the proximal segment 172b by a segment joint 174. The segment joint 174 can be open and allow fluid communication between the proximal segment 172b and the distal segment 172a (not shown) or can be closed to isolate the fluid volume of the proximal segment 172b from the fluid volume of the distal segment 172a.

[000244] The distal segment and/or the proximal segment may be inflated by a tube. The tube may be attached to the hollow shaft.

[000245] The outer wall, the inner wall, or both walls, may contain a radiopaque material as described herein.

[000246] The outer wall of the distal segment can form the first step. The segment joint can form the second step. The outer wall of the proximal segment can form the third step. The second step can be radially smaller than the first step and the second step. A device, such as a minimally invasive replacement heart valve can be attached to the outside of the balloon.

[000247] Figures 16C illustrates that the balloon 20 can have a valve 178. The valve 178 can have a first leaflet 180a, a second leaflet 180b, a third leaflet (not shown), or more. The leaflets 180 can be thin and flexible. The leaflets 180 can collapse inside the annular lumen 160 when the balloon is in a contracted configuration. The valve can allow flow through the annular lumen 160 in the distal direction and prevent flow through the annular lumen 160 in the proximal direction. The valve 178 can be fixed to the distal end of the distal segment of the balloon. The leaflets 180 can be oriented to allow flow distally through the annular lumen and impede or prevent flow proximally through the annular lumen. The leaflets 180 can be oriented to allow flow proximally through the annular lumen and impede or prevent flow distally through the annular lumen.

[000248] Figure 17A illustrates that a shell 678 can have apertures 714. The apertures may be located in the proximal taper 34 and/or the distal taper 42. There may be an equal number of apertures on the each taper. The balloon could have 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more apertures on each taper. The apertures may be aligned to fall between flutes or pleats. Apertures 714 may allow fluid, such as blood, to flow thru the inside of the shell. Apertures 714 may make the shell incapable of sustaining static pressure. Shell aperture flaps 718 may be made so that they will close apertures 714 when there is no flow through the balloon. When flow proceeds from left to right in Figure 17A with sufficient pressure, flaps 718 may open to allow flow through apertures 714. When the pressure relaxes, flaps 718 may shut to restrict flow from right to left in Figure 17A. In this way, flaps 718 may act as a one way valve.

[000249] Figure 17B shows a cutaway of an inflated annular balloon structure 682. Balloon segments 656 are compressed by shell 678. The annular balloon structure has a central fluid passage 692 and apertures 714. Together, these features may allow fluids, such as blood, to pass through the annular balloon structure even when balloon segments 656 are fully inflated. Second hollow shaft 2000b may provide a lumen thru the center of the balloon. This lumen may be used with a guidewire to locate the balloon during a medical procedure. Second hollow shaft 2000b may have some elasticity or compressibility in the axial direction. First hollow shaft 2000a may allow the provision of pressurized fluid to hollow shaft distal port 54 and balloon inflation/deflation ports 654. Provision of pressurized fluid may cause balloon segments 656 to inflate. Removal of fluids may cause balloon segments 656 to collapse and for the shell to return to a pleated or fluted state.

[000250] Figure 18A illustrates that the balloon can have segments that can be angularly adjacent to each other. For example, the segments and the segment joints can be parallel with the longitudinal axis. The second step can have a larger radius than the first step or the third step. The proximal and distal tensioners can attach to the segments and/or segment joints.

[000251] The segments may be inflated by a tube. The tube may be attached to the hollow shaft 2000. The distal and/or proximal tensioners can attach to the balloon at the segment joints and/or at the segments.

[000252] The segment walls can have a radiopaque foil and/or a wire, such as a radiopaque marker wire.

[000253] Figure 18B illustrates that the segments can be in fluid isolation from each other at cross section X-X. The segments can have a flattened circle longitudinal cross-sectional configuration. For example, the segments can be almond or eye-shaped.

[000254] Figure 18C illustrates that the segments can be in fluid communication with each other at a length along the balloon shown in Figure M1.

[000255] Figure 18D illustrates that the segments can have a circular longitudinal cross-sectional configuration. For example, the segments can be cylindrical.

[000256] Figures 19A and 19B illustrate that the balloon can have a constant outer diameter when measured along the longitudinal axis. For example, the balloon can have a single step. The balloon can have an inner wall 22a, an outer wall 22b and segment joints 174. The segment joints 174 can connect the inner wall to the outer wall. The segment joints 174 can minimize the inward radial collapse of the inner wall during inflation.

[000257] Figure 19C illustrates that the hollow shaft can have an inner lumen 154a and an outer lumen 154b. The fluid conduit can be in fluid communication with the outer lumen and the balloon. The outer lumen can deliver pressure through the fluid conduit and to the balloon. The inner lumen can be a through lumen, and the outer lumen can extend through the distal proximal tip.

[000258] Figure 20 illustrates that the balloon can have a spiral or helical configuration. The spiral can have a first winding 182a, a second winding 182b, and more (e.g., five, as shown) windings. The first winding 182a can be joined to the second winding 182b at a winding joint 184. The winding joint 184 can have an adhesive or a weld joint. The winding joint 184 can have a strip of elastic or inelastic material attached to the adjacent windings. The balloon 20 can be formed from a single continuous lumen.

[000259] Radiopaque foils, wires and any other radiopaque element or metal element herein can be made from gold, platinum, platinum-iridium alloy, tantalum, palladium, bismuth, barium,

tungsten, or combinations thereof. A radiopaque element may be a layer or a panel or a reinforcement element or a film or combinations thereof.

[000260] A radiopaque element may be low strength. A low strength material can have a tensile yield strength less than about 100 ksi (690 MPa), more narrowly less than about 50 ksi (345 MPa), still more narrowly less than about 35 ksi (241 MPa), still more narrowly less than about 25 ksi (172 MPa). The addition of the radiopaque element may increase the burst strength of the balloon no more than an insubstantial amount (e.g., by less than about 15%, more narrowly by less than about 10%, still more narrowly by less than about 5%).

[000261] A radiopaque element may be ductile. Ductility can be measured by measuring the reduction in area of a test sample when pulled until the sample is fractured. Ductile materials can have about a 30% or more reduction in area, more narrowly, about a 40% or more reduction in area, still more narrowly about a 50% or more reduction in area, still more narrowly about a 70% or more reduction in area, still more narrowly about an 80% or more reduction in area. Ductile materials, as compared to brittle materials, typically can be bent or folded with less chance of fracturing at the bend.

[000262] Any of the balloon layers can have radiopaque dyes.

[000263] Figures 21A and 22A illustrate that the first flute 84A can have a first vane 186a. The second flute can have a second vane 186b. The vanes 186 can be radiopaque elements. The vanes 186 can be panels. The vanes 186 can be embedded within or attached to the inside or outside of the balloon wall 22. All, some, one, or none of the flutes can have vanes. The vanes 186 can be reinforcements. For example, the vanes 186 can be a laminate, foil or wafer. The foil or wafer can be a plastic or metal listed herein, such as tantalum. The vane 186 can be strong enough to cut soft or hard tissue adjacent to the pleat. The vanes 186 can be rigid or flexible. Figures 21B and 22B illustrate that in an inflated or expanded configuration, the vanes 186 can lie flat along the wall.

[000264] A single radiopaque layer can encompass substantially the entire area of the balloon (as shown in Figure 1, but with a radiopaque layer congruent with the balloon 20). The radiopaque layer can be a single continuous layer, for example as a deposition or (e.g., radiopaque) foil lining with e.g. a deposition or foil of a metal such as listed herein.

[000265] The foil can be less than about 30 μm (0.0012 in) thick, for example less than about 20 μm (0.0008 in) thick, for example about 15 μm (0.0006 in), about 12 μm (0.0005 in), about 10 μm (0.0004 in) or about 8 μm (0.0003 in) thick. Radiopaque foils can be cut or patterned by laser cutting, wire EDM, die cutting or deposition. The foils may be mounted to a removable backing before cutting such that a pattern of foils may be easily applied during the balloon construction process.

[000266] The vanes 186 can cover the distal half of the balloon. The vanes 186 can cover the proximal half of the balloon. The vanes 186 can overlap in the longitudinal center of the balloon. A radiopaque foil can strengthen the balloon wall 22.

[000267] The balloon 20 can have pleats or flutes between vanes or panels. The vanes or panels can form the pleats or flutes. A panel or vane, such as a radiopaque foil, can minimize leaks from forming between fibers in the balloon during use.

[000268] Figure 23A illustrates that the vanes 186 can be spaced evenly around the balloon longitudinal axis. The vanes can be radiopaque and/or echogenic. The vanes can be rectangular, triangular, circular, oval, or combinations thereof. The vanes can be made of a metal foil. The vanes can be oblong having a major axis and a minor axis. The major axis can be parallel with the balloon longitudinal axis.

[000269] Figure 23B illustrates that the balloon can have first vanes 186a spaced evenly around the balloon longitudinal axis. The balloon can have one or more second vanes 186b at the balloon distal terminal end.

[000270] Figure 23C illustrates that the balloon can have a third vane 186c at the proximal taper. The second and/or third vanes can partially or completely circumferentially envelope the balloon around the balloon longitudinal axis.

[000271] Figure 23D illustrates that the balloon can have marker spots 188 evenly or unevenly distributed around the balloon. The marker spots 188 can be radiopaque and/or echogenic. The marker spots 188 can be circular, oval, square, triangular, rectangular, pentagonal, hexagonal, or combinations thereof. The marker spots 188 can be in a layer of the balloon wall or attached to the inner or outer surface of the balloon wall.

[000272] Figure 23E illustrates that the balloon can have a marker wire 190 in a helical configuration about the balloon longitudinal axis. The marker wire 190 can be radiopaque and/or echogenic. The wires 190 can be electrically conductive. The wires 190 can carry electrical current, for example for RF delivery, resistive heating, or combinations thereof. The marker wire 190 can be in a layer of the balloon wall or attached to the inner or outer surface of the balloon wall 22.

[000273] Figure 24A shows a pattern for a marker wire 190. Marker wire 190 may be wound around the balloon such that it partially covers the distal and proximal ends of the constant-diameter section 38 of the balloon 20. The constant-diameter section 38 may be the area of the balloon that is responsible for most or all of the expansion done by the balloon 20 in a patient.

[000274] Figure 24B shows a pattern for a marker wire 190. Marker wire 190 may be wound around the balloon on both the distal 42 and proximal tapers 34 of the balloon. The marker wire may be wound up to the distal and proximal borders of the constant-diameter section 38 without

any substantial amount of the wire being placed in the constant-diameter section 38. The marker wire may be wound in a helical pattern in both directions on the balloon or be wound in a single direction. The angle 191 between two layers of marker wire may be less than 20 degrees, more narrowly less than 10 degrees, still more narrowly less than 6 degrees.

[000275] Figure 24C illustrates that the balloon 20 can have a marker wire 190 wrapped over approximately the entire length of constant-diameter section 38. The marker wire 190 may be centered on the constant-diameter section 38. The marker wire 190 may cover only a portion of the constant-diameter section 38. For instance, the marker wire 190 may cover more than 70% of the constant-diameter section 38, more narrowly more than 80%, still more narrowly more than 90%. The marker wire 190 may cover a portion of the distal tapers 42 and proximal tapers 34. For example, the marker wire 190 may cover 100% of the distal tapers 42 and proximal tapers 34, more narrowly more than 50%, still more narrowly more than 25%. The marker wire 190 may be a latitudinal reinforcement fiber 86a.

[000276] Figure 24D illustrates that the balloon can have a marker wire 190 wrapped over substantially the whole length of the balloon 20.

[000277] The marker wire 190 can be made of any radiopaque material listed supra. The material may be chosen to be highly ductile so that it can form without fracturing as the balloon is folded. The marker wire 190 may be a round or flat wire. For example, the marker wire 190 may be circular and about 6 μm (0.0002 in) to about 25 μm (0.001 in) in diameter. The marker wire 190 may be a flat (or rectangular) wire about 6 μm (0.0002 in) to about 18 μm (0.0007 in) thick and about 12 μm (0.0005 in) to 800 μm (0.032 in) wide. For example, it may be about 12 μm (0.0005 in) thick and 75 μm (0.0015 in) wide.

[000278] The marker wire 190 can carry a tensile load. For example, the wire 190 can have a 0.001 in. diameter and maintain a tensile load of 0.3 N without yield or failure. The marker wire 190 can be low strength and/or ductile as defined herein.

[000279] Any or all of the vanes 186, the marker spots 188 or the marker wires 190 can be on the inside of the balloon wall 22, the outside of the balloon wall 22, or within the balloon wall 22.

[000280] Figure 25 illustrates that the balloon can have a resistive heating element 204 in a layer of the balloon wall or on the radial outside or radial inside of the balloon wall. The heating element 204 can have a resistive wire on a panel. The panel can be made from copper or another metal. The heating element 204, such as the resistive wire or panel, can be connected to a heating lead 206. The heating lead 206 can extend proximally along the hollow shaft 2000. The heating lead 206 can be proximally connected to a controller and power source. The system can have a heat control unit for controlling the level of energy delivery to the resistive heating

element 204. The heating element 204 can be separated positive and negative electrodes on the balloon wall outer surface and contact the target site tissue directly, within the balloon wall, or on the radial inside of the inside surface of the balloon, or combinations thereof. The heating element 204 can have a dielectric material. Radiofrequency energy can be delivered across the dielectric material of the heating element 204 to create ohmic heating in the tissue. The balloon 20 can be used to heat, cool (e.g., when the panel is a Peltier junction), emit RF power, or combinations thereof.

[000281] The heating element 204 can be substituted for or configured in combination with a UV-emitting element, visible light-emitting element, microwave-emitting element, ultrasonic-emitting element, or combinations thereof. The heating element 204 can be replaced or configured with a strain gauge, a peltier junction or a temperature measuring device, or combinations thereof.

[000282] The balloon can be used to treat abnormal mucosa in an esophagus, for example by positioning the heating element near or in contact with the abnormal mucosa and delivering heat. The mucosal layer of the esophageal wall, for example the columnar epithelium, can be injured or ablated and made necrotic with the balloon to normalize mucosa in the esophagus.

[000283] Figure 26A illustrates that the balloon wall 22 at section BB-BB or at other sections taken through a single wall of the balloon can have a layer 72 that can have a fiber matrix. The fiber matrix can have one or more monofilaments 274 and one or more resins. The resin can be a flexible adhesive 208. The flexible adhesive can remain flexible when cured or melted to form the medical inflatable device 2.

[000284] Monofilament 274 can be a reinforcement fiber 85 a reinforcement fiber 86 or reinforcement fiber 87. A reinforcement fiber can be a tow. A tow may contain one or more monofilaments. A fiber may contain one or more monofilaments. The fiber matrix may have one, two or more monofilaments 86 running substantially parallel to each other and embedded in a flexible adhesive 208. The substantially parallel monofilaments may be positioned within the flexible adhesive such that they are touching each other along their length. The substantially parallel monofilaments may be positioned such that there is flexible adhesive separating each fiber along its length.

[000285] Figure 26A illustrates fiber array layer 72 having a layer width 210 in cross-section. The layer width 210 can include a number of monofilaments 274. The layer 72 can have a linear quantity fiber density measured, for example, as the number of monofilaments 274 per unit of layer width 210. The linear quantity fiber density can be equal to or greater than about 500 monofilaments 274 per inch, more narrowly equal to or greater than about 1000 monofilaments 274 per inch, more narrowly equal to or greater than about 2000 monofilaments 274 per inch, yet

more narrowly equal to or greater than about 4000 monofilaments 274 per inch. For example, the liner quantity monofilaments 274 density can be from about 1,000 monofilaments 274 per inch to about 2,000 monofilaments 274 per inch.

[000286] The fibers 86 or monofilaments 274 can be high strength and inelastic. The fibers may have a strain to failure of less than 10%, more narrowly less than 5%. The fibers may have an ultimate tensile strength greater than 1.8 GPa (260 ksi), more narrowly greater than 2.4 GPa (350 ksi), still more narrowly greater than 2.9 GPa (420 ksi). The fibers can have a fiber or monofilament diameter 212, for example, from about 1 μm (0.00004 in.) to about 50 μm (0.002 in.), for example less than about 25 μm (0.001 in.), more narrowly less than about 20 μm (0.0008 in.). The high strength fibers may be radiolucent or radiopaque. The unidirectional fiber-reinforced matrix can have the same or different sizes and materials of fibers within the same unidirectional fiber-reinforced matrix.

[000287] The fiber matrix layer 72 can have a layer thickness 216 from about 1 μm (0.00004 in.) to about 50 μm (0.002 in.), more narrowly from about 8 μm (0.0003 in.) to about 25 μm (0.001 in.), yet more narrowly from about 10 μm (0.0004 in.) to about 20 μm (0.0008 in.)

[000288] Figure 26B illustrates that the fiber density can be less than the fiber density shown in Figure 26A. For example, the fiber density can be about 500 fibers per inch.

[000289] Figures 26C and 26D illustrate that the monofilaments 274 or fibers may have a non-circular cross section. For instance, they may have a rectangular or oval cross-section. The cross section of monofilament 274 may have a fiber maximum height 1068 of, for instance about 5 μm to about 20 μm and a fiber maximum width 1072 of, for instance, about 20 μm to about 500 μm . For example, the fiber or monofilament 274 can be about 8 μm high and 25 μm wide. For example, the fiber or monofilament 274 can be about 12 μm high and 50 μm wide.

[000290] Figure 26E illustrates that the inner layer 72b can have a fiber matrix having monofilament 274 in an adhesive 208. The outer layer 72a can have a polymer film, for example as shown in Figure 27. The laminate shown can be a part of or the entire balloon wall 22.

[000291] Figure 26F illustrates that the outer layer 72a and the inner layer 72b can be polymer films, for example as shown in Figure 27. In any variation, the polymer films can be the same or different polymers, or any combination thereof. The first middle layer 72c can be a fiber matrix.

[000292] Figure 26G illustrates the outer layer 72a, inner layer 72b, first middle layer 72c and third middle layer 72e can be polymer films, for example as shown in Figure 27. The second middle layer 72d can be a fiber matrix.

[000293] Part or all of the balloon wall 22 can have a volumetric quantitative density of monofilaments 274 measured, for example, as the number of monofilaments 274 per unit of area.

The area quantity monofilaments 274 density can be equal to or greater than about 100,000 monofilaments 274 per square inch, more narrowly equal to or greater than about 250,000 monofilaments 274 per square inch, more narrowly equal to or greater than about 1,000,000 monofilaments 274 per square inch, yet more narrowly equal to or greater than about 4,000,000 monofilaments 274 per square inch. The area quantity of fiber can be about 25% of the area of a wall cross section, more narrowly about 50%, more narrowly about 75%.

[000294] The ratio of the volume of the fiber matrix to the volume of the monofilaments 274 can be about equal to or greater than about 15%, more narrowly equal to or greater than about 30%, more narrowly equal to or greater than about 50%, yet more narrowly equal to or greater than about 75%.

[000295] Figure 26H illustrates that the outer layer 72a, and inner layer 72b can be polymer films. The first middle layer 72c and the second middle layer 72d can be fiber matrices. The first middle layer 72c and the second middle layer 72d can be positioned with the monofilaments 274 substantially parallel to each other (as shown), substantially perpendicular to each other, or at an angle to each other.

[000296] Figure 26I illustrates Figure 26H with the monofilaments 274 in second middle layer 72d substantially perpendicular the monofilaments 274 in first middle layer 72c.

[000297] Figure 26J illustrates that the outer layer 72a, inner layer 72b, second middle layer 72d, and third middle layer 72e can be polymer films. The first middle layer 72c and the fourth middle layer 72f can be fiber matrices.

[000298] Figure 26K illustrates that the outer layer 72a, inner layer 72b, second middle layer 72d, third middle layer 72e, fifth middle layer 72g, and sixth middle layer 72h can be polymer films, for example as shown in Figure 27. The first middle layer 72c, fourth middle layer 72f and seventh middle layer 72i can be fiber matrices.

[000299] Figure 26L illustrates that the outer layer 72a can be an MMA-resistant and MMA-releasing polymer film. The inner layer 72b can be a leak proof bladder made from a polymer film, for example as shown in Figure 27. The first middle layer 72c can be a fiber matrix, for example with the fibers oriented as longitudinal fibers. The second middle layer 72d can be a fiber matrix, for example with the fibers oriented as latitudinal or hoop fibers. The third middle layer 72e can be a resin or adhesive. The fourth middle layer 72f can be a radiopaque layer, such as a metal foil.

[000300] Figure 26M illustrates that the outer layer 72a can be a polymer film, for example as shown in Figure 27. The inner layer 72b can be a leak proof bladder made from a polymer film, for example as shown in Figure 27. The first middle layer 72c can be a fiber matrix, for example with the monofilaments 274 oriented as latitudinal or hoop fibers. The second middle layer 72d

can be a fiber matrix, for example with the monofilaments 274 oriented as longitudinal fibers. The third middle layer 72e can be a resin or adhesive. The outer layer 72a may serve to isolate and protect the filaments 274. For example, the filaments may be never get closer than 12 μ m, or 10 μ m, or 8 μ m or 6 μ m or 4 μ m or 2 μ m to the outside surface of the outer layer 72a. The outer layer 72a and/or the inner layer 72b may not melt when adhered to adhesive 208 using processing methods describe herein.

[000301] Figure 26N illustrates that the outer layer 72a can be a polymer film, for example as shown in Figure 27. Outer layer 72a may have perforations 782 as described infra. The inner layer 72b can be a leak proof bladder made from a polymer film, for example as shown in Figure 27. The first middle layer 72c can be an adhesive 208. The second middle layer 72d can be a polymer film. The third middle layer 72e can be a fiber matrix, for example with the monofilaments 274 oriented as latitudinal or hoop fibers. The fourth middle layer 72f can be a fiber matrix, for example with the monofilaments 274 oriented as longitudinal fibers and with marker wire 190, which is thus embedded in the wall of the balloon. The fifth middle layer 72g can be an adhesive 208.

[000302] Figure 26O illustrates that the adhesive 208 in fifth middle layer 72g may fill in perforations 782 in outer layer 72a. Fourth middle layer 72f may contain a rectangular marker wire 190.

[000303] Any of the polymer or fiber matrix layers can be leak proof, water tight, air tight, MMA-resistant, MMA-releasing, or combinations thereof.

[000304] Magnetic resonance visualization enhancement materials, such as magnetic contrast agents, can be added to the adhesive, the film or the fiber. The magnetic resonance visualization enhancement materials can enhance the visualization of the balloon during a magnetic resonance imaging (MRI) procedure. For example, the magnetic resonance visualization enhancement material can be gadolium, Omniscan, Optimark, ProHance, Magnevist, Multihance, or combinations thereof.

[000305] Any of the layers, for example the outer layer, can be tinted or dyed a visible spectrum color. For example, a pigment, coloring additive, dispersions or other coloring agents, such as a coloring additive from Plasticolors (Ashtabula, Ohio) can be added to the adhesive, laminate or fiber before consolidation. A paint or coating can be added to a layer surface or to the outer surface of the balloon wall.

[000306] The color can be selected for branding , market differentiating, as an indication of the type of device, the size of the device, or combinations thereof. For example, devices having a selected diameter, length, pressure rating, clinical indication or efficacy, other common

performance metric, or combinations thereof, can be dyed a specific color (e.g., green for a first type of device, red for a second type of device).

[000307] The layers can have one or more optical fibers. The fiber optic can be a strain sensor. The strain sensor can monitor the laminate's mechanical status in real time. The fiber optic can guide light delivery into the body. The fiber optic can visualize a target site (e.g., gather light from the body to produce a visual image).

[000308] Figure 27 illustrates polymer films from which panels 196 and/or panels 74 and/or panels 76 and/or layers 72 can be made. The thickness of the polymer films can be from about 2 μm (0.00007 in.) to about 50 μm (0.002 in.), more narrowly from about 2 μm (0.00007 in.) to about 18 μm (0.0007 in.), yet more narrowly from about 4 μm (0.00016 in.) to about 12 μm (0.0005 in.). Films may be metalized or coated to change their surface properties. Metallization or coating may take place before or after a film is formed. Films may be treated chemically or via plasma or via corona treating or by combinations thereof in order to modify their bondability, for example to make them easier to bond too.

[000309] Figure 28 illustrates materials from which the reinforcement fibers 86 or monofilaments 274 can be made. Reinforcement materials may be high strength as described supra. The reinforcement fibers 86 may be a wire or wires. The wire may have chosen with very low strain to failure (for instance, about 2%) or a high strain to failure (for instance, 10% or greater). The wire may be annealed or tempered to adjust its mechanical properties. The wire may have a breaking strength of greater than about 150 ksi, more narrowly greater than 250 ksi, still more narrowly greater than 400 ksi. The wire may be less than 25 μm in diameter. The wire may be substantially rectangular and less than about 25 μm in thickness 1068, more narrowly less than about 15 μm in thickness 1068 when integrated into the wall of the balloon. The ratio of the width 1072 of the wire to the thickness 1069 of the wire may be greater than or equal to about 3, more narrowly greater than or equal to about 5, more narrowly greater than or equal to about 10. The density of the wire may be greater than about 2.4 g/cm³, more narrowly greater than about 6.9 g/cm³, more narrowly greater than about 15 g/cm³.

[000310] The reinforcement fiber or wire 86 may be substantially radiopaque when used under a fluoroscope as part of a medical procedure in the human body. The physician may use an inflation medium, such as saline, which is not radiopaque when inflating a balloon 20.

[000311] The reinforcement fibers or wires 86 may be coated. The coating may be an adhesive or otherwise increase adhesion of the fibers or wires 86. The coating may be a thermoplastic chosen from one of the materials (or combinations thereof) listed in Figure 29. The thermoplastic may be melted as part of the process of applying reinforcement fibers 86 to a balloon 20.

[000312] Figure 29 illustrates that the adhesive 208 can be an elastomeric thermoset material, an elastomeric thermoplastic material, an epoxy, a coating or a combination thereof. The adhesive can be selected from any of the materials, or combinations thereof, listed in Figure 29. The matrix can have a resin and a fiber. The resin can be an adhesive.

METHOD OF MANUFACTURE

[000313] Figures 30A and 30B illustrate that the device can be partially or completely manufactured in a pressure chamber 219. The pressure chamber 219 can be in a pressure chamber case 218. The pressure chamber case 218 can have a case top 220a separable from a case bottom 220b. The case top 220a can have a case top port 222. The case bottom 220b can have a case bottom port 224. The case top port 222 can be in fluid communication with the top of the pressure chamber 219. The case bottom port 224 can be in fluid communication with the bottom of the pressure chamber 219.

[000314] The case top can screw or otherwise tightly join to the case bottom. The pressure chamber case can have one or more o-rings (not shown) in o-ring seats 226.

[000315] The pressure chamber can have a mandrel seat 228. The mandrel seat 228 can be configured to receive a mandrel 230. The mandrel seat 228 can have holes or pores. The holes or pores in the mandrel seat 228 can allow pressure from the case bottom port and the bottom of the pressure chamber to reach the top surface of the mandrel seat around the mandrel and/or directly under the mandrel.

[000316] The mandrel 230 can have the inner dimensions of the balloon 20.

[000317] The mandrel 230 can be a water soluble mandrel. The mandrel 230 may be made from a low melting point wax or metal, a foam, some collapsing structure or an inflatable bladder. The mandrel 230 can be made from a eutectic or non-eutectic bismuth alloy and removed by raising the temperature to the melt point of the metal. The mandrel 230 can be made from aluminum, glass, sugar, salt, corn syrup, hydroxypropylcellulose, ambergum, polyvinyl alcohol (PVA, PVAL or PVOH), hydroxypropyl methyl cellulose, polyglycolic acid, a ceramic powder, wax, ballistic gelatin, polylactic acid, polycaprolactone or combinations thereof.

[000318] Figure 31 illustrates characteristics of bismuth alloys from which the mandrel 230 can be made. The characteristics are characterized by melting temperature (as shown in the third row of Figure 31) of the bismuth alloy.

[000319] The mandrel 230 can be transparent or translucent to light and/or an electron beam. The mandrel 230 can be hollow. The outside surface of the mandrel 230 can be coated in a release agent. The mandrel 230 may be molded, machined, cast, injection molded or combinations thereof.

[000320] The mandrel 230 can be in the mandrel seat 228 and a first panel 196a to be formed into about half of the inner layer of the balloon wall 22 can be placed between the case top 220a and the case bottom 220b. The case top can then be secured to the case bottom.

[000321] Figure 32A illustrates that the outer surface of the mandrel 230 can have some glue or first adhesive 208a. The first adhesive 208a can be located around the perimeter of the first panel's 196a contact area with the mandrel. The first adhesive 208a can be water soluble. The first adhesive 208a can be a sugar syrup. A panel 196a may be positioned over the mandrel. The panel 196a may be a single layer or multiple layers. For instance, the panel could be a layer of film (for example, taken from Figure 27) and meltable adhesive (for example, taken from Figure 29). The panel 196a can be positioned with film on the side that touches the mandrel and adhesive on the radially outer side. The panel 196A may be perforated as described infra. The panel may not be capable of sustaining pressure between the top and bottom of the panel.

[000322] Figure 32B illustrates that a positive pressure can be applied to the top 220a of the pressure chamber (e.g., through the case top port 222) and/or a negative pressure or differential pressure or suction or vacuum applied to the bottom 220b of the pressure chamber (e.g., through the case bottom port 224). The panel 196A can get sucked and/or pressed down and/or formed onto the mandrel 230. The first panel can be smoothly fitted to the mandrel 230 and adhered to the mandrel at the first adhesive 208A. Heat may be applied to panel 196a before forming onto mandrel 230. Forming of one panel 196a may be done more than once on different sized mandrels before the panel 196a reaches the form shown in Figure 32B.

[000323] Forming of panel 196a may also be accomplished with a mechanical die. The mechanical die may be heated and conform closely to the shape of the mandrel 230. The mechanical die may have a shape similar to the mandrel seat 228.

[000324] The mandrel 230 and panel 196a can be mounted into a trimming jig. Any excess portion of the first panel 196a extending from the mandrel 230 can be trimmed with a blade, with a laser, with a water jet cutter, with a die cut tool or combinations thereof. The trimming jig can cover the mandrel 230 and the first panel 196a attached to the mandrel. Several panels 196a and/or layers 72 can be formed over the mandrel 230 and cut. The panels 196a and/or layers 72 may be trimmed at the same time or one at a time.

[000325] Figure 32C illustrates that the mandrel can have the excess area of the first panel 196A removed in preparation for attachment of the second panel 196b.

[000326] Figure 32D illustrates that a second adhesive 208b can be applied to the first panel 196a around the perimeter of the second panel's 196b contact area with the first panel 196a. The second adhesive 208b can be an epoxy, urethane, a thermoplastic, a cyanoacrylate, a UV curing adhesive, or combinations thereof. The mandrel 230 can be seated in the mandrel seat 228 with

the first panel 196a in the mandrel seat. The second panel 196b can be placed on the mandrel 230 as shown (upside down relative to the Figures 30A and 30B for illustrative purposes).

[000327] Figure 32E illustrates that after the case top 220a is secured to the case bottom 220b, the positive and/or negative pressures can be applied to the pressure chamber as described infra. The second panel 196b can be smoothly fitted or pressure formed to or against the mandrel 230 and adhered to the first panel 196a at the second adhesive 208b. Adhesion can be accomplished by the application of heat. The first and second panels (196A and 196B) can form the inner layer 72b or bladder 52 of the balloon wall. The inner layer may be leaktight. The inner layer may be capable of sustaining pressure. Multiple layers can be made by repeating the method described infra. The pressure chamber can be heated, for example, to decrease the viscosity of and decrease the modulus of the panels.

[000328] Figure 32F shows a cross section of 32E with the mandrel 230 omitted. The process in Figures 32A thru 32E may be repeated on the part shown in Figures 32E and 32F to produce the bladder 52 cross section shown in Figure 32G. Panels 196c and 196d may be formed. Each panel may have an adhesive 208c and 208d facing radially inward. Balloon third and fourth internal seams 69c and 69d may be oriented about midway between balloons first and second internal seams 69a and 69b. The bladder 52 may be leaktight.

[000329] Figure 33A illustrates that a first panel 196a can rest on top of the female mold half 378a. (The first panel 196a can be a see-through polymer for illustrative purposes. For example, the contours of the mold may be seen.) The first panel 196a can be a polymer, such as a nylon, PET, polycarbonate, urethane or those materials shown in Figure 27 or any other polymer that can be readily formed or combinations thereof. The first panel can be about 0.002 inches (50 μm) thick, more narrowly about 0.001 inches (25 μm), thick yet more narrowly about 0.0005 inches (12 μm) inches thick.

[000330] Figure 33B illustrates that the first panel 196a can be formed to the contours of mold. Molding could be via heat or vacuum or pressure or combinations thereof.

[000331] Figure 33C illustrates that the first panel 196a can be lifted free of the mold half 378a. The first panel 196a can have a panel flat 390 that did not enter the form of the female mold during forming. The panel 196a can be trimmed, for example in a trimming jig.

[000332] Figure 33D illustrates that first and second panels (196a and 196b respectively) can have their flats 390 trimmed. The two panels can be closed tightly around a mandrel 230 and a mandrel shaft 392. The panels can then be bonded to each other at the seam 66b where they overlap. The seam 66b may connect all or some of the material that overlaps. The seam 66b may be leak tight to the passage or air and water. The bonding of the seam 66 and/or 67 and/or 69 may be caused by addition of an adhesive, by the application of heat, by the application of

ultrasonic energy, by use of a laser, by the application of radio frequency energy, by the application of pressure or by combinations thereof. A material may be added to the seam, for example to bond the seam. The material may absorb laser light to generate heat in the seam.

[000333] Figure 34A shows a bladder 52. The bladder 52 may be a thin-walled, blow-molded balloon. The bladder 52 may have a wall thickness of less than about 0.001 inches (0.025 mm), more narrowly less than about 0.0005 inches (0.0125 mm). The bladder 52 may have a constant or variable wall thickness along the length of the bladder 52 and/or around the circumference of the bladder 52. The bladder 52 may form the inner wall of a balloon 20 and be leak-tight.

[000334] The inner volume of the bladder 52 may be filled with a mandrel material (types of mandrel material are described herein). The filling may be by injection or by pouring or combinations thereof. The filling may occur after the bladder 52 has been formed. The mandrel material may be chosen to match the thermal expansion properties of the fibers 86.

[000335] Figure 34B shows a cut 350 that may be made through the wall of the bladder 52. The cut 350 may be a longitudinal cut running the entire length of the bladder 52. The cut 350 could be made mechanically (i.e., with a knife), with a laser, a water jet cutter, an ultrasonic blade, a heated blade or combinations thereof. The cut 350 may allow one side of the bladder 52 to be opened. The cut 350 in Figure 34F may leave the bladder 52 in one piece. The cut 350 can extend along a portion (e.g., from one terminal end to a mid-point, or from a first mid-point to a second mid-point), or the entire length of the bladder 52.

[000336] Figure 34C shows a cut 350 through the bladder 52 at a cut angle 351. Cut angle 351 may be about 0° to about 70°, more narrowly about 0° to about 50°, still more narrowly about 25° to about 45°. Figure 34D shows a cut 350 through the bladder 52. The cut 350 is a spiral, with a maximum cut angle 351. Figure 34E shows a cut 350 through the bladder 52 at a cut angle 351 of 0°. The cut 350 may separate the bladder 52 into a first detached bladder portion 52a and a second detached bladder portion 52b. The first and second detached bladder portions 52a and 52b can each be half of the bladder 52 or can otherwise together comprise the complete bladder 52. The first bladder portion 52a can be symmetric or asymmetric with the second bladder portion 52b.

[000337] Bladder portions 52 can also be formed separately and then joined as described infra. For instance bladder portions 52 could be formed by thermoforming, injection molding, physical vapor deposition, dip molding or combinations thereof.

[000338] Figure 34F shows the bladder 52 in Figure 34B after being fit over a mandrel 230 (mandrel 230 is inside bladder 52 and not directly shown in Figure 34F). The bladder 52 may be made slightly larger in diameter and/or longer in length than the mandrel 230 onto which the bladder 52 is fit. This may allow the bladder 52 to be re-assembled on the mandrel 230 with an

internal seam 66 that may be sealed. Figure 34F shows a longitudinal seam 66 running the length of the bladder 52. The seam 66 may be sealed with adhesive, by fusing, by heating, with a solvent or combinations thereof. The sealed bladder 52 may form the inner layer 72b of a balloon 20 and be leak-tight. Seam 66 may be an external seam 66a or internal seam 66b.

[000339] Figure 34G through 34I illustrate the bladder 52 of Figures 34C, 34D, and 34E, respectively, after being fit over a mandrel 230 (mandrel not shown). The first bladder portion 52a can overlap at a lap joint or overlap (as shown), abut at an abutment, or flange with the second bladder portion 52b at the seam 66.

[000340] Figure 34G shows that an angled seam 66 may be formed when the bladder 52 is reassembled on the mandrel 230. Figure 34H illustrates that a spiral seam 66 may be formed when the bladder is reassembled on the mandrel 230. Figure 34I shows that a 90 degree seam 66 may be formed when the bladder is reassembled on the mandrel 230. The seam 66 may be sealed as described supra.

[000341] Figure 35 shows a panel 196. Panel 196 may be constructed of a thin film such as those shown in Figure 27. The thin film may be a thermoplastic with a thickness less than about 20 μm , more narrowly less than about 15 μm , still more narrowly less than about 10 μm , still more narrowly less than about 6 μm . Panel 196 may have a similar outline to the panel described infra in Figures 40.

[000342] Figure 36 shows panel 196 applied to mandrel 230 (not shown). Distal caul 260a and proximal caul 260b may be applied over the panel 196. As demonstrated in Figure 53 the assembled parts may be placed in a vacuum bag and heated until panel 196 fuses into a leak-tight bladder 52. The cauls 260 may be removed and the remainder of the balloon built on top of the bladder 52 and mandrel 230 as formed. As shown in Figures 34A through 34I, the bladder 52 may be cut such that the bladder 52 can be removed from one mandrel 230 and placed on another mandrel 230. A seam 66 may be formed. The bladder 52 may preferentially adhere to the cauls 260 allowing for easier handling and subsequent placement of bladder 52.

[000343] Figure 37 shows a panel 196 being wrapped onto mandrel 230. The panel 196 may be wrapped onto the mandrel 230 such that each successive wrap slightly overlaps the previous wrap. Cauls 260 (not shown) may be placed over panel 196. The assembled parts may be placed in a vacuum bag, heated and processed into a bladder 52 as described herein.

[000344] A bladder 52 may be formed by deposition. For example, a metal such as gold (or other materials listed herein) may be deposited to form a bladder 52. A bladder 52 may be formed by vapor deposition, such as physical vapor deposition, chemical vapor deposition or combinations thereof. For example, materials such as parylene, polyimide, polynaphthalene, Polyphenylene Vinylenes, Polyazomethine, poly-fluorohydrocarbons, poly-perfluorocarbons, or

combinations thereof may be deposited to form a bladder 52. The vapor deposited bladder can advantageously be pinhole free, thereby enhancing the leak-resistance of the balloon. Furthermore, vapor deposition allows for the bladder to be advantageously mass-produced.

[000345] Referring to Figure 74, in some embodiments, the bladder 52 can include a plurality of sublayers 1213a,b,c,d of vapor deposited material(s), such as parylene. Each sublayer 1213, because it is vapor deposited over a solid mandrel 230, can be a smooth continuous sublayer, i.e., can be formed without seams. Further, each sublayer can be less than 12 microns, such as less than 5 microns, such as less than 3 microns, such as approximately 2 microns. The resulting bladder 52 can be less than 20 microns thick, such as approximately 22, 18, 12, 8 or 6 microns thick. In one embodiment, as shown in Figure 74, there can be approximately four sublayers 1213, though a different number of sublayers (such as 2, 3, 5, or 6 sublayers) is possible. Advantageously, if the bladder 52 is bent, such as when the balloon 20 is folded or insertion into a body, by using a plurality of vapor deposited sublayers 1213, the bending stresses in the bladder 52 can be reduced from that which would result from an equivalent thickness bladder made of one layer. For example, as the sublayers 1213 can move relative to one another and thus cannot transfer significant shear stress across the bladder 52, bending stress in bladder 52 can be reduced. Moreover, by using a plurality of sublayers, additional protection from cracking or leaking is provided; if one sublayer 1213 cracks or leaks, the other sublayers can remain intact. Fiber reinforcements, as described here, can be used to further increase the strength and/or yield characteristics of a balloon having a parylene bladder 52.

[000346] In some embodiments where multiple sublayers 1213 of vapor deposited materials are used to make the bladder 52, a treatment can be applied to lower the adhesion between layers. For instance, implantation of fluorine, fluorine compounds, a fluoropolymer, or silicone dioxide can be performed after one sublayer 1213 is deposited before the next sublayer 1213 is deposited. This technique may reduce the adhesion of the sublayers 1213 to one another to ensure that the stresses within the bladder 52 are kept at a minimum. In addition, in some embodiments, a treatment (such as a plasma treatment, e.g., with oxygen molecules in a near vacuum) can be applied to increase the adhesion between layers or to increase the adhesive properties of the outermost surface. In one embodiment, a treatment can be used on the outer sublayer 1213d to increase adhesiveness of the bladder 52 to the remaining layers of the balloon.

[000347] A bladder 52 may be formed from a heat shrink tube. The tube may be formed in manufacture to fit the mandrel 230, blown out to size, then placed over the mandrel 230 and shrunk to fit the mandrel. Shrinking may be accomplished by the application of heat.

[000348] Figure 38A shows a cross section of a tow 270. A tow 270 may be or have one or more reinforcement fibers 86. A tow 270 may have one or more monofilaments 274. For

example, the tow 270 may contain about 6, 25, 100, 500 or 1500 monofilaments. The tow 270 may have a tow height 271 and a tow width 272. The tow 270 may be approximately circular. For example, the tow height 271 and tow width 272 may be about 0.025 mm (0.001 in) to about 0.150 mm (0.006 in), more narrowly 0.050 mm (0.020 in) to about 0.100 mm (0.040 in), more narrowly 0.075 mm (0.003 in). The tow 270 may be loosely held together by a polymer finish (not shown).

[000349] Figure 38B shows that tow 270 may contain a marker wire 190. Marker wire 190 may be circular, as shown, and radiopaque. Figure 38C shows that the marker wire 190 in tow 270 may be rectangular with dimensions as described supra.

[000350] Figure 38D shows the tow 270 after the tow 270 has been spread. The tow 270 may be flattened or spread by passing the tow 270 through a closely spaced set of rollers that form a narrow pinch gap. The tow 270 may be spread by pulling the tow 270 under tension over a set of rollers or pins. After spreading, the tow 270 may have a tow height 271 less than about twice the fiber height 1068, for example about the same as fiber height 1068. The fiber height 1068 and fiber width 1072 may be substantially unchanged after spreading. For example, the fiber width 1072 and fiber height 1068 may be about 15 μm (0.0006 in), tow width 272 may be about 210 μm (0.008 in) and tow height 271 may be about 15 μm (0.0006 in). The marker wire 190 is not shown in Figure 38D but may be present after the tow 270 has been spread.

[000351] Figure 38E shows the tow 270 from 38D after the tow 270 has had additional processing to flatten the monofilaments 274. The monofilaments 274 may be flattened by, for example, running the flattened tow 270 as shown in Figure 38D through a precision rolling mill. The fiber width 1072 may be about 25 μm (0.001 in). The fiber height 1068 may be about 9 μm (0.0004 in). The tow height 271 may be about 9 μm (0.0004 in). The tow width 272 may be about 350 μm (0.0014 in). The marker wire 190 is not shown in Figure 38E but may be present after the tow 270 has been spread and the fibers flattened.

[000352] Figure 39A illustrates that a layer of fiber matrix can be made on a roller 232. The roller 232 can be configured to rotate about a roller axle 234. The roller 232 may have a diameter from about 100 mm (3.9 in) to about 1,000 mm (39.4 in). The roller 232 may be made or coated with an anti-stick material such as a fluoropolymer.

[000353] Figure 39B illustrates that a releaser 236, such as a release layer, can be placed around the circumference of the roller 232. The release layer can be a low friction film or coating. The release layer may be a thin and/or flexible fluoropolymer sheet.

[000354] Figure 39C shows that an adhesive 208 can be placed on the releaser or directly onto the roller 232 (e.g., if no releaser 236 is used). The adhesive 208 may be a thermoplastic film.

The adhesive 208 may be a thermoset adhesive. The adhesive 208 may be a solvated thermoplastic or thermoset. The adhesive 208 may have a backing film, such as paper.

[000355] Figure 39D shows the application of the reinforcement fiber 86 to the roller 232. The fiber 86 may be unwound from a spool (not shown) and rolled onto the top surface of the adhesive 208. The fiber 86 may contain one or more monofilaments 274. Before winding, the fiber 86 may be infused or coated with an adhesive 208, a solvent, or both. The coating may be a thermoplastic. The fiber 86 may have been previously flattened as detailed supra. The fiber 86 may have a non-circular cross section, such as a rectangle or an ellipse. Any coating or sizing on the fiber may have been removed using a solvent. The fiber 86 may be placed with a gap between each successive fiber wrap. The gap may be less than 200 μm (0.008 in), more narrowly less than 5 μm (0.0002 in). A heat source or a solvent may be used to fix the fiber 86 to the adhesive 208 (i.e., tack the fiber 86 in place on the adhesive 208), to melt or solvate a material onto the release layer 236, to melt or solvate a material on the fiber 86 or combinations thereof. For example, a separate resistive heater, a laser, a source of hot air, or an RF welder may be used. A solvent such as methyl ethyl ketone or tetrahydrofuran may be used. The fiber 86 can be wound with a pitch of 3000 to 30 turns per 1 inch (25.4 mm). The pitch can be chosen based on the total size of the fiber 86 or tow 270 being applied and the chosen gap between each subsequent fiber 86 or tow 270 on the roller 232. Applications of a single monofilament 274, which may be a wire, can have pitches from about 2000 to about 100 turns per 1 inch (25.4 mm).

[000356] Figure 39E shows reinforcement fiber 86 on top of adhesive 208 on top of release layer 236. Figure 39E may show a cross section after the operation shown in Figure 39D is performed.

[000357] Figure 39F illustrates that the roller can be placed between a vacuum top sheet 238a and a vacuum bottom sheet 238b, for example in a vacuum bag. A vacuum seal tape 240 can surround the roller 232 between the vacuum bottom and top sheets 238b and 238a, respectively. Air can be removed from between the vacuum top and bottom sheets 238a and 238b and within the vacuum seal tape, for example by suction from a suction tube 242. Inside and/or outside of the vacuum bag, the roller 232 can be heated, for example to melt or cure the adhesive 208. Roller 234 can be removed from the vacuum bag, for example after melting or curing of the adhesive is complete.

[000358] Figure 39G shows the removal of the panel 196. For instance, a cut may be made substantially perpendicular to the fiber. The panel 196 may be peeled away from the release layer. The panel 196 may be substantially foldable and/or flexible.

[000359] Figure 39H illustrates that the panel 196 of fiber matrix can be removed from the roller 232. For example, the panel 196 can be peeled off the releaser 236. The panel 196 can be

repositioned on the roller 232 at about 90 degrees to the layer's previous angle and additional reinforcement fibers 86 can be applied as shown in Figure 39D. This may result in a panel 196 with fibers 86 running perpendicular to each other (e.g., a "0-90" layer, so called for the angle the two layers of fiber make with respect to each other). The panel 196 can be cut into a smaller panel. For instance, the panel 196 can be cut with a trimming jig, a laser, a water jet cutter, a die cut tool, or a combination thereof.

[000360] Figure 40A shows that a panel 196 may have reinforcement fibers 86b oriented substantially parallel to panel longitudinal edge 332. The panel 196 can have a panel width 334. The panel width 334 can be about equal to the circumference of the balloon 20 in the constant-diameter section 38. The panel 196 can have a panel length 335. The panel length 335 can be greater than the balloon length 28. The panel 196 can have a panel rectangular section 336 and one or more panel serrations 338a, 338b and 338c. Each panel serration 338a, 338b and 338c can have a portion of the panel 186 that forms a portion of the stem 30 or 43 and taper 34 or 44. Each serration 338a, 338b and 338c can have a serration edge 339a, 339b and 339c, respectively. The angle between the serration edges 339 and a line parallel to the reinforcement fibers 86b can be a panel serration angle 340. The panel serration angle 340 can be about 30°, about 20°, about 10°, or about 0°. A first panel serration 338a can be substantially in line with a second panel serration 338b. One or more fibers 86b may run from the terminal end of the first serration 338a to the terminal end of the second serration 338b.

[000361] Figure 40B illustrates that longitudinal reinforcement fiber 86b can be parallel with longitudinal edge 332. Second longitudinal reinforcement fiber 87b can be parallel with the fiber 86b. Fibers 86b and 87b can be separated by fiber separation areas 614. The fiber separation areas 614 may separate fibers 86b and 87b by about 2 mm (0.079 in), more narrowly less than about 1 mm (0.039 in), still more narrowly less than about 0.25 mm (0.01 in). The fiber separation areas 614 may be distributed on the panel such that no area 614 substantially overlaps any other area in the X and/or Y direction. The fiber separation areas 614 may be positioned in the X and Y directions on the panel 196 in a pattern sufficient to prevent any fiber from reaching all the way across the panel rectangular section in the X direction. The balloon 20 in Figure 9G may be built in part with the panel 196 shown in Figures 40B or 41B. Fibers 86b and 87b may have fiber lengths 88 less than about 80% of the balloon length 28 more narrowly less than about 75% as long, more narrowly less than about 70% as long, still more narrowly less than about 65% as long, still more narrowly less than about 60% as long as the balloon length 28.

[000362] Figure 40C illustrates a magnified view of panel area of separations 818. Fiber separation areas 614 are located on fiber separation bands 617. Fiber separation bands are arranged parallel to the Y-axis and are separated by fiber separation spacing 615. Each fiber

separation areas 614 may be rectangular and have a fiber separation width 613 oriented in the Y-direction and a fiber separation length 611 oriented in the X-direction.

[000363] Load path 750 may have a load path width 762. The load path 750 may be substantially aligned with fiber separation width 613 along the X axis. The load path width 762 may be about equal to the fiber separation width 613. The upper edge of separation area 614a may be substantially inline with the lower edge of separation area 614b. The lower edge of separation area 614a may be substantially inline with the upper edge of separation area 614c. By substantially inline it is meant that there may be an overlap between areas 614 of 0mm (0 in.) to about 0.2mm (0.008 in.).

[000364] There may be from 2 to 25 separation bands 617, more narrowly 4 to 12, still more narrowly, 6 to 10. There may be 7 separation bands 617. Fiber separation width 613 may be from about 0.10 mm (0.004 in.) to about 2mm (0.08 in.), more narrowly from about 0.2 mm (0.008 in.) to about 1.0 mm (0.04 in.), still more narrowly from about 0.3 mm (0.012 in.) to about 0.75 mm (0.03 in.). Fiber separation spacing 615 may be from about 0.50 mm (0.020 in.) to about 12.5mm (0.5 in.), more narrowly from about 1.0 mm (0.04 in.) to about 6 mm (0.24 in.), still more narrowly from about 2 mm (0.08 in.) to about 4 mm (0.16 in.).

[000365] Shear load length 772 between load paths 750 will always be at least about 2 times separation spacing 615. During heating and consolidation of the balloon 20 during manufacture (for example, the process shown in Figures 55A, 55B and 55C), Separation areas 614 may allow the balloon 20 to expand in the longitudinal direction without placing the fibers 86b in significant stress, for example, stress in excess of 10% of the yield stress.

[000366] Figure 41A shows that a panel 196 can have a panel rectangular section 336 and one or more panel serrations 338a, 338b and 338c. Panel serration 338b can be oriented in the Y direction substantially midway between panel serrations 338a and 338c. Panel serration 338b can be oriented in the Y direction substantially closer to either panel serrations 338a or 338c. The longest reinforcement fiber length 88 in panel 196 may be less than 75% of the length of the balloon, more narrowly less than 70% of the length of the balloon.

[000367] Figure 41B illustrates that first longitudinal reinforcement fiber 86b can be parallel with longitudinal edge 332. The second longitudinal reinforcement fiber 87b can be parallel with first longitudinal fiber 86b. The first and second longitudinal fibers 86b and 87b can be separated by the fiber separation areas 614. The fiber separation areas 614 may be positioned in the X and Y directions on the panel 196 in a pattern so the first and second longitudinal reinforcement fibers 86b and/or fiber 87b have fiber lengths 88 less than about 80% of the balloon length 28, more narrowly less than about 75%, more narrowly less than about 70%, still more narrowly less than about 65%, still more narrowly less than about 60% of the balloon

length 28. A continuous fiber 86 may connect from a first terminal end of the panel 196 to the second terminal end of the panel 196, where the first terminal end of the panel 196 is in the opposite X direction of the second terminal end of the panel 196.

[000368] Figure 42A shows that a panel 196 may have reinforcement fibers 85a and 85b oriented at equal and opposite angles 341 to panel longitudinal edge 332. Angle 341 may be, for example, about 10°, about 15°, about 20° or about 25° to the panel longitudinal edge 332. Fibers 85a and 85b can be at about 50°, about 55° or about 60° to the balloon longitudinal axis.

[000369] Figure 42B shows that the panel serration angle 340 can be about 0°.

[000370] Figures 43A and 43B show that a panel 196 can be made from two panels 196a and 196b. Panels 196a and 196b can be overlapped in reinforcement fiber overlap area 612. The long axis of overlap area 612 may be substantially perpendicular to the reinforcement fibers 86b and 87b. The panels can be joined with adhesive or by melting the adhesive in the fiber matrix. The panel 196 in Figure 43A may be used to make the balloon 20 shown in Figure 9E

[000371] Figures 43C and 43D show that the long axis of reinforcement fiber overlap area 612 can be at an angle 341 to the Y axis. For example, overlap area 612 can be at an angle 341 of from about 0° to about 50° to the Y-axis, more narrowly from about 5° to about 45°, still more narrowly from about 15° to about 40° to the Y-axis. The panel 196 in Figure 44A may be used to make the balloon 20 shown in Figure 9F.

[000372] Figure 44A shows a panel 196 similar to the panel shown in Figure 40A. However, reinforcement fiber 86b forms reinforcement fiber loop back 774. The reinforcement fiber 86b can make about a 180° turn at the loop back 774. Reinforcement fiber 86b may be continuous through loop back 774. Reinforcement fiber 86b may have a continuous length longer than panel length 335.

[000373] Figure 44B shows that a panel 196 may have a panel width about from about $\frac{1}{4}$ to about $\frac{1}{10}$ the circumference of the balloon 20, more narrowly from about $\frac{1}{6}$ to about $\frac{1}{8}$ the circumference of the balloon 20. The circumference of the balloon 20 may be balloon outer diameter 50 multiplied by pi. A panel 196 may have a first panel serration 338a and second panel serration 338b.

[000374] Figure 44C shows a variation of the panel 196 in Figure 44B. Panel 196 may have fibers 86b that are parallel to panel serration edge 339 within the panel serration 338. Fibers 86b may end on the centerline of the long axis of panel 196

[000375] Figure 44D shows that panel 196 may contain reinforcement fibers 85a and 85b arranged in a woven pattern. A woven pattern can have fibers 85a and 85b that alternately pass over and under each other.

[000376] Figure 44E shows that the panel 196 may contain reinforcement fibers 85 in a braided configuration.

[000377] Figure 44F shows that the panel 196 may contain reinforcement fibers 85 of various lengths in random orientations, sometimes referred to as chopper fiber.

[000378] Figure 44G shows that a panel 196 may contain a panel arc section 810 and panel legs 800. In panel arc section 810, fibers 86b may travel on a radius of the arc section 810. In the panel legs 800, fibers 86b may travel on a line parallel to the edge of the panel legs. First panel 800a may have a panel length 802a from about 50% to about 100% of the constant-diameter section length 40, more narrowly from about 60% to about 80%. Second panel 800b may have a panel length 802b from about 10% to about 50% of the constant-diameter section length 40, more narrowly from about 20% to about 40%. The panel leg width may be about $1/3$ to about $1/6$ of the balloon outer diameter multiplied by pi, more narrowly, about $1/4$. The panel 196 shown in Figure 44G may be applied to a balloon 20. The panel arc section 810 may substantially cover the taper of the balloon. Panel legs 800 may cover a portion of the constant-diameter section 38. A second panel 196 as shown in Figure 44G may be applied similarly on the opposite taper. The two panels may interleave, substantially covering the balloon outer wall 22b.

[000379] Figure 44H show that panel length 802 may be about 100% of the constant-diameter section length 40. Panel serrations 338 may be appended. Panel serrations may be applied to a balloon taper as described herein. The panel in Figure 44H may substantially cover the balloon outer wall 22b when applied to a balloon 20.

[000380] Panels 196 can be flattened. For instance, a panel 196 may be flattened in an industrial press by applying pressure and, optionally heat. A panel may be passed thru a precision pinch gap roller and flattened. Flattening may comprise changing the shape of monofilaments 274 (as shown in Figure 38E) and/or redistributing with the panel some or all of adhesive 208.

[000381] Figure 66A illustrates an exemplary panel 196 having a rectangular section 336 and a plurality of panel serrations 338 extending from the proximal and distal edges of the rectangular section 336. There can be, for example, between 4 and 20 panel serrations along each of the proximal and distal edges, such as between 6 and 10 panel serrations, such as 8 serrations. In contrast to the panel serrations of Figures 40A-44H, the panel serrations 338 of the panel 196 of Figure 66A can each be made of a substantially tapered or triangular section 1201 that ends in a point 1203. The points 1203 can form the distal and proximal edges 1205 of the panel 196. The angle α at each point 1203 can be between 10 and 40 degrees, such as between 15 and 30 degrees, such as about 20 degrees. Moreover, as shown in Figure 66B, the panel serrations 338 can be trapezoidal, i.e., can be made of a substantially tapered section 1231 that ends in a blunt

tip 1233. The blunt tips 1233 can form the distal and proximal edges 1205 of the panel 196. The angle β near the blunt tips 1233 can be, for example, between 10 and 30 degrees, such as about 15 degrees. In some embodiments, the blunt tips 1233 are approximately straight and can be parallel with the inner edges 1271 of the rectangular section 336. The panel serrations 338 of the panel 196 of Figures 66A and 66B thus do not include a rectangular section, but rather are tapered through the entire length.

[000382] Figures 67A, 67B, and 67C illustrate an exemplary fiber separation configuration that can be used with any of the panels 196 described herein. The fiber separation areas 614 can be located entirely within the rectangular portion 336 of the panel. Further, as shown in Figures 67A-C, some or all of the fiber separation areas 614 can be angled relative to the latitudinal or x-axis of the panel (which will result in the separation areas extending at that same angle relative to the circumferential axis of the balloon onto which the panel 196 is applied). Thus, some or all of the fiber separation areas 614 can extend at an angle of 0 to 90 degrees, such 10-45 degrees, e.g., 15-35 degrees, relative to the latitudinal axis, such as approximately 25 degrees (see Figure 67G). Each segment 1239 (including two corresponding triangular sections 1201 or trapezoidal sections 1203 and the portion of the rectangular section 336 extending therebetween) of the panel 196 can have a regular pattern 1241 of fiber separation areas 614. The pattern 1241 can result in having the fiber separation areas 614 extend throughout the panel 196 such that no two neighboring fibers are of equal length.

[000383] Figure 67D shows a close-up of the pattern 1241 of fiber separation areas 614 (placed on a matrix of dotted lines for clarity). This pattern 1241 can repeat in each segment 1239 of the panel, such as within each of the eight segments 1239 shown in Figure 67A or 67C. As shown in Figure 67E, the length of each fiber separation area 614 in the pattern 1241 can be between 0.005 and 0.050 inches, such as 0.020 and 0.025 inches. Each fiber separation area 614 can thus cut through approximately 10 to 100 fibers, such as 20 to 60 fibers (or approximately 1.5 tows). The length of the fiber separation areas 614 can be optimized to ensure both that the load transfer of stress across the panel is not hindered by having a cut length that is too long (thereby making it difficult to transfer a tensile load via shear around the cuts) and that the cut length is long enough to allow the cut to be accurately and consistently made across a plurality of fibers with the laser. As is further shown in Figure 67E, there can be a vertical (circumferential when on the balloon) overlap of fiber separation areas 614 of between 0.001 to 0.010 inches, such as 0.002 to 0.006 inches, such as approximately 0.004 inches. Thus, the length of the fiber separation areas 614 can be about 5 to 6 times the length of the overlap.

[000384] Referring still to Figures 67D and 67E, the fiber separation areas 614 can be arranged in a regular pattern and can be spread out approximately evenly to ensure that the panel

maintains a constant strength throughout the rectangular section. Further, the fiber separation areas 614 can be arranged such that, within a single pattern 1241, there is only one fiber separation area 614 extending along a line (such as lines A through N) in the longitudinal directions (aside from the areas of overlap discussed above). The longitudinal distance between overlapping fibers can be maximized so as to allow for a maximum distance to transfer the tensile load via shear, as shown by lower shear length for fiber separation area 614 at position 5C and the upper shear length for fiber separation area 614 at position 5C.

[000385] Moreover, separation areas 614 can be aligned such that a limited number of fiber separation areas extend along the same vertical or circumferential lines (such as lines 1 through 7) within a single pattern 1241. For example, less than 4 separation areas 614 can extend along a single vertical line, such as less than 3, such as 2 separation areas 614. There can be between 2 and 20 vertical or circumferential lines of fiber separation cuts, such as between 4 and 10 vertical or circumferential lines, such as 7 vertical or circumferential lines.

[000386] Thus, as shown in Figure 67D, the pattern 1241 can include between 5 and 40 fiber separation areas 614, such as between 10 and 20 fiber separation areas 614, such as 14 fiber separation areas 614. To keep the shear length maximized, fiber separation areas can be placed on each of lines 1 through 7 and A through N. Every other fiber separation area 614 in the longitudinal direction can be placed one vertical line above the previous. Thus, referring to Figure 67D, for example, there can be a fiber separation area 614 at A1, B3, C5, and D7. Further, every fiber separation area 614 along a single circumferential line can be spaced 7 longitudinal lines apart. For example, there can be a fiber separation area 614 at A1 and H1.

[000387] As shown in Figure 67D, a portion of the fiber separation areas 614, such as between 40 and 50% (for example, 6 out of 14 fiber separation areas 614) can be parallel to the circumferential lines, i.e., can be unangled. The unangled fiber separation areas 614 can be the outermost fiber separation areas 614 in the pattern 1241 in the circumferential direction. For example, fiber separation areas A1, B3, C5, and L2, M4, and N6 can be unangled. Referring to Figures 67F and 67G, in some embodiments, the unangled fiber separation areas 614 can be aligned with the tapered edge 1243 of the serrations of a panel, such as the taper of the triangular or trapezoidal sections 1201, 1231 while the angled fiber separation areas 614 can be aligned with the blunt edges 1245 of the serrations of the panel, such as the blunt edge 1233 of the trapezoidal section 1231. Accordingly, in one configuration, none of the longitudinally extending fibers 86b have the same length as a neighboring fiber 86b.

[000388] Figures 45A, 45B, 45C and 45D illustrate that a panel 196 may be applied to a mandrel with none, one or more layers 72 on the mandrel 230. The panel 196 may be joined to layers 72 by the application of adhesive or by heat or by combinations thereof. The panel 196,

when folded onto the shape of the mandrel 230 may give a substantially complete coverage of the mandrel 230 with minimal or no overlap of the panel 196. Panel rectangular section 336 may cover the balloon constant-diameter section 38. Panel serrations 338 may cover proximal taper 34, distal taper 42, proximal stem 30 and distal stem 43.

[000389] Referring to Figures 66C and 66D, the panel 196 having triangular sections 1201 or trapezoidal sections 1231 can likewise be applied to a mandrel 230.

[000390] As shown in Figure 66C, if a panel 196 with triangular sections 1201 is used, the points 1203 can be extended slightly off the mandrel 230, such as onto a sacrificial shaft (which can be removed during or after manufacturing the rest of the balloon). By extending the points 1203 off the mandrel 230, the panel 196 can provide substantially complete coverage of the balloon with the rectangular section 336 covering the constant diameter section and the triangular sections 1201 covering both the proximal and distal tapers and the proximal and distal stems. Moreover, the triangular sections can overlap with one another within the proximal and distal tapers and stems. For example, the area of overlap can range from 0% in the constant diameter section to approximately 50% at the end of the balloon and/or in the sacrificial shaft. Having overlap of the pattern 196 in the proximal and distal tapers and/or stems of the balloon can advantageously provide additional wall stiffness to the balloon at the proximal and distal tapers. The resulting wall stiffness of the proximal and distal tapers and/or stems can thus be greater than the stiffness of the constant diameter section 38. Such additional wall stiffness can advantageously keep the balloon from folding or inverting in on itself at the tapers or stems during use.

[000391] As shown in Figure 66D, if a panel 196 with trapezoidal sections 1231 is used, like the panel with triangular sections, the blunt edges 1233 can be extended slightly off the mandrel 230, such as onto a sacrificial shaft 1235 (which can be removed during or after manufacturing the rest of the balloon). Alternatively, because the blunt edges 1233 provide a stretch of material even at the edges of the panel 196, the blunt edges 1233 can be placed directly on the edge of the balloon. With either method, the panel 196 with trapezoidal sections 1231 can provide substantially complete coverage of the balloon with the rectangular section 336 covering the constant diameter section and the trapezoidal sections 1231 covering both the proximal and distal tapers and the proximal and distal stems. Moreover, the trapezoidal sections can overlap within the proximal and distal tapers and stems. For example, the area of overlap can range from 0% in the constant diameter section to approximately 50% at the end of the balloon and/or in the sacrificial shaft. Having overlap of the pattern 196 in the proximal and distal tapers and/or stems of the balloon can advantageously provide additional stiffness to the balloon at the proximal and distal tapers. The resulting wall stiffness of the proximal and distal tapers and/or stems can thus

be greater than the wall stiffness of the constant diameter section 38. Such additional wall stiffness can advantageously keep the balloon from folding or inverting in on itself at the tapers or stems during use.

[000392] Figures 45B and 45C show that a die 778 may be used to press the panel 196 onto the balloon 20. The die 778 may be heated and the panel 196 may contain a thermoplastic. The die 778 may melt the thermoplastic and adhere the panel 196 to the balloon 20. The die may be shaped to match the mandrel 230 shape. After attaching two serrations 338 (one serration at each end of the mandrel 230. See Figure 45C), the mandrel 230 may be rotated about its longitudinal axis to advance the next set of serrations 338 into place under the die 778. The die 778 may again press two serrations 338 into place on the balloon 20. Subsequent use of the die in this manner may attach substantially the entire panel 196 to balloon 20.

[000393] Figure 46 shows a method of attaching longitudinal reinforcement fiber 86b to balloon 20. A tool wheel 248 mounted to a tool arm 246 follows a longitudinal path on balloon 20. As the wheel 248 rolls, it presses into place tow 270. Adhesive (not shown) may be added to tow 270 before application so that tow 270 will stick to balloon 20. The tow may be cut when the tool wheel 248 reaches the end of the mandrel 230, the mandrel 230 may be rotated about its longitudinal axis, and a second track of reinforcement fiber 86B may be applied as shown in Figure 46.

[000394] Figure 47A illustrates that fiber 86 can be wound over the mandrel 230 or over balloon 20. The fiber 86 may be continuous or discontinuous. The mandrel can be rotated, as shown by arrow 252, about the mandrel longitudinal axis 250 or balloon longitudinal axis. The first spool 244a can be passively (e.g., freely) or actively rotated, as shown by arrow 254, deploying fiber 86 (shown) or tow 270. Before or during winding, the fiber may be infused or coated with an adhesive, a solvent, or both. The coating may be a thermoplastic. A fiber distal end can fix to the balloon 20 or directly to the mandrel 230.

[000395] The fiber 86a may be wound with a gap between each successive fiber wind. The gap can be less than about 200 μm (0.008in), more narrowly less than about 5 μm (0.0002in).

[000396] The fiber 86 can be wound with a pitch of about 3000 to about 30 winds per 1 inch (25.4mm). The pitch can be chosen based on the total size of the fiber 86 or tow 270 being applied to the part from first spool 244a and the chosen gap between each subsequent fiber 86 or tow 270 on the part. Applications of a single monofilament, which may be a wire, can have pitches from about 2000 to about 100 turns per inch.

[000397] A tool arm 246 can be attached to a rotating tool wheel 248. The tool arm 246 can rotate and translate, as shown by arrows 256 and 258, to position the tool wheel 248 normal to and in contact with the balloon 20. A second tool wheel 248' (attached to tool arm 246') can

have a range of motion sufficient to apply pressure normal to the surface of a balloon taper section.

[000398] The tool wheel 248 can press the fiber 86 or tow 270 against the balloon 20 and spread the monofilaments 274 as shown in Figure 47B. The tool wheel 248 may help to adhere the tow 270 to the balloon, for example by applying pressure and following closely the surface of the balloon. The tool wheel 248 can be heated to soften or melt the material on the surface of the balloon 20. Another heat source or a solvent may be used to tack the fiber in place, to melt or solvate a material on the balloon, to melt or solvate a material on the fiber or combinations thereof. A separate resistive heater, a laser, a UV light source, an infrared light source, a source of hot air, or an RF welder may be used with or without the tool wheel 248 to attach the fiber. A solvent such as methyl ethyl ketone or tetrahydrofuran or alcohol or combinations thereof may promote adhesion of the fiber 86 and may be used with or without the tool wheel 248. The tool wheel 248 can be made of or coated with a non-stick material. The tool wheel 248 may not rotate. The tool wheel 248 may comprise a hard surface, for example carbide.

[000399] A second spool 244b may deploy marker wire 190 during a winding operation. Second spool 244b may also deploy a reinforcement fiber 85 (not shown). Marker wire 190 (or reinforcement fiber 85) may be applied simultaneously with fiber 86 and/or tow 270 to the balloon. Marker wire 190 may interleave with reinforcement fiber 86 to form a single fiber layer on balloon 20, for example as shown in Figure 47C. Marker wire 190 may be deposited on top (for example, as shown in Figures 47E and 47H) or below another existing fiber layer.

[000400] The resulting layer deposited in Figure 47 can have a layer thickness 216 of from about 1 μm (0.00004 in) to about 50 μm (0.002 in), more narrowly from about 8 μm (0.0003 in) to about 25 μm (0.001 in).

[000401] Figure 47B illustrates that a hoop wind can deposit a layer 72 of monofilaments 274 side by side on the balloon 20.

[000402] Figures 47C and 47F illustrate that a hoop wind can deposit a layer 72 of monofilaments 274 side by side on the balloon 20 and that one of those monofilaments may be a marker wire 190

[000403] Figure 47C shows that a radiopaque marker wire 190 or radiopaque filament may be located between first monofilament 274a and second monofilament 274b. Monofilaments 274a and 274b may be deposited on subsequent winds of one tow. That is, marker wire 190 may be between the successive winds of one tow and occupy the same layer 72 as the monofilaments 274a and 274b.

[000404] Figures 47D and 47G illustrate that a hoop wind can deposit a layer 72 of monofilaments 274 side by side on the balloon 20 and that one of those monofilaments may be a marker wire 190 and that an adhesive 208 may surround those monofilaments in the layer 72.

[000405] Figures 47E and 47H illustrate that a hoop wind can deposit a layer 72c of monofilaments 274 side by side on the balloon 20 and may deposit a second hoop wind layer 72d comprising a marker wire 190. Layers 72c and 72d may comprise an adhesive 208.

[000406] Panels 196 may also be formed in the cross sectional configuration shown in Figures 47B-H.

[000407] Figure 48A shows a close-up cross-sectional view of the fiber application process in Figure 47. Tow 270 is herein shown to contain 6 monofilaments 274 spread flat and being wound on a balloon taper angle 90. The tow contains a lowest monofilament 608 and a highest monofilament 610. Monofilaments 608 and 610 can be monofilament 274.

[000408] Figure 48B shows a further magnification of the wind cross-section in Figure 48A. Monofilaments 608 and 610 spiral around the balloon taper. Single turn distance 602 gives the distance between each instance of the fiber in cross section. Lowest monofilament 608 has a lowest monofilament wind radius 604a to the balloon longitudinal axis at a first position and lowest monofilament wind radius 604b at a second position. The first and second groups of fibers shown in cross section may correspond to a single wind around the balloon. Similarly, highest monofilament 610 can have a highest monofilament wind radius 606a at a first position and a highest monofilament wind radius 606b at a second position.

[000409] Based on geometry, the radius 604b is equal to $\text{radius } 604a + \sin(\text{angle } 90) * (\text{distance } 602)$. The "*" symbol denotes multiplication, the "/" symbol denotes division and the "sin" symbol denotes a sine operation. The average radius between the first position and the second position is therefore $\text{radius } 604a + \sin(\text{angle } 90) * (\text{distance } 602/2)$. Finally, based on average radius, we can calculate an approximate monofilament length from the first to the second position of lowest monofilament 608 of $2 * \pi * (\text{radius } 604a + \sin(\text{angle } 90) * (\text{distance } 602/2))$. For example, the monofilament length for lowest monofilament 608 for a radius 604a of about 2.000 mm a distance 602 of about 0.250 mm and angle 90 of about 35.000 degrees is about 13.017mm

[000410] If monofilaments are assumed to lay down flat in a single layer (as shown in Figures 48), radius 606a can be shown to be equal to $\text{radius } 604a + (\sin(\text{angle } 90) * (\text{fiber diameter } 212 * (\text{number of fibers} - 1)))$. Similarly, the average radius between radius 606a and radius 606b is therefore about equal to $(\text{radius } 604a + (\sin(\text{angle } 90) * (\text{fiber diameter } 212 * (\text{number of fibers} - 1)))) + (\sin(\text{angle } 90) * (\text{distance } 602/2))$. With the average radius we can calculate monofilament length. For example, the monofilament length for highest monofilament 608 for a radius 604a of

2.00mm, a fiber diameter 212 of 25 μ m, 6 fibers, a distance 602 of 0.250mm and an angle 90 of 35.00 degrees is about 13.47 mm

[000411] In the previous two examples monofilament length is calculated for the lowest and highest monofilaments in a given tow as 13.017 mm and 13.467 mm, respectively. The highest monofilament would need to be about 3.5% longer than the lowest monofilament. Over long distances, the monofilaments cannot significantly slide longitudinally with respect to one another, the uphill monofilament would need to strain (change its length) about 3.5%. High strength fibers typically have strains to failure of less than about 5%. The lowest fiber can experience no strain. The highest fiber can experience strain near the failure point of the highest fiber. Alternately, the highest fiber can relieve the strain by sliding down the curve. The fiber tow can transform from a flat 1x6 layer of fiber as shown in Figure 48 to more of a bundle in which the tow 270 is significantly thicker than a single monofilament diameter (for example, the tow 270 shown in Figure 38A). The difference in strain may cause the tow 270 (or filaments in the tow) to pull away from the balloon and thus have poor adhesion.

[000412] At an instantaneous point in the wind of a tapered part wherein the tow is spread to a single monofilament thickness, the difference in strain between the highest monofilament and the lowest monofilament is about:

$$\text{Strain} = (C/R) * 100\%$$

Where $C = (\sin(\text{angle } 90) * (\text{fiber diameter } 212 * (\text{number of fibers} - 1)))$

$R = \text{radius of lowest monofilament } 604a$

Note that strain is a function of the sine of the angle, a linear function of the number of fibers, and that for larger R, the strain is far less than for a small R.

[000413] The balloon stem 30 may have a small radius. Hoop winding may begin at the stem 30, progress up the proximal taper 34 and continue in the constant-diameter section 38. It may be desirable to minimize balloon proximal taper length 36 while minimizing strain in the tow 270.

[000414] Figure 48C shows that a first angle 600a may be used initially as the wind begins, for instance, at the proximal taper 34. A second angle 600b may be used after the diameter of the balloon has grown larger than the balloon stem 30 diameter. Second angle 600b may be larger than first angle 600a. Additional angles may be used as the balloon diameter at the point of application of the tow 270 increases. These angles may be chosen to keep the difference in strain between the highest and lowest monofilament at or below a certain value, for example less than 4%, or less than 3%, or less than 2% or less than 1%. A curve 601 with a continuously variable radius of curvature, as shown in 48D may be used that holds the difference in strain at or below a certain value, for example less than 4%, or less than 3%, or less than 2% or less than 1%.

[000415] The flattened fiber tow width may be the fiber diameter 212 multiplied by the number of fibers. For instance, for a fiber diameter of about $17\mu\text{m}$ and 8 fibers, the fiber tow width may be about $136\mu\text{m}$. For instance, for a fiber diameter of about $17\mu\text{m}$ and 12 fibers, the fiber tow width may be about $204\mu\text{m}$. For instance, for a fiber diameter of about $23\mu\text{m}$ and 5 fibers, the fiber tow width may be about $115\mu\text{m}$. The fiber tow width may be less than $300\mu\text{m}$, more narrowly less than $250\mu\text{m}$, still more narrowly less than $200\mu\text{m}$, still more narrowly less than $160\mu\text{m}$.

[000416] Figure 49A illustrates that a fiber 86a can be helically wrapped around the balloon 20.

[000417] Figure 49B illustrates that a fiber 85a can be wrapped at an angle 132 to the longitudinal axis. A second layer 85b may be wound at equal and opposite angle. Fibers substantially parallel to the longitudinal axis may be omitted. Angle 132 may be less than about 75° , more narrowly less than about 60° , for example about 51° . Angle 132 may be about 40° , about 35° , about 30° , about 25° , about 20° , or about 15° .

[000418] Referring to Figures 47A and 75A-75D, one method of winding the fibers 85a, 85b at an angle (for example, such as to obtain the angular winds shown in Figure 9H), can include continuously winding a single fiber (or fiber tow) around the balloon, i.e. the fibers 85a and 85b can be formed from a single, continuous fiber tow 270. For example, referring to Figure 47A, in one embodiment, a tool wheel 248 mounted to a tool arm 246 can be configured to wind a single fiber tow 270 continuously around the mandrel 230 (which, as described herein, can include additional layers, thereon, such as a bladder layer). To obtain the angular wind, tool wheel 248 mounted to the tool arm 246 can be moved longitudinally along the mandrel 230 while rotating the mandrel 230 in a clockwise or counterclockwise direction about the longitudinal axis (as shown by the arrow 252). As the head tool arm 246 reaches the end of the balloon, the wheel can stop, the mandrel can be rotated a set distance, and the wheel can be moved longitudinally in the opposite direction. This process can be repeated until the desired pitch and wind is obtained. In some embodiments, the ends of the balloon (including fiber spooled at the ends) can be removed to eliminate the built-up tow material. Further, in some embodiments, the entire winding process can be automated.

[000419] Referring to Figures 47A and 74A-74D, in one embodiment, the tool arm 246 can be configured to lay the fiber tow 270 down in a first direction to create a first wind of fiber 85a, the tool arm 246 can reverse to lay the fiber tow down in a second direction to create a first wind of fiber 85b, the tool arm 246 can then reverse again to lay a second wind of fiber 85a directly adjacent to the previously laid wind of fiber 85a, and the head tool arm 246 can reverse again to lay a wind of fiber 85b directly adjacent to the previously laid fiber 85b. Each new wind of fiber

can be laid down over all of the previously laid fibers. This process can be repeated until the desired wind is achieved.

[000420] In one embodiment, the angular fiber winding method can result in a non-woven fiber layer having negative transverse fibers (labeled as 85b) and positive transverse fibers (labeled as 85a) that there is minimal change between relative over/under positions with one another (termed “cross-over” herein) . For example, a positive transverse fiber 85a can extend over greater than 10, such as greater than 20, greater than 30, greater than 40, or greater than 50 negative transverse fibers 85b before reaching a cross-over point in which the positive transverse fiber 85a extends under the negative transverse fibers 85b. The fibers 85a,b are therefore not woven – they do not interlace nor cross over with one another frequently, and the fibers 85a,b can be formed of a single continuous fiber tow. The wind resulting from the method described with respect to Figure 75 can have several substantially linear areas of fiber cross-over. For example, as shown in Figures 75A-75D (where the grey bars indicate a point of cross-over), the resulting wind can have two substantially linear areas 1221a, b, of fiber cross-over, each located 180 degrees around the balloon from the other. There may be other numbers of substantially linear areas of fiber cross-over, such as 1-10 areas, for example 1, 2, 4, or 5 linear areas of fiber cross-over.

[000421] Figures 50A and 50B illustrate that a panel 196 may have perforations 782. A perforation 782 may be defined as a hole or absence in a panel 196 or gap between panels 196. A perforation 782 may be circular, elliptical, rectangular, substantially linear or combinations thereof. A perforation 782 may be formed mechanically (for example with a sharp tool or with a roller covered in spikes that extend radially outward), with a laser, a water jet cutter, via photolithography or combinations thereof. A perforation 782 may be formed by applying two or more panels with a gap.

[000422] Figure 50A shows a panel 196 with substantially circular perforations 782. The perforations 782 may have a diameter of about 0.025mm (0.001 in.) to about 3.0mm (0.12 in.), more narrowly about 0.10mm (0.004 in.) to about 0.50 mm (0.02 in.), still more narrowly from about 0.10mm (0.004 in.) to about 0.25 mm (0.01 in.). The perforations may be placed on the panel 196 in a pattern. The perforations may separated from each other in the X direction by perforation X-axis gap 783 and perforation Y-axis gap 784. Gaps 783 and 784 may be about 0.10mm (0.004 in.) to about 12mm (0.47 in.), more narrowly about 0.5 mm (0.02 in.) to about 6.0 mm (0.24 in.), still more narrowly about 1.0mm (0.039 in.) to about 4.0 mm (0.16 in.). Gaps 783 and 784 may between columns (A column is line of holes in the Y direction) and rows (A row is a line of holes in the X direction).

[000423] Figure 50B shows a panel 196 with rectangular perforations 782 having perforation width 786 and perforation length 790. Width 786 and length 790 can be from about 0.025mm (0.001 in.) to about 12mm (0.47 in.), more narrowly from about 0.025mm (0.001 in.) to about 6.0 mm (0.24 in.).

[000424] Panel 196 may have a perforation density of about 10 to about 1000 perforations 782 per square inch (per 645 square millimeters), more narrowly about 25 to about 500, still more narrowly about 50 to about 250.

[000425] Perforations 782 may pass thru one or more panels 196, one or more layers 72 or thru the entire balloon wall 22.

[000426] Figure 51A illustrates that the outer surface of balloon 20 may have a glue or first adhesive 208A. A panel 196c may be positioned over the mandrel. The panel 196c may have a panel length 197 and a panel width 199. The panel length 197 may be equal to or less than twice the balloon length 28. The panel width 199 may be equal to or less than 4 times the balloon diameter 50. The panel 196c may be a single layer or multiple layers. For instance, the panel could be a layer of film and meltable adhesive 208. The panel 196c can be positioned with adhesive on the side that touches the reinforcing fibers with the film facing radially outwards. The panel 196c may be perforated as described supra. The panel 196c may not be capable of sustaining pressure between the top and bottom of the panel 196c.

[000427] Figure 51B illustrates that a positive pressure can be applied to the top 220a of the pressure chamber (e.g., through the case top port 222) and/or a negative pressure or suction or vacuum applied to the bottom 220b of the pressure chamber (e.g., through the case bottom port). The panel 196c can get sucked and/or pressed down onto the balloon 20. The first panel can be smoothly fitted to the partially built balloon and adhered at the first adhesive 208A.

[000428] Panel 196c and/or 196d may be adhered to balloon 20 by melting an adhesive in or on panel 196c and/or 196d. This melting can be accomplished with light (for example, infrared), with hot air, with a laser, with UV light, via an RF welding process or by using a hot metal part to iron the panel 196c and/or 196d into place. The panel 196c and/or 196d can be mounted into a trimming jig and trimmed as described supra.

[000429] Figure 51C illustrates that the balloon can have the excess area or the first panel 196c removed in preparation for attachment to the second panel 196d.

[000430] Figure 51D illustrates that a second adhesive 208b can be applied to the first panel around the perimeter of the second panel's contact area with the first panel. The second adhesive can be an epoxy, urethane, a thermoplastic, a cyanoacrylate, a UV cure, or combinations thereof. The mandrel can be seated in the mandrel seat with the first panel in the mandrel seat. The

second panel 196d can be placed on the mandrel as shown (upside down relative to the Figures 30A and 30B for illustrative purposes).

[000431] Figure 51E illustrates that after the case top 220a is secured to the case bottom 220b, the positive and/or negative pressures can be applied to the pressure chamber as described infra. The second panel 196d can be smoothly fitted or pressure formed to or against the balloon 20 and adhered to the first panel 196c at the second adhesive 208b. The first and second panels (196c and 196d) can form the outer layer 72a of the balloon wall. The outer layer may be leak-tight. The outer layer may be capable of sustaining pressure.

[000432] Figure 51F illustrates that a perforated panel 196 may be applied to the balloon 20. Perforations 782 may have been formed on the panel 196 before it was formed onto balloon 20 after it was formed onto balloon 20. Perforations 782 may have changed size during a forming operation. A perforated panel may have been formed with a second leaktight panel 196e to maintain differential pressure or suction or vacuum during forming. Panel 196e may be not become part of the balloon wall 22.

[000433] Panels 196 may be made from films that are highly permeable. By “highly permeable” it is meant that the panel has a nitrogen transmission rate of greater than 60 and a CO₂ transmission rate of greater than 1000. More narrowly, Panels 196 may be made from films in which the panel has a nitrogen transmission rate of greater than 200 and a CO₂ transmission rate of greater than 2000. Still more narrowly, Panels 196 may be made from films in which the panel has a nitrogen transmission rate of greater than 500 and a CO₂ transmission rate of greater than 5000. The units of transmission rate are cc (at STP)/sq. meter atm-day (for example, cubic centimeters at STP per square meter atmosphere-day). STP is 0 Centigrade and 1 atm. Normalized thickness is 0.5mm (0.02” in.).

[000434] The outer layer may be substantially smooth and homogenous. The outer layer may completely encapsulate reinforcement fibers 85 and/or 86 and/or 87b and provide protection from catching or pulling or abrasion or damage of these fibers when in the body.

[000435] The outer layer (for example, layer 72a) may perfuse a chemical, such as a drug.

[000436] Any methods of adding a layer to the mandrel or previous layer can be repeated to add additional layers, such as an outer layer of an MMA-resistant film.

[000437] The mandrel and the layers, including the panels, strips, wires or fibers, rosette, or combinations thereof, can be adhered, heated and/or pressurized, for example, to melt solvate, or otherwise bond the layers, for example by creating molecular bonds and decreasing the viscosity and modulus of the layers.

[000438] Figure 52 illustrates that a panel 196 may be applied to a balloon 20 to form an outer layer 72a. The panel 196 may be a film, such as those listed in Figure 27. The panel 196 may be applied in a manner similar to that shown in Figures 45A-45D.

[000439] Methods described supra for forming bladders 52 can also be used to form the outer layer 72a. For example, Figures 33A-33D, Figures 34A-34I, Figure 35, Figure 36 and Figure 37 disclose methods for applying a bladder 52 to a mandrel 230. These same methods may be used for applying an outer layer 72a to a balloon 20.

[000440] The outer layer 72a may be formed by deposition, such as deposition of a metal such as gold or parylene. A parylene or other vapor deposited outer layer can advantageously be pinhole free, thereby enhancing the leak-resistance of the balloon. Furthermore, vapor deposition allows the outer layer to advantageously be mass-produced. Moreover, a vapor deposited layer can advantageously provide fiber capture of the fibers of the balloon, thereby protecting the fibers from catching on external features (such as stents, lesions or calcifications) during use of the balloon. As described above with respect to the bladder 52, in some embodiments, the outer layer 72a can be formed as a plurality of individual vapor deposited sublayers.

[000441] The outer layer 72a may be formed from a heat shrink tube. The tube may be formed in manufacture to fit the balloon 20, blown out to size, then placed over the balloon 20 and shrunk to fit the balloon. Shrinking may be accomplished by the application of heat.

[000442] Figure 53A illustrates that after the layers 72 of the balloon have been assembled on the mandrel 230, a distal caul 260a can be placed over the distal end of the balloon. A proximal caul 260b can be slid over the mandrel and the proximal end of the balloon. The proximal caul 260b can be sealed to the distal caul 260a. The cauls 260 can be made from a fluoro-polymer. The cauls 260 can have thermoformed FEP with a 0.005 in (127 μ m) initial thickness.

[000443] Figure 53B illustrates that the assembly in Figure 53A can be placed between top and bottom vacuum sheets 238a and 238b. Sheets 238 may be sealed to each other with vacuum seal tape 240 to form a vacuum bag. The interior of the vacuum bag can be heated. The vacuum bag can be inserted inside of an oven or autoclave. The layers of the balloon on the mandrel can be thermally cured or melted, for example under from about 15 psi (103 kPa) to about 450 psi (3100 kPa) of pressure. The suction tube 242 can suction the interior of the vacuum bag. For example the pressure in the vacuum bag can be less than about 1.5 psi (10 kPa).

[000444] Figure 54 illustrates that a wash tube 264 can be inserted into a mandrel washout port 262. A dissolving or solvating fluid can be delivered through the wash tube and into the washout port 262. The mandrel can be removed by delivery of a fluid solvent such as water, alcohol or a ketone. The solvent may be applied during the consolidation process such that the solvent melts

or partially softens the mandrel and concurrently pressurizes the bladder. The mandrel 230 can be removed by raising the mandrel to a melting temperature for the mandrel. The mandrel 230 can be removed by deflating the mandrel or by collapsing an internal structure.

[000445] Figure 55A illustrates that the balloon before final consolidation 620 may be placed in a balloon mold 622 containing a balloon pocket 624. The balloon mold may be porous such that substantial amounts of gas may be drawn from balloon pocket 624 thru the wall of balloon mold 622 and out into the surrounding atmosphere. The balloon may have a tube placed in its inner volume that may extend out either end of the balloon 622 (not shown). The tube may be thin and very flexible. The tube may be a silicon rubber.

[000446] A coating may be sprayed into mold 622 that bonds to the balloon during cure and forms an outer layer 72a on the balloon 20.

[000447] Figure 55B illustrates that the balloon mold may be closed around the balloon 620. Pressure may be applied thru balloon second fluid port such that the balloon expands to contact the inside of balloon pocket 624. Alternately, the tube extending out either end of the balloon (not shown) may be pressurized to force the balloon into contact with pocket 624.

[000448] Figure 55C shows Pressure P inside the balloon volume 24 pressing the balloon wall 22 outwards. Mold 622 may be placed in an oven and heated. Mold 622 may have built in heaters. The balloon mold may be placed under vacuum (as per Figure 53B) or placed in a vacuum chamber during heating.

[000449] Heating the balloon under pressure may cause one or more layers to melt and fuse with adjoining layers. The melting under pressure may remove voids in the balloon wall. The outer inner and outer film may not melt. Heating the balloon under pressure may cause the walls of balloon before final consolidation 620 to fuse or laminate into one continuous structure. The balloon outer wall 22b and/or outer layer 72a may be substantially smoothed by this process. The balloon outer wall 22b and/or outer layer 72a may be permeable or perforated such that gas or other material trapped in the balloon wall 22 during manufacture may escape when the balloon is heated under pressure.

[000450] The final balloon outer diameter 50 may be very accurate and repeatable. For instance, at a given pressure, the outer diameter of a group of parts may all fall within about 2% (+/- 1%) of each other. For instance, if the nominal dimension of the outer diameter 50 of the balloon is about 24 mm (0.945 in) at about 60 psi (414 kPa) all parts may have an outer diameter of about 23.76 mm (0.935 in) to about 24.24 mm (0.954 in).

[000451] Figure 56A illustrates that a pleated balloon 20 in an expanded or inflated configuration can be substantially circular in cross-section.

[000452] Figure 56B illustrates that a balloon can be clamped in a pleating tool 266 with two, three, four, five or more removable pleating blocks 268. Heating the pleating blocks 268 to about 80C and then pressing them against the balloon for about 1 minute causes the balloon to become pleated or fluted. Commercial pleating machines such as balloon folding machinery from Interface Associates (Laguna Niguel, CA) can also be used. A small amount of wax may be used to hold the pleated and folded balloon into its desired shape.

[000453] Figure 56C illustrates that a pleated balloon in a deflated or contracted configuration can have one or more pleats or flutes 84. The balloon 20 may reform these pleat after inflation when vacuum is applied to balloon volume 24.

[000454] Additional laminates can be added to areas of a balloon that might require extra strength for certain procedures or uses. A balloon may have different amounts of fiber, adhesive or polymer film in different portions of the balloon wall. A balloon may have different number of fiber layers in different portions of the balloon wall.

[000455] In some embodiments, additional elements or materials can be added on top of or around the base mandrel. These additional elements can be the same or similar materials to those that make up the catheter shaft of the balloon. Alternatively, the additional elements can be of a material chosen such that it can be readily be heat bonded to the catheter shaft. Using such additional elements that are either made of the same material as the catheter shaft or that can be readily heat bonded to the catheter shaft advantageously allows the balloon to be rapidly and reliably attached to the catheter shaft or tip without the need for a liquid adhesive. In some embodiments, the additional elements used to enhance attachment to the catheter shaft or tip can be cut from thin film tubes, thereby creating thin film cylinders when placed around the mandrel. In some embodiments, the additional elements can have their outer surface modified to enhance bonding (e.g., bonding of the additional balloon layers) thereto. The surface modification can be accomplished, for example, by chemical treatment, plasma treatment or mechanical treatment, such as sanding or bead blasting. The additional elements can be performed and then placed over the mandrel or can be formed directly on top of the mandrel. The inner layers of the balloon, including those made of parylene or other vapor deposited materials, can be built on top of the additional elements. After the balloon is created, and the mandrel is removed, the additional elements can make up the balloon's inner wall in the shaft region.

METHOD OF USE

[000456] The device 2, for example including the balloon 20, can be used for Kyphoplasty, angioplasty including CTO dilation, stent delivery, sinuplasty, valvuloplasty, drug or other fluid delivery through the balloon, radiopaque marking, incising the inside of a vessel (e.g., to open or

expand a vessel), brachytherapy, intentionally obstruct a vessel, or combinations thereof. The device 2 can be used to deliver one or more stents and/valves and/or emboli filters to the coronary blood vessels (e.g., arteries or veins), carotid artery, peripheral blood vessels, the GI tract, the biliary ducts, the urinary tract, the gynecologic tract, and combinations thereof. The device 2 can be used to prepare a cardiac annulus and/or the leaflets of a natural heart valve for open or percutaneous (minimally invasive) valve replacement. The device 2 can expand and deploy a percutaneously delivered heart valve

[000457] Figure 57A illustrates a cross section of a balloon 20 (layers 72 are not shown). The balloon 20 can be in a substantially inflated condition. The cross section area is shown. The balloon wall 22 can have a balloon wall area 432.

[000458] Figure 57B illustrates a cross section of balloon 20 in a substantially deflated and folded configuration. The balloon 20 is shown in a delivery tube 428 or cannula with a delivery tube inside diameter 436 and a delivery tube inside diameter cross sectional area 434. The balloon 20 may be able to slide in the tube.

[000459] The compression ratio of the balloon can be from about 3:1 to about 10:1, more narrowly from about 5:1 to about 8:1, still more narrowly about 6:1 to about 7:1. The compression ratio can be the ratio between the outside diameter 50 of the substantially inflated balloon (e.g., as shown in Figure 57a) and the inside diameter of the delivery tube 436 (e.g., the tube as shown in Figure 57B). For instance, a balloon 20 with balloon outer diameter 50 equal to 24mm (0.945in) may be folded to about 3.6mm (0.142in).

[000460] The balloon can have a packing density equal to or greater than about 40%, more narrowly greater than or equal to about 55 %, yet more narrowly equal to or greater than about 70%. The packing density can be the percentage ratio between the cross sectional area 432 of the walls of the balloon and the delivery tube inside diameter cross sectional area 434.

[000461] The packing density and compression ratios for the balloon can remain substantially constant and the wall strength of the balloon can remain substantially constant with repeated packing and unpackings, and/or compressings and uncompressings.

[000462] The balloon can be folded into the cannula and expanded about eight times or more while not significantly degrading the strength of the balloon wall.

[000463] Figure 58 illustrates that the diametric elasticity of existing medical inflatable devices can be approximately 0.06 in./ATM and a typical burst pressure is about 3atm. The medical inflatable device 2 can have an exemplary diametric elasticity of 0.0004 in./ATM and a burst pressure above 20atm. Medical inflatable device 2 and balloon 20 can be substantially inelastic.

[000464] Figure 59 illustrates that the inflation system 470 can be attachable to a syringe 472 or other source of flow and pressure. The inflation system 470 can include part or all of the

hollow shaft 2000, an inner shaft 477a, a stiffening shaft 476, a hollow shaft lumen 154, a stiffening shaft lumen 478, an inflation port 482 and a stiffening rod control 480. The distal end of the stiffening shaft 476 can have a stiffening rod tip 484.

[000465] The syringe 472 can be detachable or non-detachable from the remainder of the inflation system 470. The balloon 20 may be inflated by pushing inflation fluid, such as water or dye, from the syringe 472, into the inflation port 482, through the hollow shaft lumen 154 and into the balloon 20. The removable stiffening shaft 476 may be left in place to stiffen the inflation system 470 while positioning the balloon 20 in the body. Once the balloon 20 is in place, the removable shaft stiffener 476 can be removed to allow the hollow shaft 2000 additional freedom of motion outside the body.

[000466] The stiffening shaft 476 can be integral with or removably attached to the stiffening rod 474. The stiffening rod tip 484 can have atraumatic geometry, or a soft plastic or elastomeric tip that will minimize puncture or damage the distal end of the balloon. The stiffener 476 can be withdrawn manually automatically.

[000467] A flexible tether (not shown) may be attached near or at where balloon 20 bonds to hollow shaft 2000. The flexible tether may pass thru the inside of hollow shaft 2000 and be anchored to the proximal end of hollow shaft 2000. The flexible tether may act as a safety strap. The safety strap may act as an emergency retrieval tool in case the balloon becomes detached in the patient. The flexible tether may be made of one or more of the materials listed in Figure 28.

[000468] Figure 60 shows that inflation fluid may be provided by detachable syringe 472 thru catheter Y-fitting 634. Inflation fluid may flow between in the inside wall of the outer catheter tube 2000a and the outside wall of the inner catheter tube 2000b. Inflation fluid may flow into balloon volume 24 to inflate the balloon. A guide wire may be inserted at guidewire port 632 and pass thru the inside of the inner catheter tube 630.

[000469] Figure 61 shows a cross section of the heart 562. The heart 562 has an aorta 568, a left ventricle 570 and an aortic valve 564

[000470] Figure 62A shows a folded balloon 20 with a prosthetic heart valve 626 crimped over it. In Figure 62B expansion of balloon 20 from a deflated state to an inflated state may cause prosthetic heart valve 626 to deploy to a larger size. Balloon 20 may be substantially non-compliant as described herein. Non-compliance may allow the heart valve to deploy to a very precise inner diameter regardless of pressure applied.

[000471] Figures 63A, 63B and 63C illustrate that a guidewire 572 can be inserted through the aorta 568 and positioned in the left ventricle 570 of the heart 562. The device 2 can be slidably inserted over the guidewire through the aorta 568. The device 2 may be in a deflated state when first placed in the aortic valve 564. The device 2 can be positioned to align along the guidewire

the balloon 20 with the aortic valve leaflets 566. The device 2 can also be rotated about the balloon longitudinal axis to align with the aortic valve 564, for example when cutting apart attached leaflets 566 in a bicuspid aortic valve with a flange, vane, blade, other cutting element described herein, or combinations thereof.

[000472] Figure 63D shows the balloon 20 in an expanded configuration. The device 20 can be non-compliant and open the aortic valve 564 to a precise dimension (for example, about 20 mm (0.787in) or about 24 mm (0.945in)). The balloon 20 can fixedly reconfigure and press the aortic valve leaflets 566 against the outer wall or annulus 582 of the aortic valve 564. The balloon 20 can radially expand the aortic valve annulus 582.

[000473] The balloon can have an annular lumen 160, as shown in Figures 16 through 20. Natural blood flow through the aortic valve can flow through the annular lumen 160 when the balloon 20 is in an inflated or expanded configuration in the aortic valve. The device can have a device valve 178. The device valve 178 can open and close, for example depending on the ventricular pressure against the device valve.

[000474] Figure 63E illustrates that the balloon 20 can be deflated, contracted and withdrawn from the aortic valve 564.

[000475] Figure 63F shows the aortic valve 564 in an opened configuration at a larger dimension than before the procedure.

[000476] The method described supra can be performed on an aortic, mitral, pulmonary, tricuspid or vascular valve.

[000477] Referring now to Figures 64A-64F, the balloon 20 can be used to deploy a prosthetic valve 626 in, for instance, the aortic valve 564 near the coronary ostia 583. A guidewire 572 may first be introduced thru the aorta 568 into the left ventricle 570. Next, as shown in Figure 64B, a balloon catheter carrying prosthetic heart valve 626 and deflated balloon 20 may be introduced over guidewire 572 into aortic valve 564. In Figure 64C, balloon 20 is quickly inflated to expand the prosthetic heart valve into the aortic valve 564. The inflation is performed quickly as, when balloon 20 is fully inflated, cardiac output may be zero. If a balloon 20 with an annular lumen 160 is used (not shown), blood may continue to flow from the heart 562 and into the aorta 568 even with the balloon expanded and balloon inflation and deflation may not be quick. In Figure 64D, the balloon is quickly deflated, leaving the valve prosthesis 626 behind in the aortic valve. Figures 64E show the prosthetic valve closing (64E) and opening (64F) immediately after the balloon 20 is withdrawn

[000478] Referring to Figures 68A-72, in some embodiments, a marker wire 190 or marker wires 190 in the balloon wall can be configured so as to indicate the relative angular position of the balloon in situ relative to the fluoroscope used by the physician during implantation of the

balloon. That is, when any of the balloons described herein are inflated in the aortic annulus, the balloon may align itself to an axis perpendicular to the plane of the aortic valve typically defined by the three nadirs of the Sinuses of Valsalva. Marker wires 190 on the balloon can allow the physician to visualize the orientation of this axis with respect to the fluoroscopic axis, and thus to align the two axes to perpendicularity. The marker wires 190 can be made of a metal, such as gold, that is both ductile enough to allow the balloon to be folded tightly and dense enough to be radiopaque. The marker wires 190 can be 0.0002 inches to 0.032 inches thick, such as 0.0005 inches, 0.0001 inches, or 0.00015 inches.

[000479] Figures 68A-68B show one embodiment of a balloon having a plurality of marker wires 190 in the form of radiopaque rings around the circumference of the balloon. In one embodiment, as shown in Figures 68A-68B, there can be three rings with two rings near the distal and proximal tapers 34, 42 and one ring in the center of the constant diameter section 38. However, other ring arrangements, such as two rings, one ring, and/or different placements of the rings are possible. If the fluoroscope is aligned properly, and thus the axis of the fluoroscope and the axis perpendicular to the plane of the aortic valve typically defined by the three nadirs of the Sinuses of Valsalva are aligned perpendicular to one another, the resulting image will show only the front edge 1207 of the rings, as shown in Figure 68A. In contrast, if the fluoroscope is not aligned properly, the resulting image will show both the front edge 1207 and the back edge 1209 of the rings, i.e. the rings will show up as an ellipse, as shown in Figure 68B.

[000480] Similarly, Figures 69A-69B show one embodiment of a balloon having a plurality of marker wires 190 in the form of bands extending around the circumference of the balloon, with each band having at least two spaced apart marker lines (e.g., 190a and 190b are in the same band, and 190c and 190d are in the same band). In one embodiment, as shown in Figures 69A-69B, there can be four circumferential bands (each with two lines) located approximately equidistant from one another within the constant diameter section 38. However, other band and line arrangements, such as two or three circumferential bands and/or three or more lines per band and/or different placements of the bands are possible. If the fluoroscope is aligned properly, and thus the axis of the fluoroscope and the axis perpendicular to the plane of the aortic valve typically defined by the three nadirs of the Sinuses of Valsalva are perpendicular, the resulting image will show that the markers in the same band (e.g., 190a and 190b or 190c and 190d) are collinear with one another, as shown in Figure 69A. In contrast, if the fluoroscope is not aligned properly, the resulting image will show that the marker lines of the same band (e.g., 190a and 190b or 190c and 190d) are parallel but offset (not collinear), as shown in Figure 69B.

[000481] It should be understood that other configurations of the marker wires 190 are possible while still providing guidance as to the relative angular position of the balloon relative to the

fluoroscope. For example, the marker wire 190 could be a continuous spiral (as shown in Figures 70A and 70B).

[000482] Referring to Figure 71A, in one embodiment, the marker wire or wires 190 can be wound between the middle layers 72f and 72e, which can comprise parallel and hoop fibers, as described above. This position between parallel and hoop fiber layers advantageously securely holds the marker wires 190 in place while protecting the balloon should the wires 190 fracture during pleating. Referring to Figure 71B, the marker wires 190 can be radially outside middle layer 72f (shown), radially outside layer 72g (not shown) or radially outside outer layer 72a (not shown).

[000483] Referring to Figure 72, in another embodiment, the hoop wind can have breaks 1211 along the longitudinal axis of the balloon to create space for the marker wire or wires 190 to be placed therein. For example, the breaks 1211 can have a width approximately equal to the width that 2-10 hoop winds would otherwise occupy. In one embodiment, the breaks 1211 can be achieved during manufacturing by momentarily lowering the pitch. This break in the hoop wind can advantageously be used without significantly reducing the strength of the balloon, as the hoop strength at any one point is strongly affected by the hoop winds in the vicinity; a small break in the hoop winds has a minimal effect on the overall strength of the balloon.

[000484] In use, the balloon with marker wires 190 can be put into position in the body, for instance in the aortic valve. A fluoroscopic image can then be taken to detect the position of the balloon. If the fluoroscopic image shows that the fluoroscope and balloon are misaligned, for example as shown in Figures 68B or 69B, then the position of the fluoroscope can be adjusted. The adjustment can be performed (with additional images as necessary) until the fluoroscope is properly aligned, for example as shown in Figures 68A or 69A. Thus, the marker wires 190 can advantageously be used to orient the fluoroscope used in a BAV or TAVI procedure correctly, i.e. such that the axis of the fluoroscope and the axis perpendicular to the plane of the aortic valve typically defined by the three nadirs of the Sinuses of Valsalva are aligned perpendicular to one another. Having the fluoroscope oriented correctly advantageously allows the subsequent valve implantation to be more accurately positioned. For instance, it allows the height of the valve placement (or placement along the longitudinal axis normal to the plane formed by the roots of the tri-cuspid valve leaflets and/or to a plane defined by the aortic annulus) to be well controlled. Placing the valve in the appropriate position advantageously reduces the amount of leakage of the valve, which improves safety and patient life expectancy. The plane formed by the three nadirs of the Sinuses of Valsalva may be substantially parallel to the plane containing the aortic annulus.

[000485] In some embodiments, the marker wires may also show the shape of the aortic annulus. For instance, if the balloon is inflated in an aortic annulus that is substantially elliptical, the marker wire may follow the shape of the aortic annulus. Viewing the marker wire on a fluoroscope may allow the physician to see the shape of the aortic annulus. Knowing the shape of the annulus may allow a physician to treat a patient more effectively in a TAVI procedure, for example, by allowing him or her to select a prosthetic valve size, type or brand more accurately.

[000486] In some embodiments, the marker wires 190 can also act as fiducials for an automatic system to detect and view. For example, a computer or controller can be configured to process the fluoroscopic image, identify the markers, and then automatically move the fluoroscopic head into position and/or guide the physician to move it.

[000487] Referring to Figures 70A and 70B, the marker wires 190 arranged as described herein can further advantageously provide information related to the relative amount of refolding that the balloon has undergone. For example, as shown in Figure 70A, if the balloon is almost fully refolded, then marker wires 190 in the form of a continuous spiral will show up as short segments in the resulting image. In contrast, as shown in Figure 70B, if the balloon is not fully refolded, then marker wires 190 in the form of a continuous spiral will show up as longer segments in the resulting image.

[000488] In some embodiments, the balloon with marker wires 190 can advantageously be used to replace radiopaque markers normally placed on the guidewire lumen and/or can reduce or eliminate the need for radiopaque inflation solution.

[000489] In some embodiments, a marker wire 190 may be attached to the outside of a balloon. The marker wire 190 may have no outer covering. The balloon may be a fiber reinforced balloon as described herein or it may be a common blow molded balloon, such as one made of PET, Nylon, PEBAX or combinations thereof.

[000490] Figure 65A illustrates that the balloon can be positioned in a narrowed, atherosclerotic length of a blood vessel 574 having atherosclerotic plaque 576 on the interior of the vessel wall 578. The vessel 574 can have a vessel lumen 580 through which blood can flow.

[000491] Figure 65B illustrates that the balloon 20 can be inflated and expanded. The balloon 20 can remodel the vessel, pushing the sclerotic plaque 576 radially away from the balloon longitudinal axis. The balloon 20 can deploy a vascular stent to the sclerotic length of the vessel.

[000492] Figure 65C illustrates that the balloon 20 can be deflated, contracted and removed from the narrowed length of the vessel 574. The vessel lumen 574 can remain patent after the balloon is removed, for example restoring blood flow past the treated atherosclerotic length.

[000493] The balloon 20 can be implanted in the body semi-permanently or permanently. The balloon 20 can have one, two or more openings for fluid entry and/or exit.

[000494] In summary, the following items pertain to the invention disclosed herein:

1. A method of aligning a fluoroscope for valvuloplasty, comprising:
inserting a balloon having a plurality of radiopaque markers thereon into an aortic root;
imaging the balloon with a fluoroscope;
using the image to determine that the radiopaque markers on the balloon are not properly aligned, wherein having the radiopaque markers not properly aligned indicates that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane of the aortic valve; and
adjusting a position of the fluoroscope until the radiopaque markers on the balloon are properly aligned such that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane of the aortic valve.
2. The method of item 1, wherein the radiopaque markers are radiopaque rings around the balloon, and wherein using the image to determine that the radiopaque markers on the balloon are not properly aligned comprises identifying elliptical features in the image corresponding to the radiopaque rings.
3. An inflatable medical device comprising:
a balloon; and
a radiopaque marker on the balloon, the radiopaque marker configured to provide a signal in a fluoroscopic image indicative of the orientation of the balloon relative to the fluoroscope taking the image.
4. The inflatable medical device of claim 3, wherein the radiopaque marker includes a radiopaque ring around the circumference of the balloon.
5. An inflatable medical device comprising:
a balloon having a constant diameter section, proximal and distal tapered sections, and proximal and distal stem sections;
a first layer over the balloon comprising a fiber extending circumferentially around the balloon, the fiber having a pitch in the proximal and distal tapered sections that is greater than a pitch of the fiber in the constant diameter and proximal and distal stem sections.
6. An inflatable medical device comprising:
a leak resistant bladder, the leak resistant bladder comprising a plurality of sublayers of a vapor deposited material, the sublayers of vapor deposited material configured to slide relative to one another; and
a layer of fiber over the leak resistant bladder.
7. The inflatable medical device of item 6, wherein the vapor deposited material is parylene.

8. The inflatable medical device of item 6, wherein the plurality of sublayers of vapor deposited material include an adhesion retardant therebetween.
9. The inflatable medical device of item 6, wherein the adhesion retardant is fluorine.
10. The device of item 6, wherein the bladder is less than 20 microns thick.
11. The inflatable medical device of item 6, wherein each sublayer of vapor deposited material is less than 5 microns thick.
12. An inflatable medical device comprising:
 - a balloon having at least one layer of fibers; and
 - a leak resistant outer layer, the leak resistant outer layer comprising a plurality of sublayers of a vapor deposited material.
13. The device of item 12, wherein the vapor deposited material is parylene.
14. The device of item 12, wherein the plurality of sublayers of vapor deposited material include an adhesion retardant therebetween.
15. The device of item 14, wherein the adhesion retardant is fluorine.
16. The device of item 12, wherein the outer layer is less than 20 microns thick.
17. The device of item 12, wherein each sublayer of vapor deposited material is less than 5 microns thick.
18. A method of making an inflatable medical device comprising:
 - vapor depositing a plurality of sublayers onto a solid mandrel to form a leak resistant bladder;
 - applying at least one layer of fiber over the bladder; and
 - vapor depositing a plurality of sublayers over the at least one fiber layer to form a leak resistant outer layer.
19. A method of making an inflatable medical device comprising:
 - rotating a mandrel about a longitudinal axis;
 - running a single fiber tow in a first direction along the longitudinal axis onto the rotating mandrel so as to create a positive transverse wind, the positive transverse wind forming an angle of approximately 40 to 60 degrees with the longitudinal axis; and
 - running the fiber tow in a second direction opposite to the first direction along the longitudinal axis onto the rotating mandrel so as to create a negative transverse wind, the negative transverse wind forming an angle of approximately -40 to -60 degrees with the longitudinal axis.
20. An inflatable medical device comprising:
 - a balloon having a constant diameter section, proximal and distal tapered sections, and proximal and distal stem sections; and

a panel covering the balloon, wherein the panel comprises a plurality of fibers extending substantially parallel with a longitudinal axis of the balloon, and wherein the panel comprises a rectangular section and a plurality of triangular or trapezoidal sections, the rectangular section substantially covering the constant diameter section of the balloon, and the triangular or trapezoidal sections substantially covering the proximal and distal tapered sections and the proximal and distal stem sections.

21. The inflatable medical device of item 20, wherein the triangular or trapezoidal sections overlap in the proximal and distal tapered sections of the balloon.

22. The inflatable medical device of item 20, wherein the proximal and distal tapered sections have a stiffness that is greater than the stiffness of the constant diameter section.

23. An inflatable medical device comprising:

a balloon having a constant diameter section, proximal and distal tapered sections, and proximal and distal stem sections; and

a panel covering the balloon, wherein the panel comprises a plurality of fibers extending substantially parallel to a longitudinal axis of the balloon, the panel further comprising a plurality of fiber separation areas within the constant diameter section, the fiber separation areas arranged in a pattern such that no adjacent fibers have the same length.

24. The inflatable medical device of item 23, wherein at least some of the fiber separation areas extend through the fibers at an angle greater than 0 degrees and less than 90 degrees relative to the circumferential axis of the balloon.

25. The inflatable medical device of item 24, wherein the angle is between 10 and 45 degrees.

26. The inflatable medical device of item 25, wherein the angle is approximately 25 degrees.

27. The inflatable medical device of item 23, wherein at least some of the fiber separation areas extend through the fibers parallel with the circumferential axis of the balloon.

[000495] Any elements described herein as singular can be pluralized (i.e., anything described as “one” can be more than one), and plural elements can be used individually. Characteristics disclosed of a single variation of an element, the device, the methods, or combinations thereof can be used or apply for other variations, for example, dimensions, burst pressures, shapes, materials, or combinations thereof. Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The term “comprising” is not meant to be limiting. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

CLAIMS

What is claimed is:

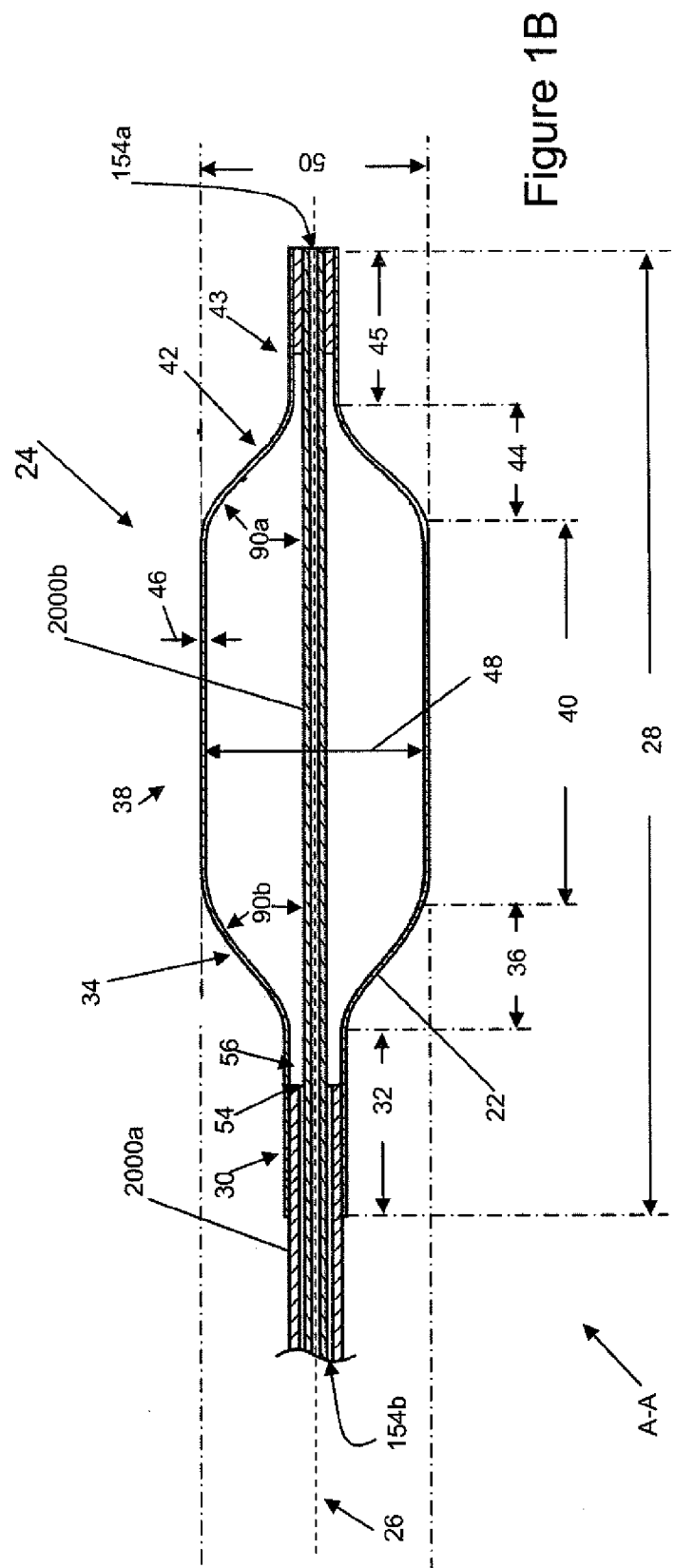
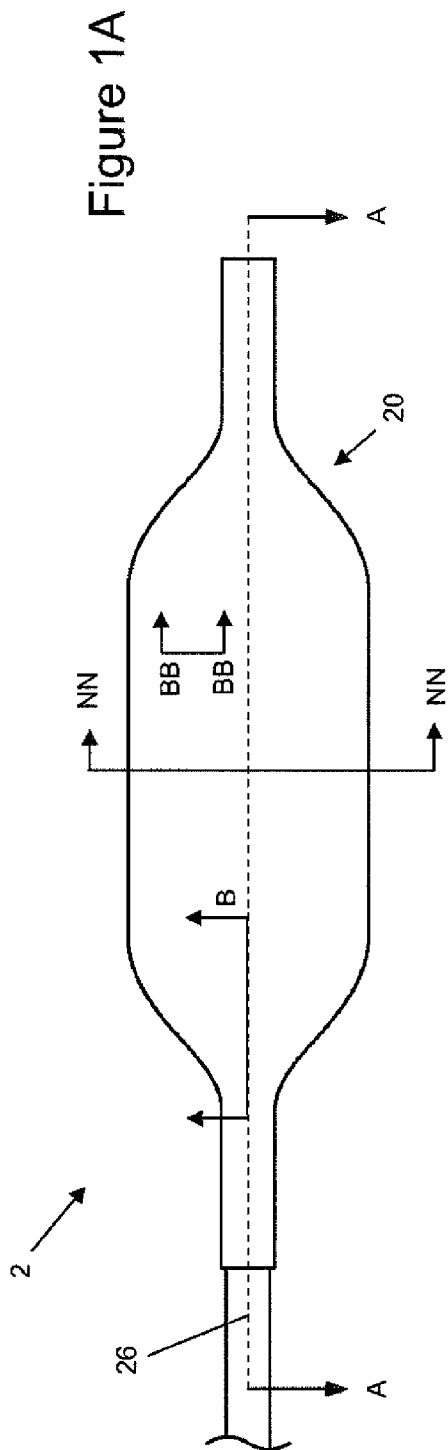
1. An inflatable medical device for performing a valvuloplasty in an aortic root, comprising:
a balloon adapted for positioning in the aortic root; and
a radiopaque marker on the balloon, the radiopaque marker configured to provide a fluoroscopic image indicative of the orientation of the balloon relative to a fluoroscope taking the image.
2. The device of claim 1, wherein the balloon comprises a constant diameter section having a diameter of less than about 30 millimeters, said constant diameter section including the radiopaque marker.
3. The device of claim 2, further including a plurality of radiopaque markers on the balloon.
4. The device of claim 3, wherein the radiopaque markers are spaced in the circumferential direction.
5. The device of claim 4, wherein the radiopaque markers comprise a plurality of groups of radiopaque markers spaced in the circumferential direction, each group of radiopaque markers also being spaced in the longitudinal direction.
6. The device of claim 3, wherein the radiopaque markers comprise three substantially identical bands spaced in the longitudinal direction.
7. The device of claim 6, wherein a first radiopaque marker is positioned at each end of the constant diameter section and a second radiopaque marker is between the first radiopaque markers.
8. The device of any of the foregoing claims, wherein the radiopaque marker or each of the plurality of radiopaque markers extends a distance of between about 0.0002 inches and 0.032 inches in the longitudinal direction.
9. The device of any of the foregoing claims, wherein the radiopaque marker or each of the plurality of markers comprises a wire.

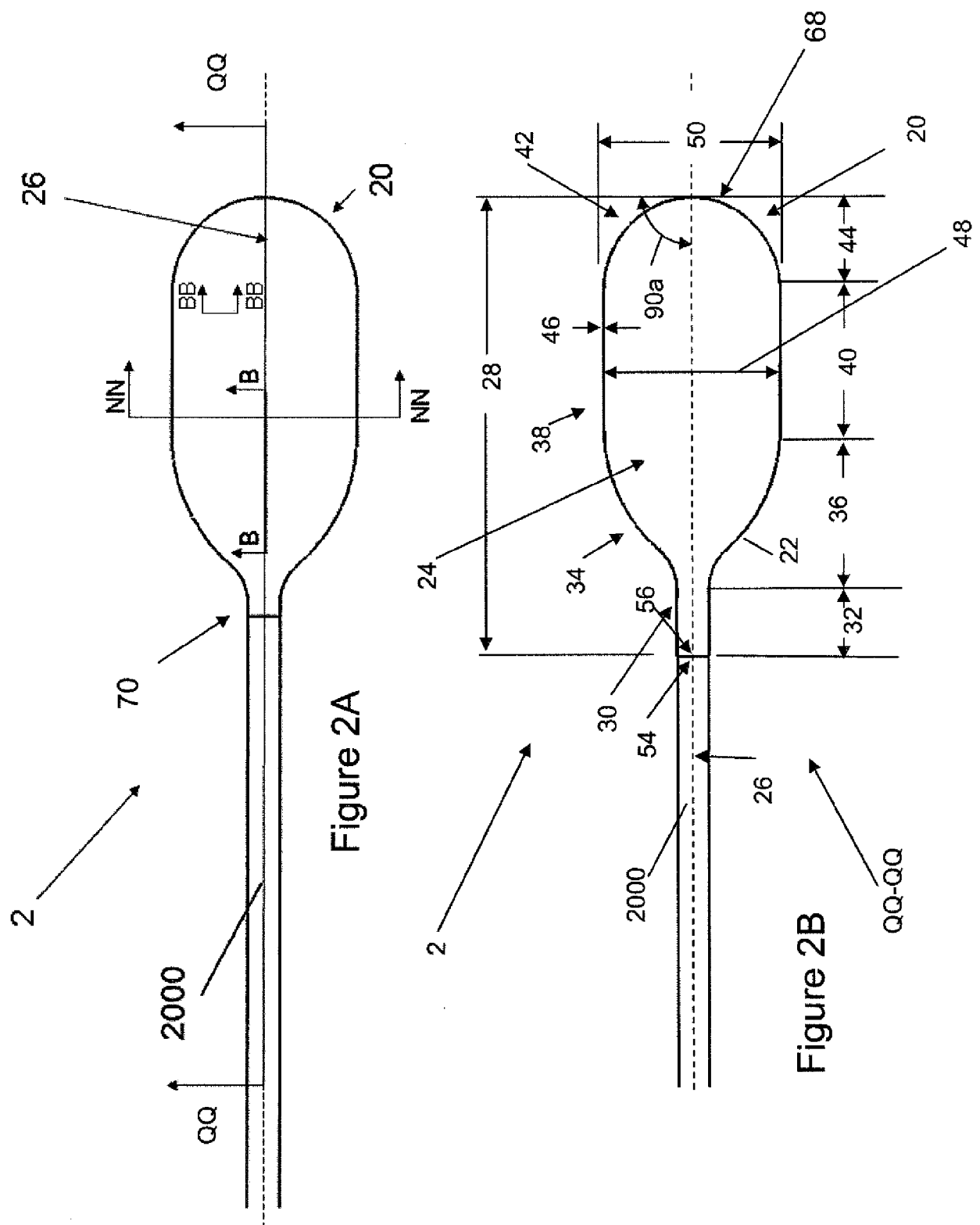
10. The device of claim 5, wherein the wire is round or flat.
11. The device of any of the foregoing claims, wherein the radiopaque marker or each of the radiopaque markers comprises an annular band.
12. The device of any of the foregoing claims, wherein the radiopaque marker or markers comprise gold.
13. The device of any of the foregoing claims, wherein the balloon comprises at least one fiber, the fiber being arranged so as to form a gap for receiving the radiopaque marker.
14. The device of any of the foregoing claims, wherein the balloon comprises at least one fiber layer including the radiopaque marker.
15. The device of any of the foregoing claims, wherein the radiopaque marker comprises a continuous spiral.
16. The device of any of the foregoing claims, wherein the radiopaque marker is embedded in a wall of the balloon.
17. A method of manufacturing a balloon, comprising:
providing a metal radiopaque marker in a wall of the balloon.
18. The method of claim 17, wherein the providing step comprises embedding a metal wire within the balloon wall.
19. The method of claim 17, wherein the providing step comprises providing the metal radiopaque marker within a fiber layer forming the wall of the balloon.
20. The method of any of claims 17-19, wherein the providing step comprises embedding a gold wire in the balloon wall.
21. The method of any of claims 17-20, wherein the providing step comprises embedding a plurality of wires in the wall of the balloon.

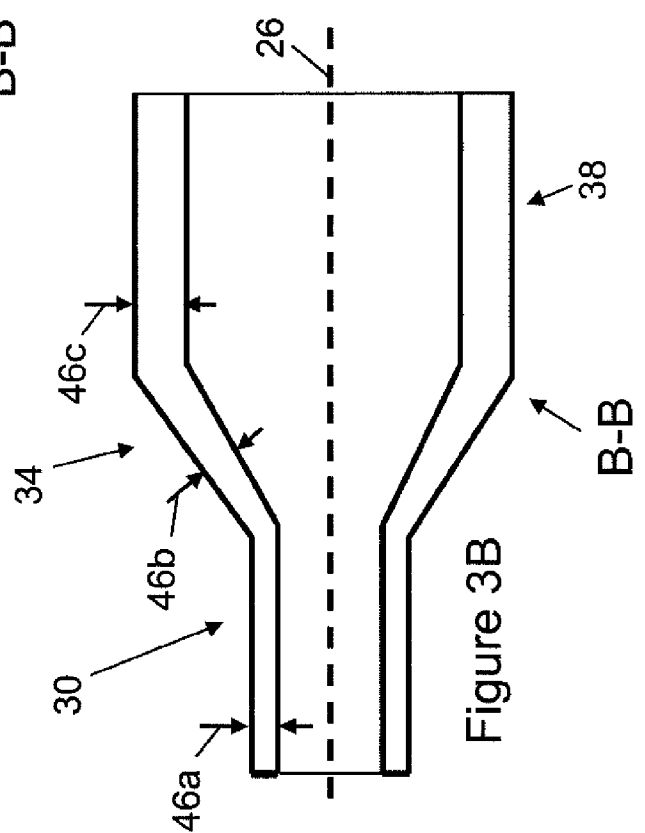
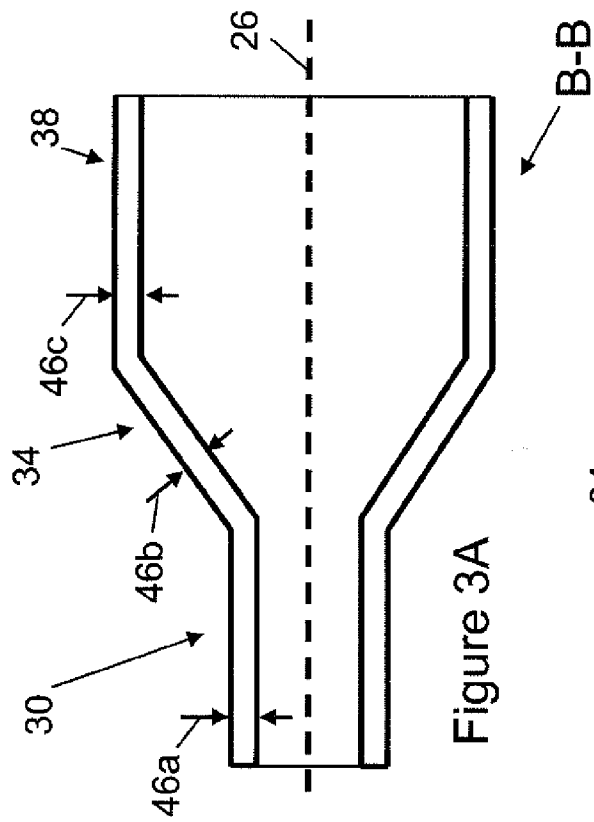
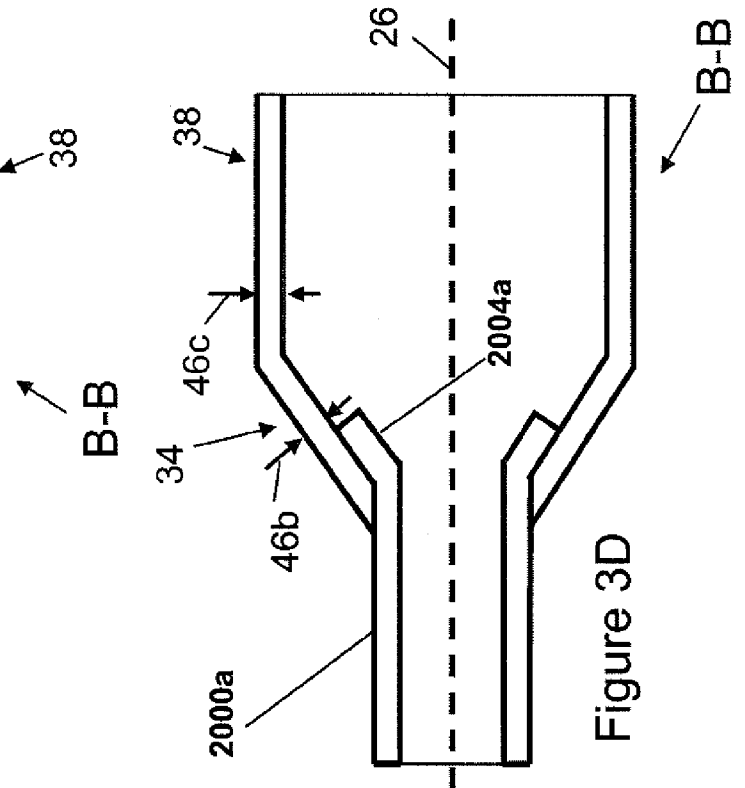
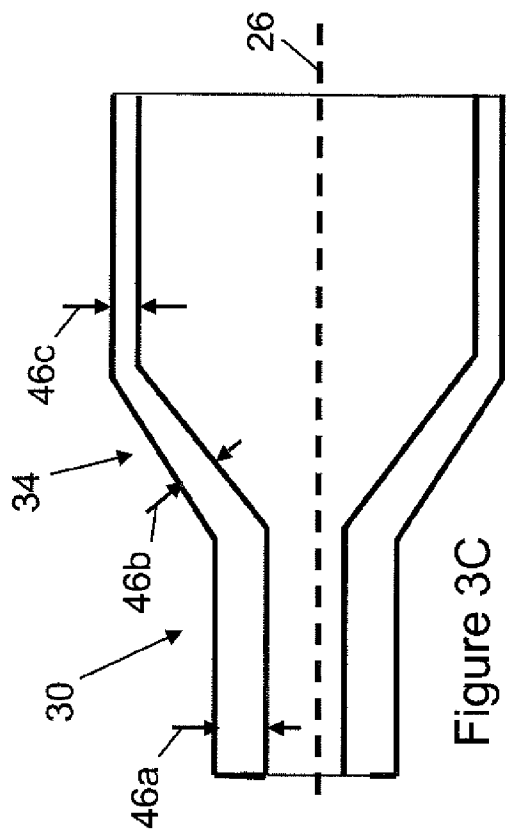
22. A method of aligning a fluoroscope for valvuloplasty, comprising:
imaging the balloon of claim 1 with a fluoroscope;
using the image to determine that the radiopaque marker on the balloon is not properly aligned, wherein having the radiopaque marker not properly aligned indicates that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane of an external structure; and
adjusting a position of the fluoroscope until the radiopaque marker on the balloon is properly aligned such that the axis of the fluoroscope is aligned perpendicularly with the axis that is perpendicular to the plane.
23. The method of claim 22, wherein the radiopaque marker comprises a radiopaque ring around the balloon, and wherein using the image to determine that the radiopaque marker on the balloon is not properly aligned comprises identifying elliptical features in the image corresponding to the radiopaque ring.
24. A method of for use in connection with performing a valvuloplasty on an aortic valve, comprising:
inserting the balloon of claim 1 into the aortic root;
inflating the balloon;
imaging the balloon with a fluoroscope; and
using the image to determine a profile of the aortic root.
25. An inflatable medical device, comprising:
a balloon including a balloon wall fully encasing at least one metal wire extending around the balloon in a circumferential direction.
26. The inflatable medical device of claim 25, wherein the wire comprises a band.
27. The inflatable medical device of any of claims 25-26, wherein the balloon comprises a constant diameter portion, and further including a plurality of spaced wires on the constant diameter portion of the balloon.
28. The inflatable medical device of any of claims 25-26, wherein the wire or each wire extends a distance of between about 0.0002 inches and 0.032 inches in a longitudinal direction of the balloon.

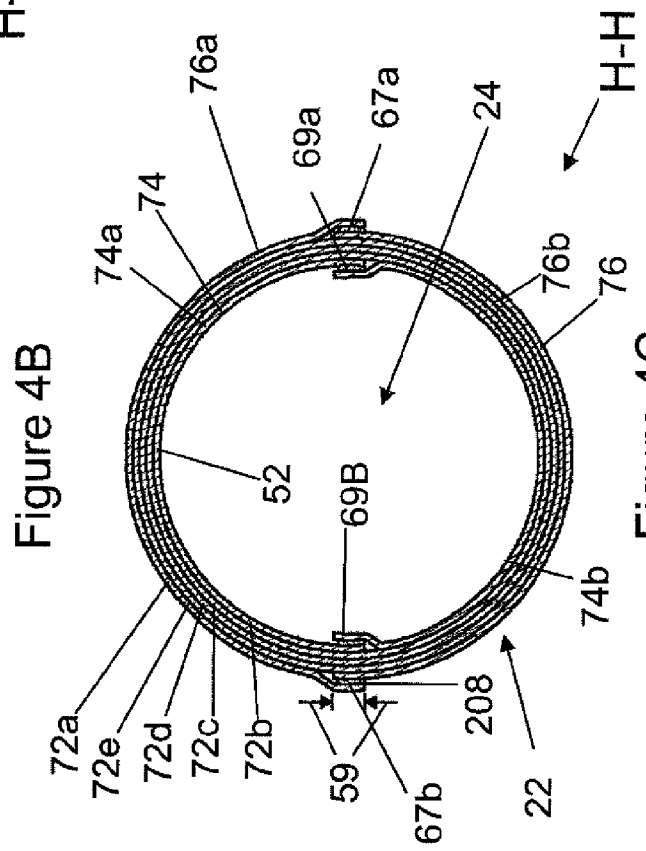
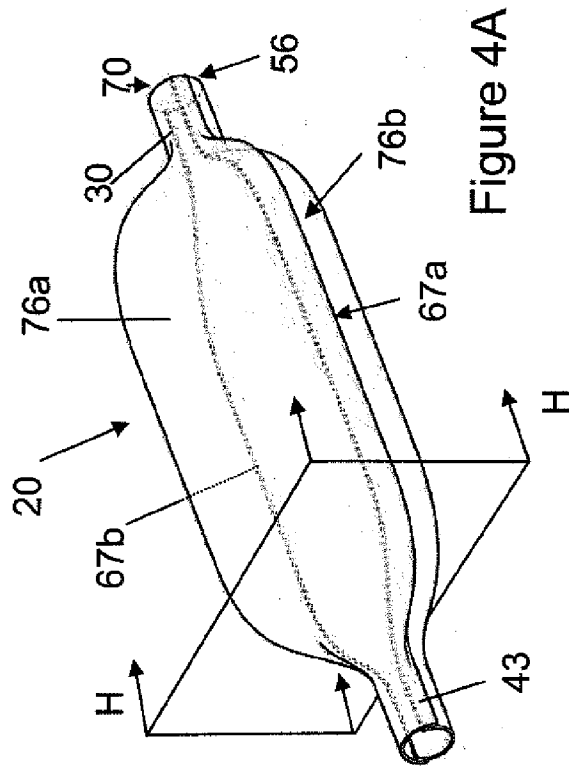
29. The inflatable medical device of any of claims 25-28, wherein the wire or each wire is round or flat.
30. The inflatable medical device of any of claims 25-29, wherein the wire or each wire comprises gold.
31. The inflatable medical device of any of claims 25-30, wherein the balloon further includes at least one fiber layer, and the metal wire forms a part of the fiber layer.
32. The inflatable medical device of claim 31, wherein the at least one fiber is arranged to form a gap for receiving the metal wire.
33. An inflatable medical device, comprising:
a balloon having a longitudinal direction and a circumferential direction; and
a plurality of radiopaque markers on the balloon, the plurality of radiopaque markers comprising at least one group of at least two radiopaque markers elongated in the circumferential direction and spaced from each other in the circumferential direction.
34. The inflatable medical device of claim 33, further including a plurality of groups of radiopaque markers spaced in the circumferential direction, each group of markers also being spaced in the longitudinal direction.
35. The inflatable medical device of claim 33 or claim 34, wherein each radiopaque marker comprises a wire.
36. The inflatable medical device of any of claims 33-35 wherein each radiopaque marker comprises metal.
37. The inflatable medical device of any of claims 33-36 wherein each radiopaque marker comprises gold.
38. The inflatable medical device of any of claims 33-37, wherein each radiopaque marker is embedded in a wall of the balloon.

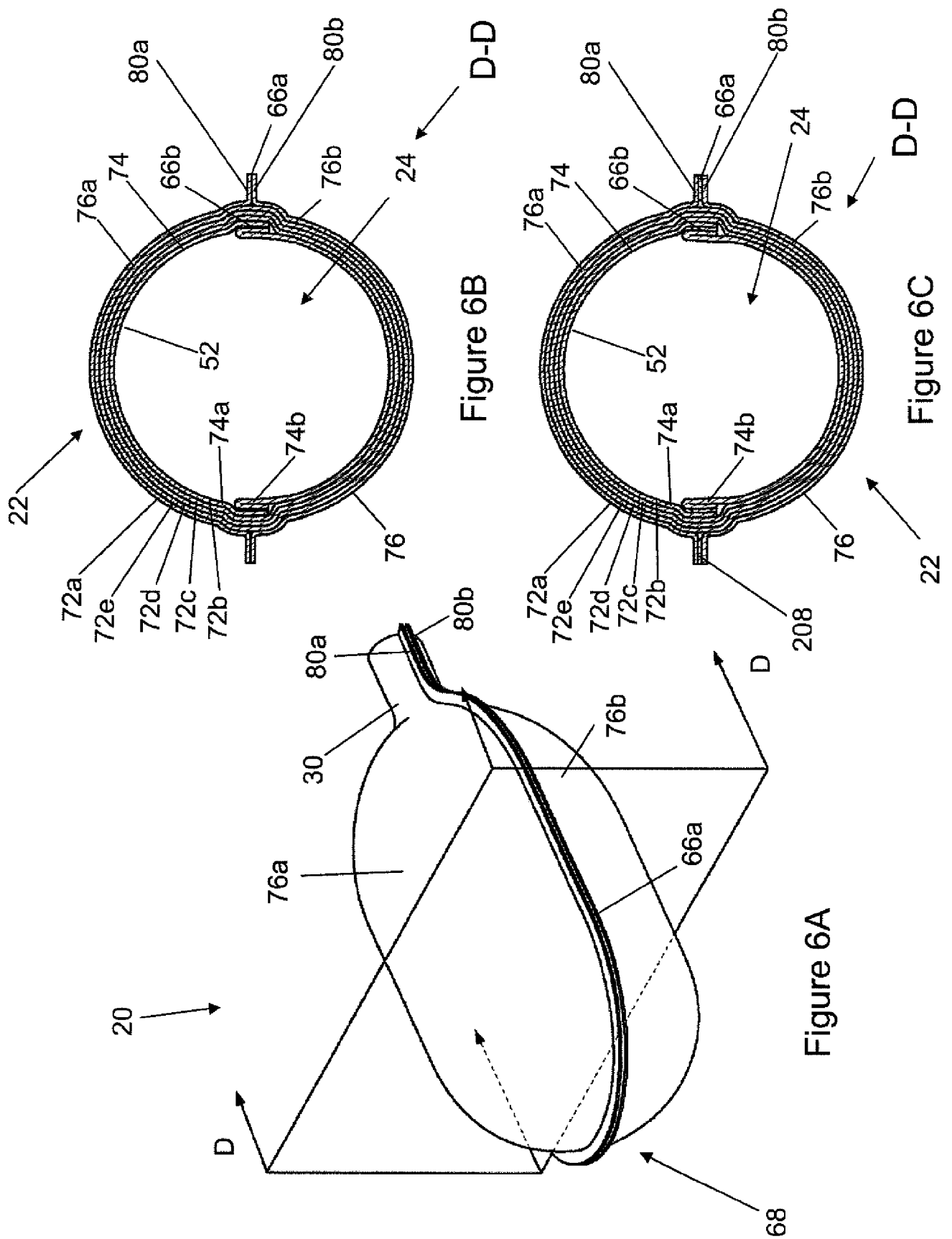
39. The inflatable medical device of any of claims 33-37, wherein each radiopaque marker forms part of a fiber layer forming a wall of the balloon.
40. An inflatable medical device, comprising:
a balloon having at least two radiopaque markers that appear to join under fluoroscopy in one orientation of the balloon but appear to separate under fluoroscopy in a different orientation of the balloon.
41. The inflatable medical device of claim 40, wherein the markers comprise circumferentially extending, metal wires embedded in a wall of the balloon.
42. A method of determining the proper orientation of a fluoroscope, comprising:
imaging a radiopaque marker on a balloon, the radiopaque marker configured to provide a fluoroscopic image indicative of the orientation of the balloon relative to a fluoroscope taking the image.
43. The method of claim 42, further including the step of inserting the balloon into the vasculature prior to the imaging step.

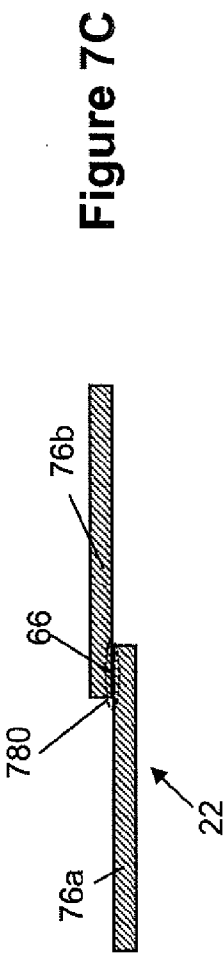
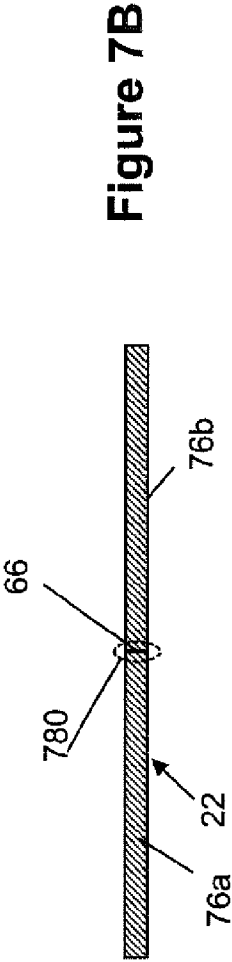
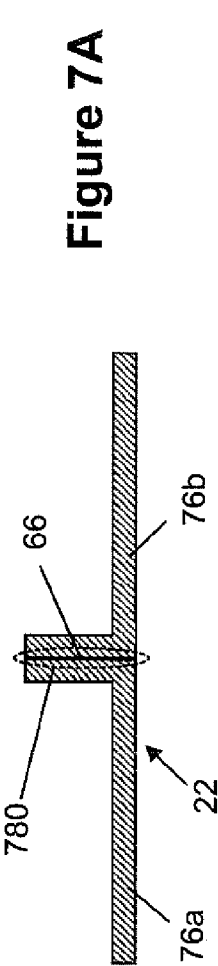


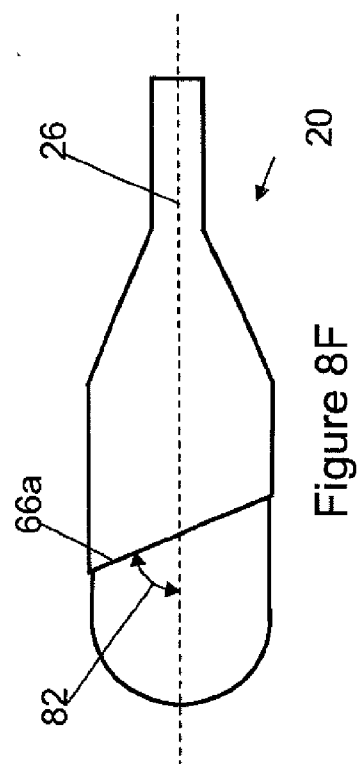
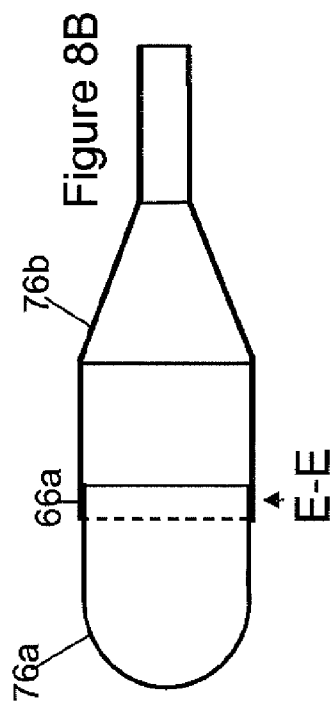
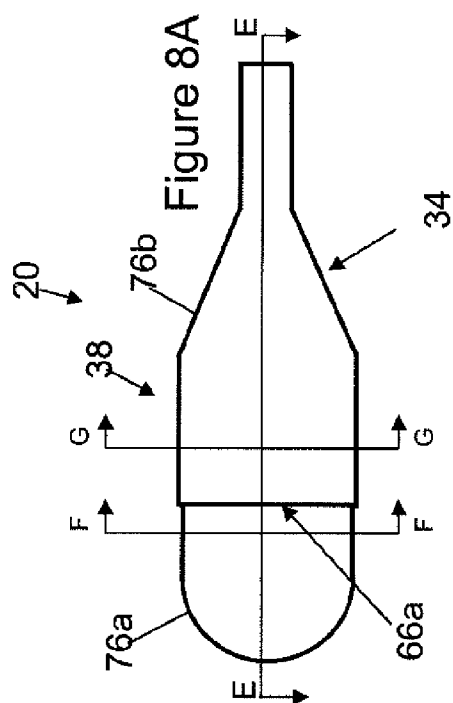
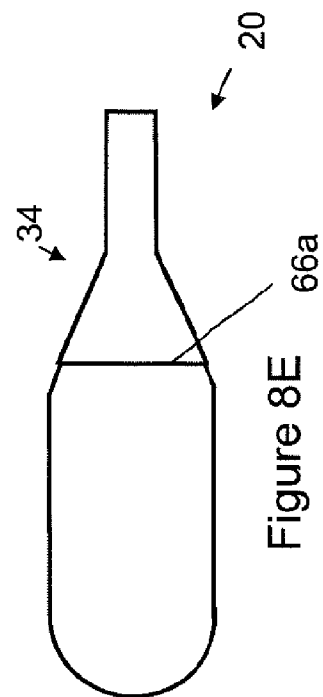
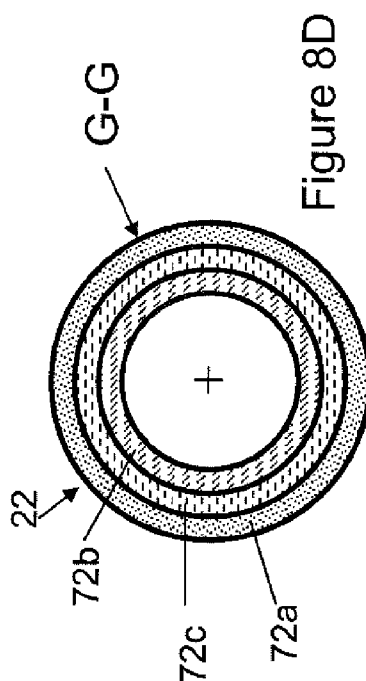
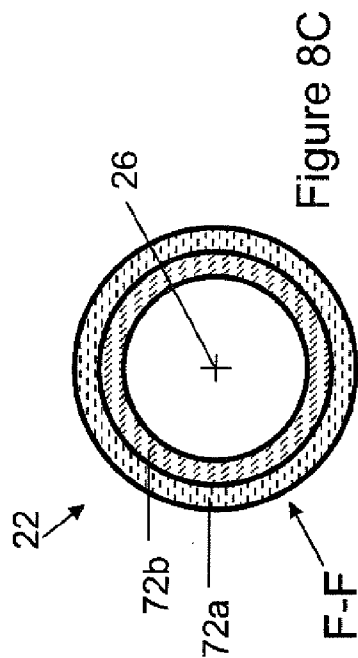


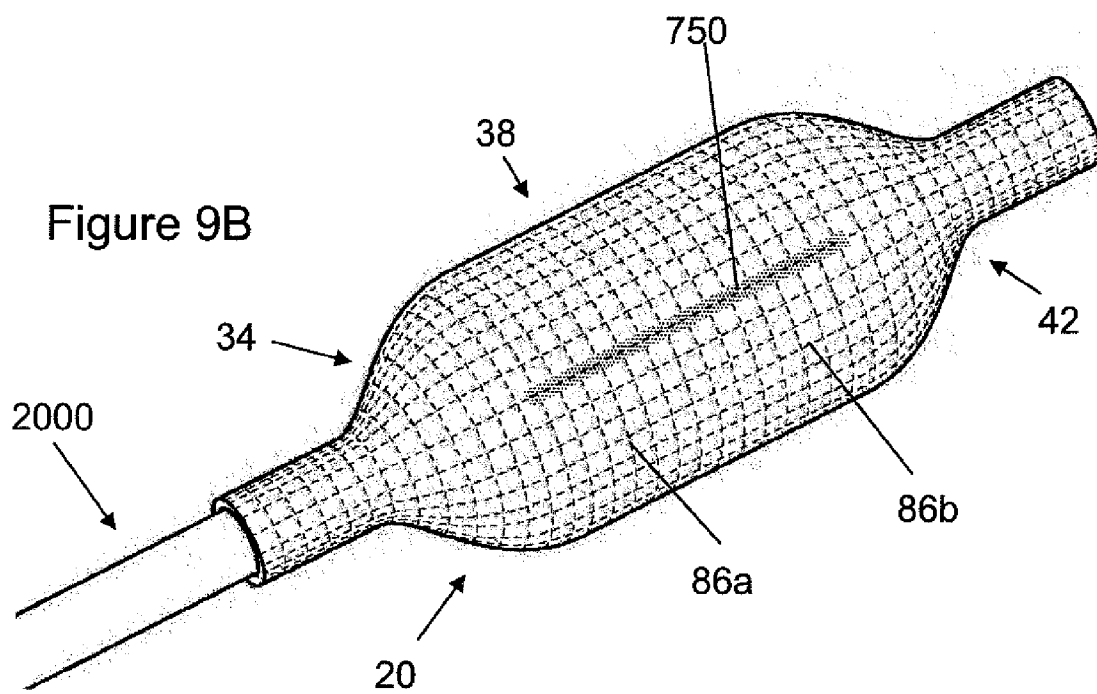
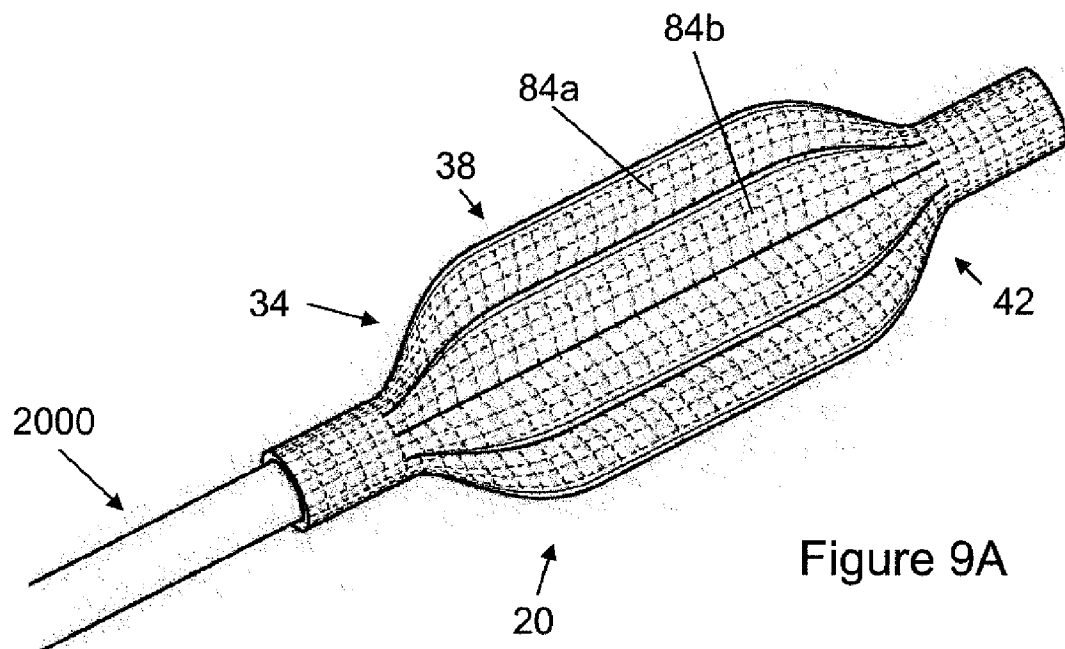












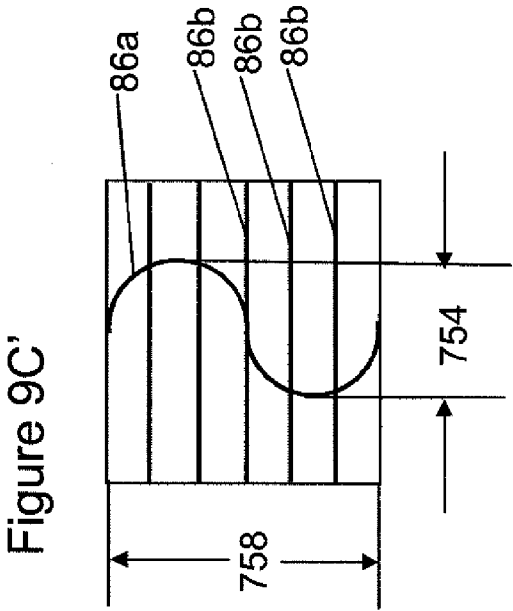
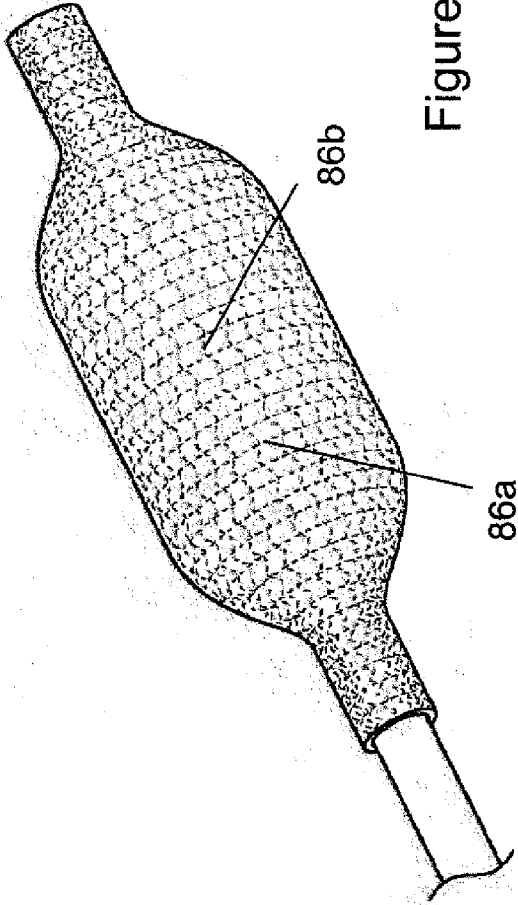
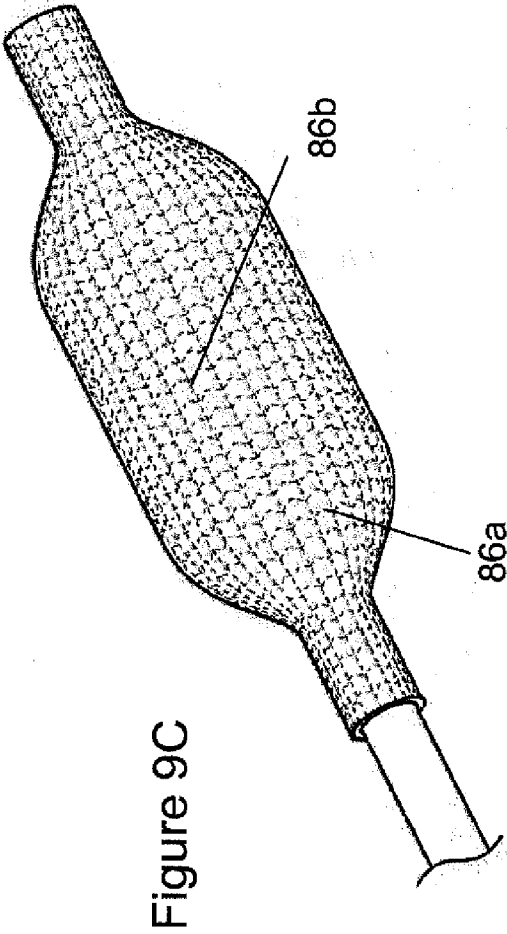


Figure 9E

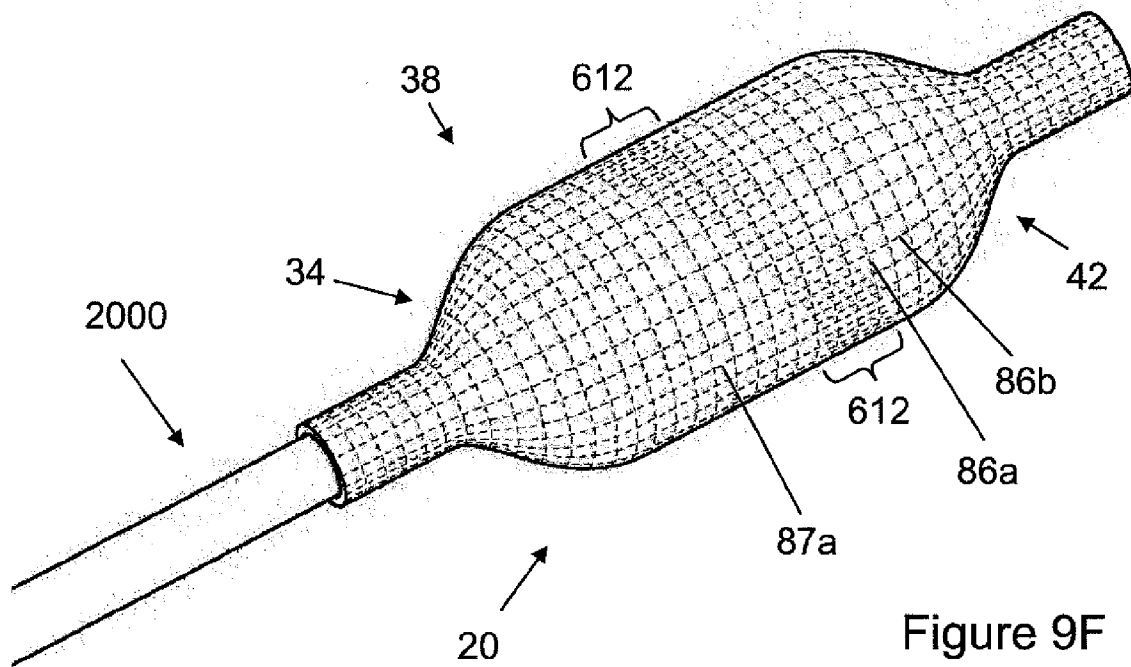
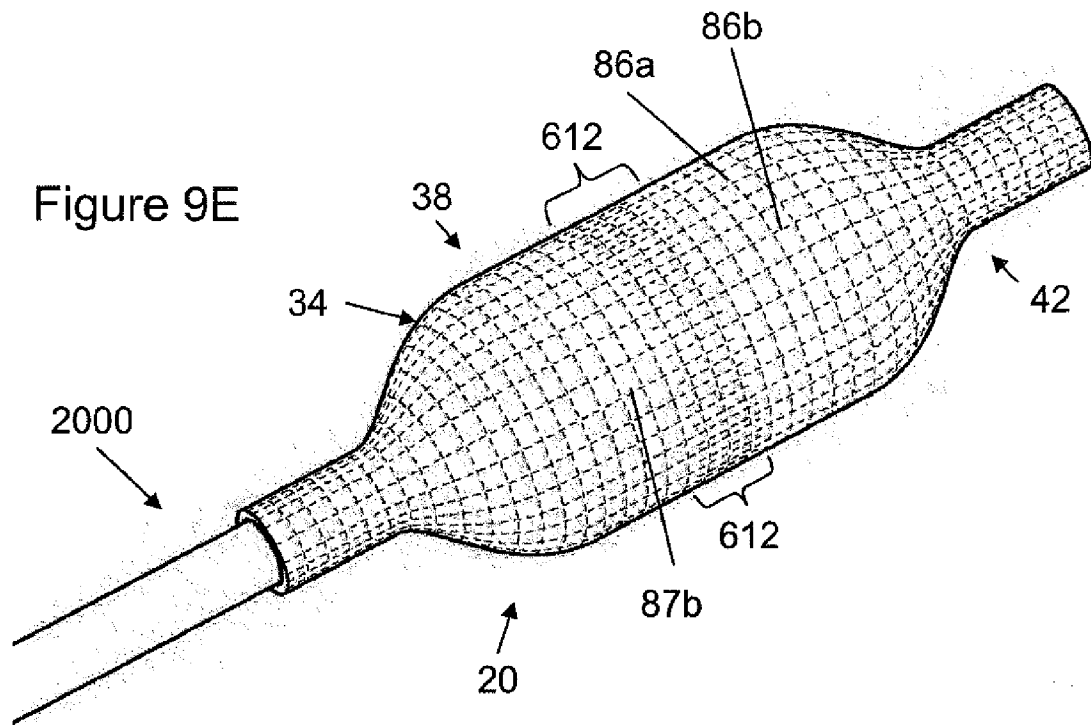


Figure 9F

Figure 9G

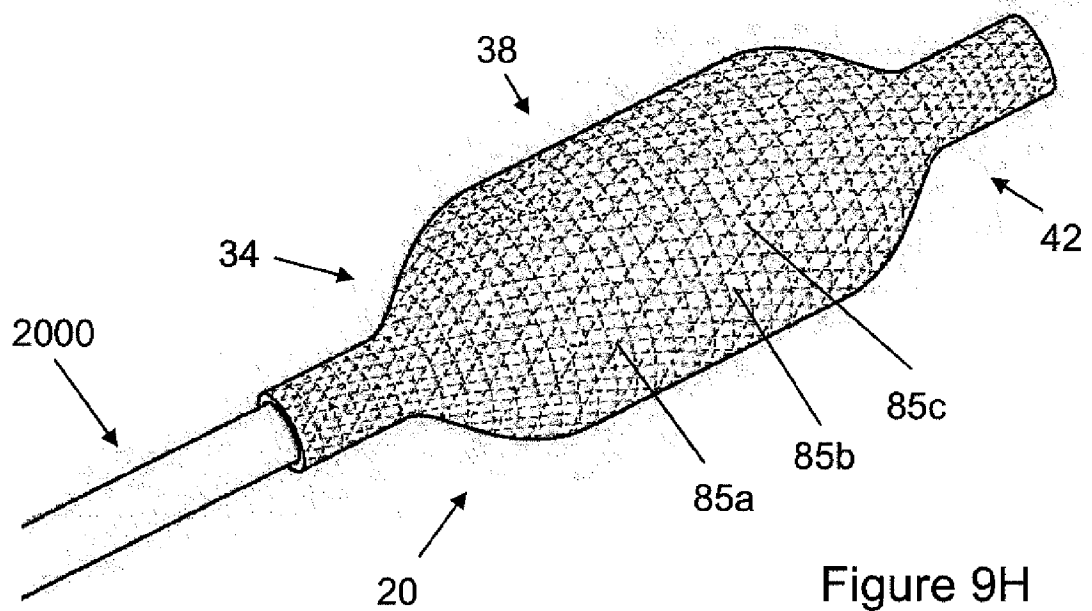
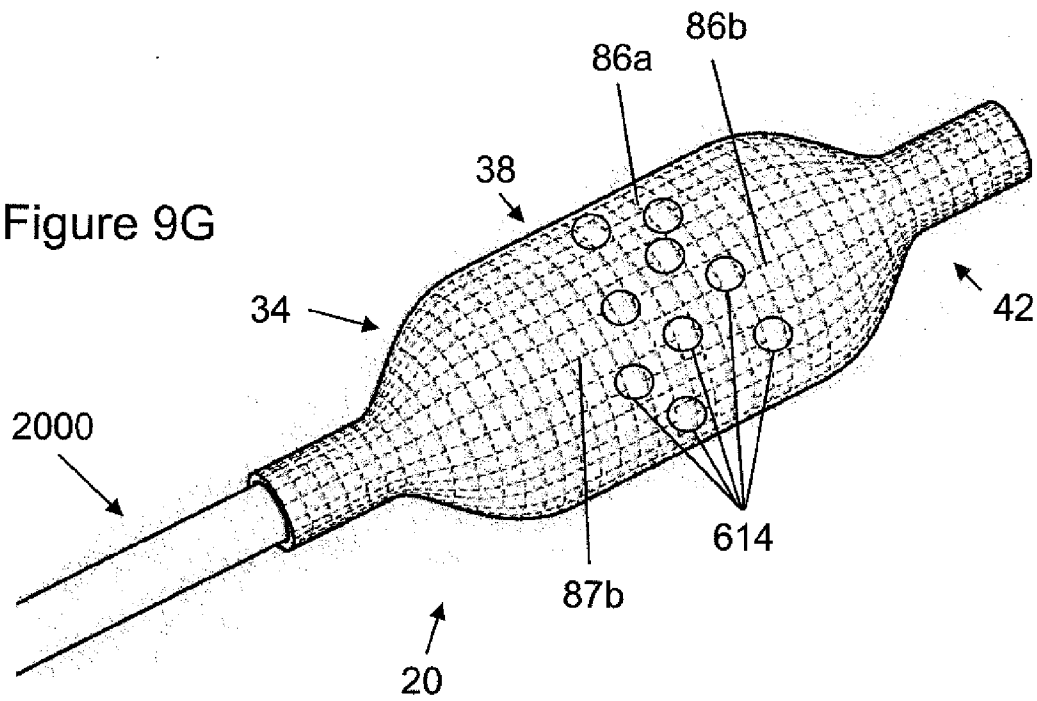
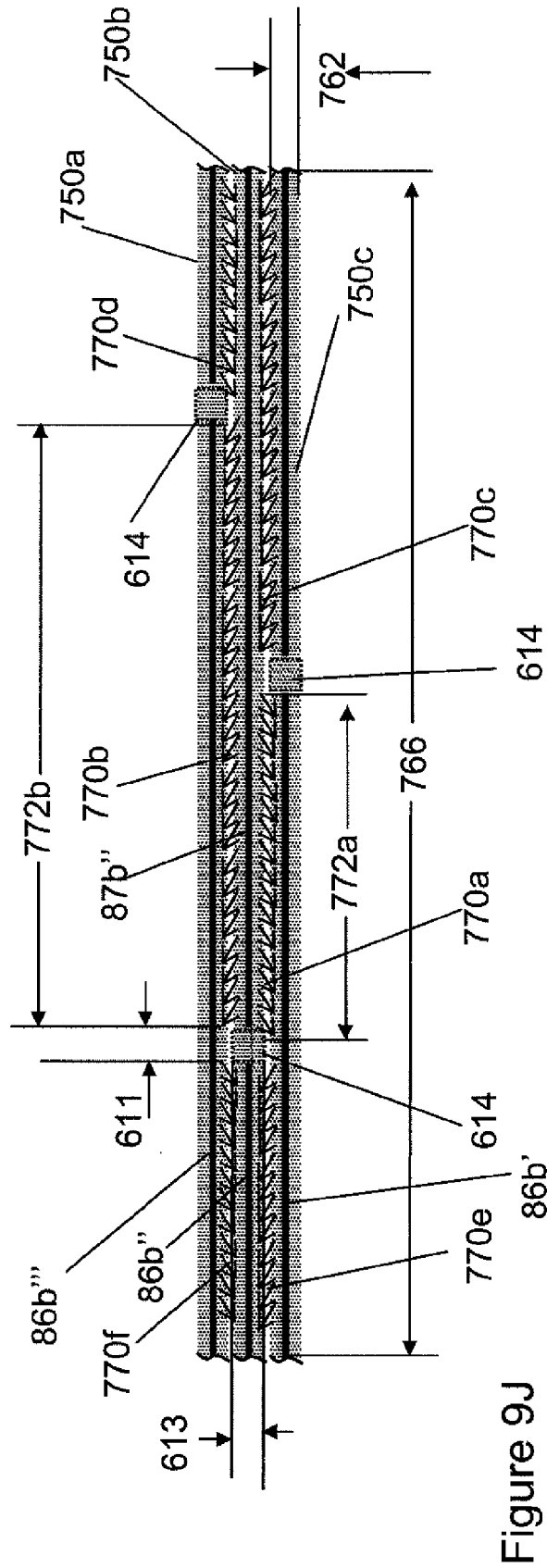
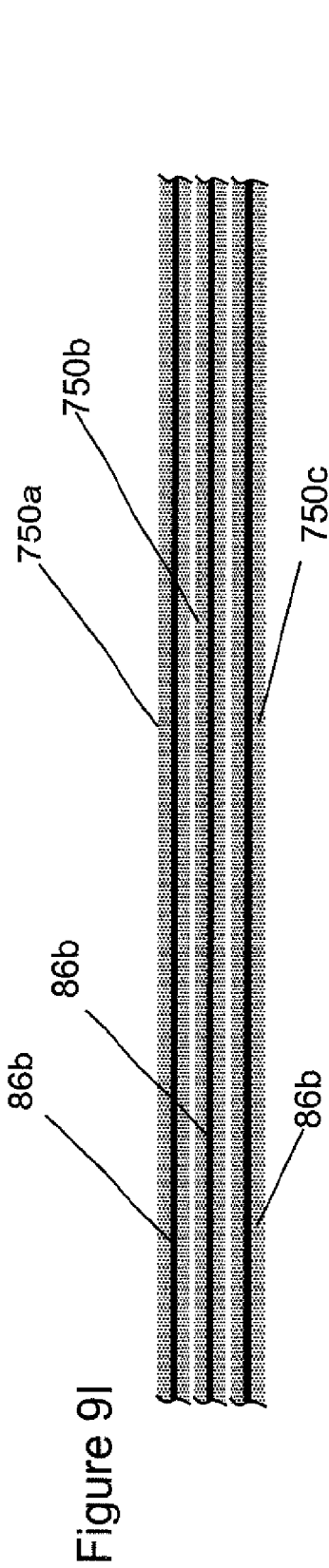
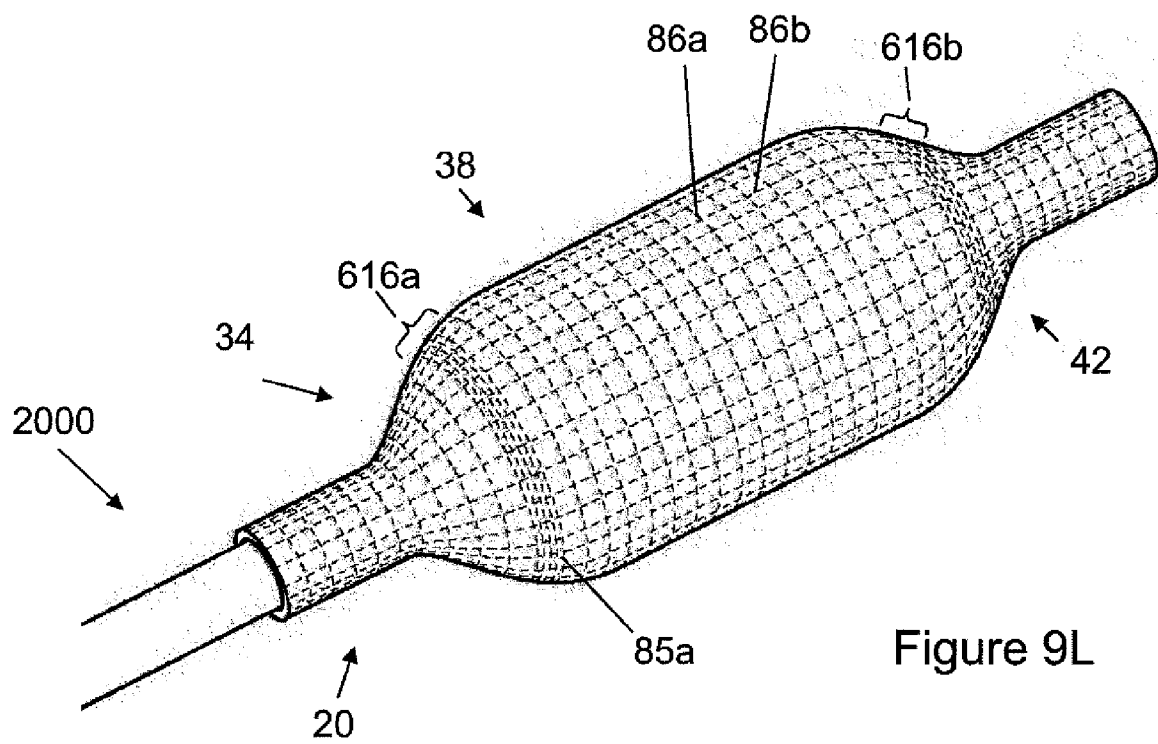
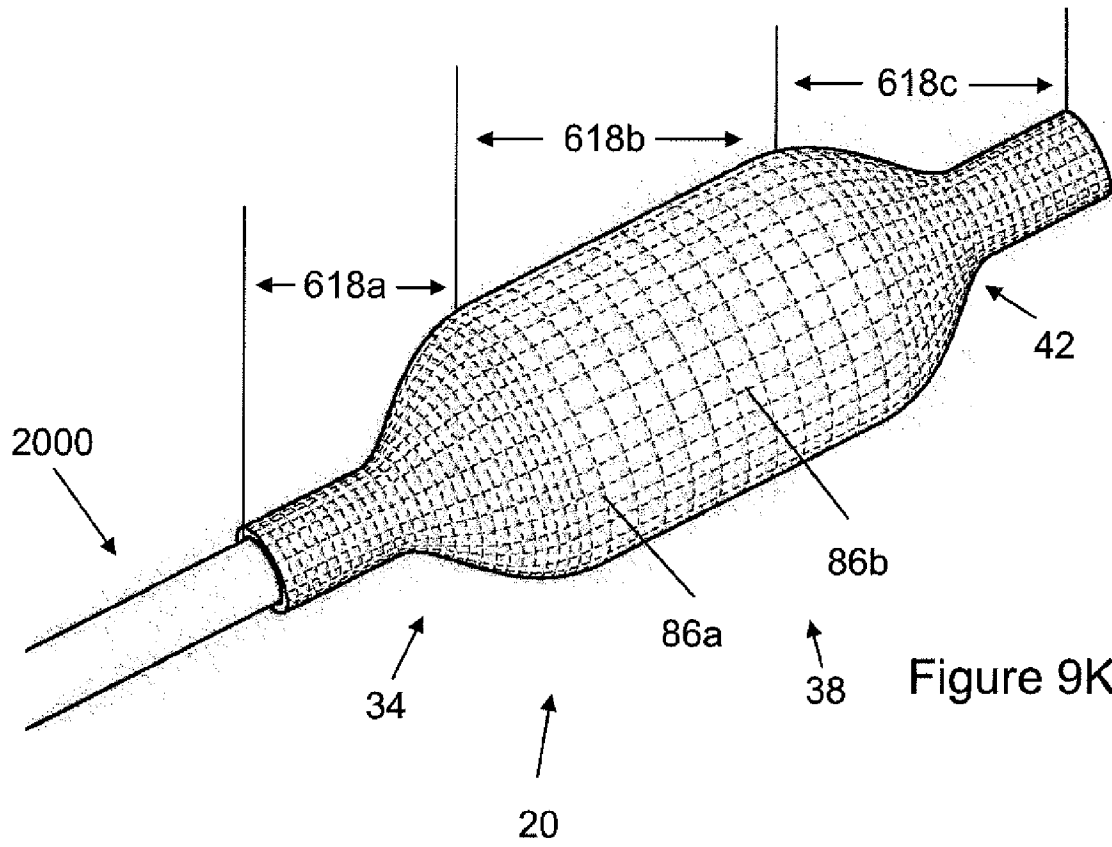


Figure 9H





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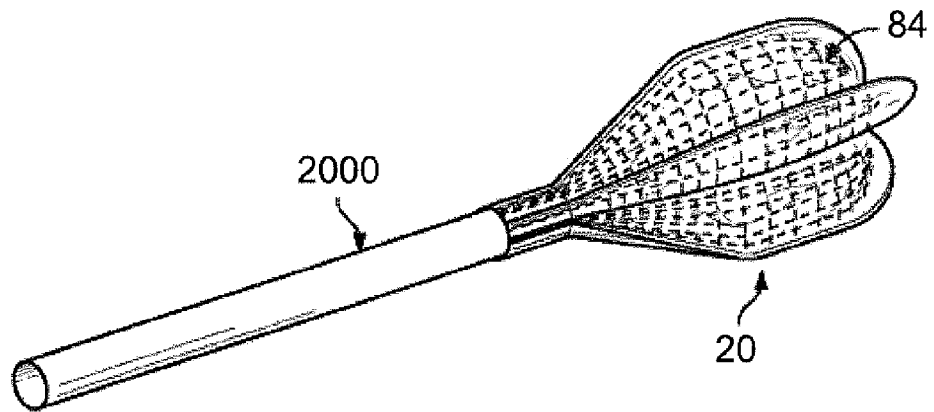


Figure 10A

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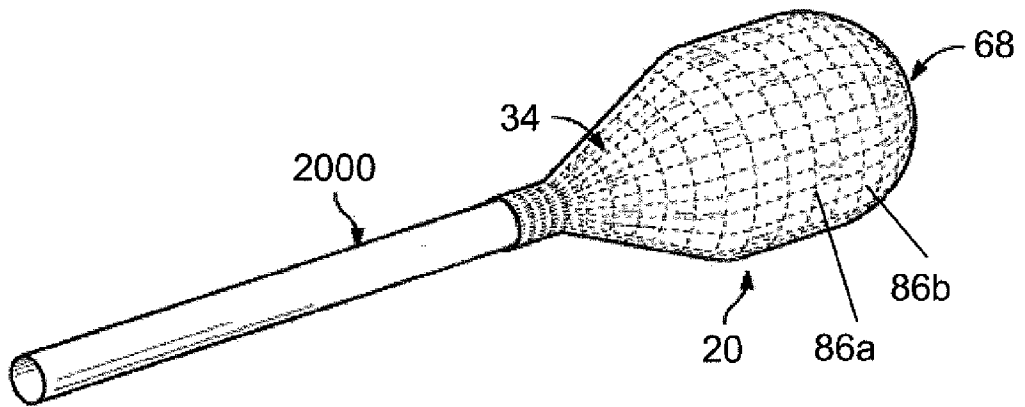


Figure 10B

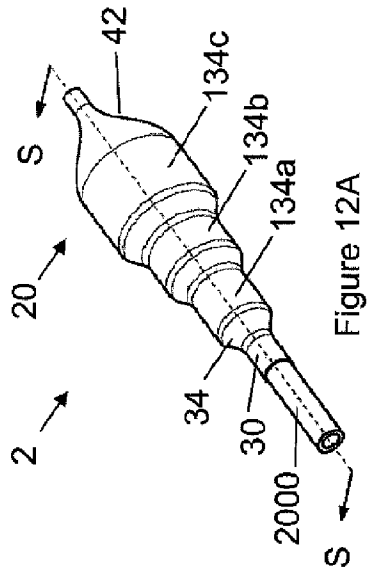


Figure 12A

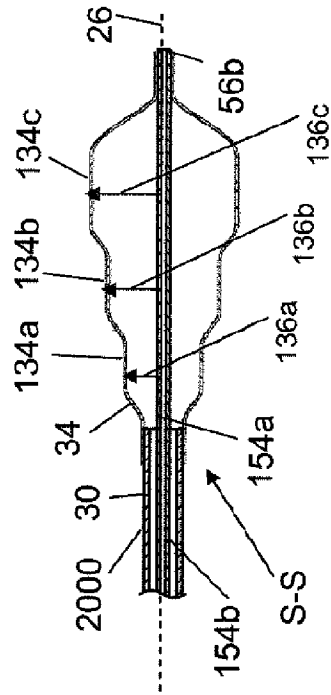


Figure 12B

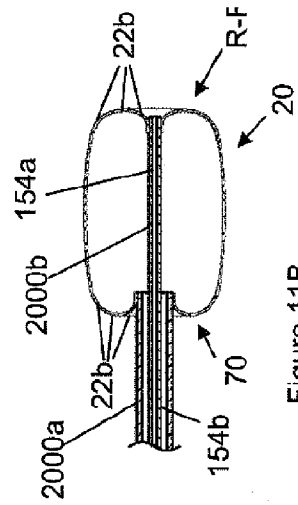


Figure 11B

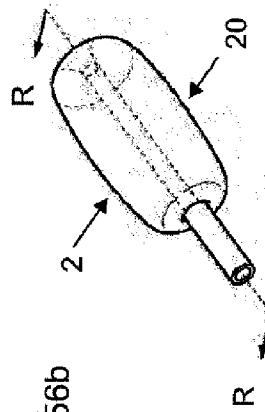


Figure 11A

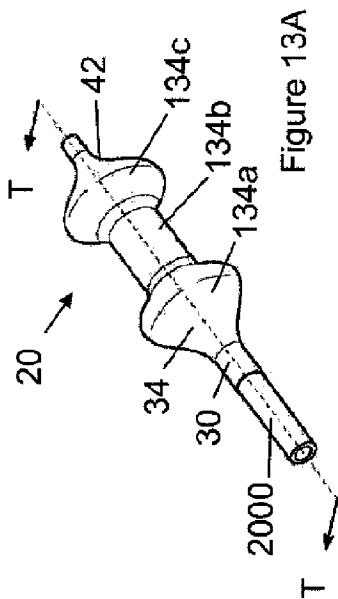


Figure 13A

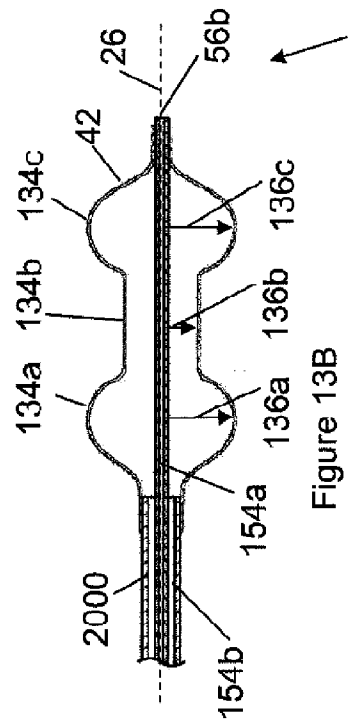


Figure 13B

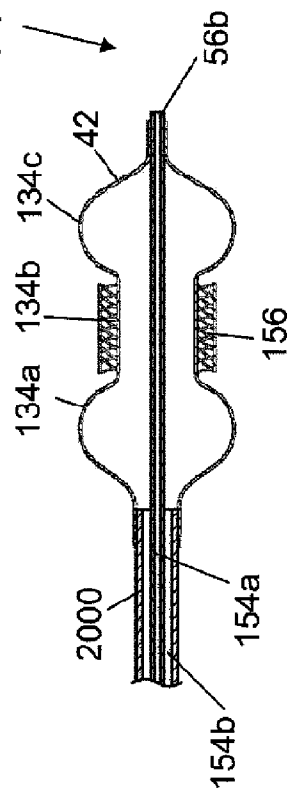
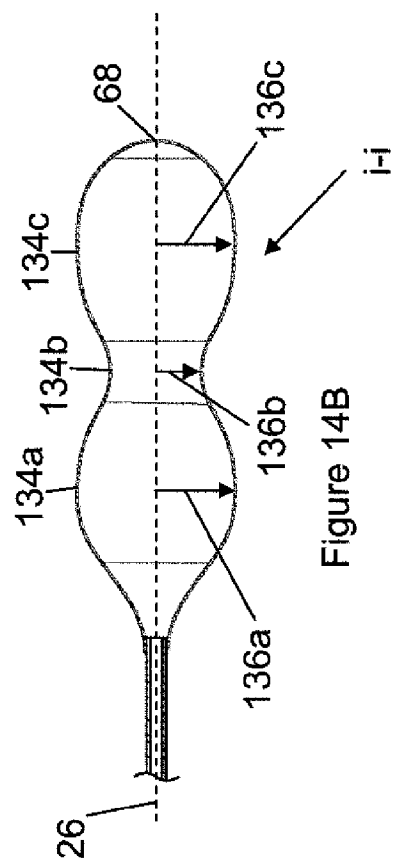
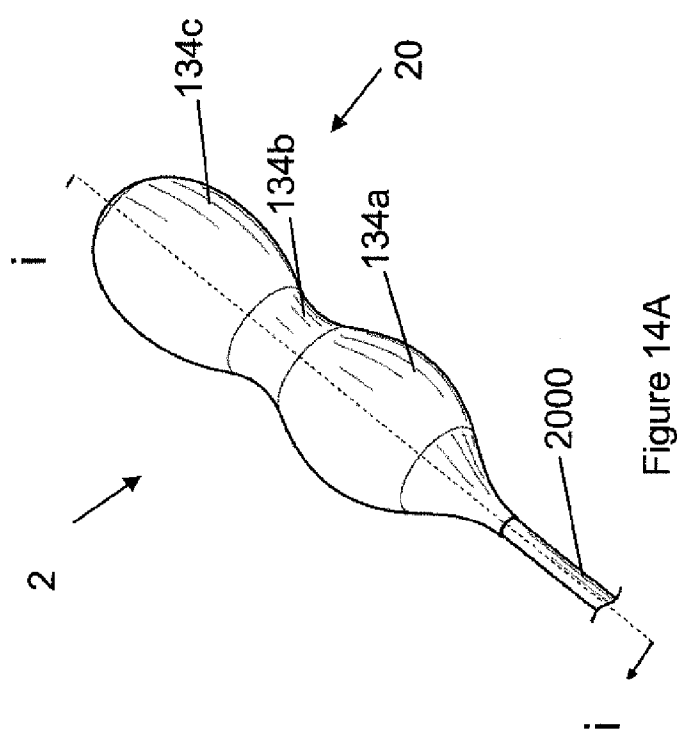
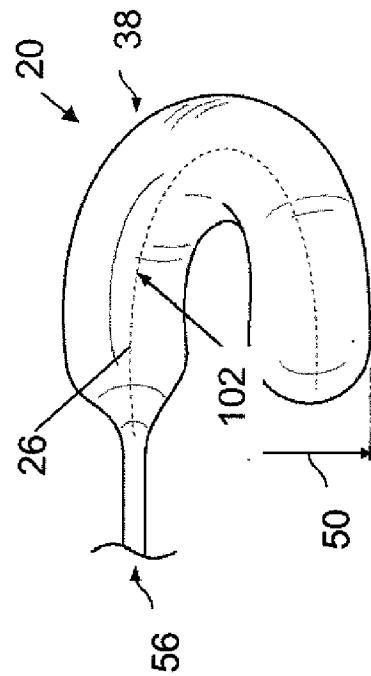
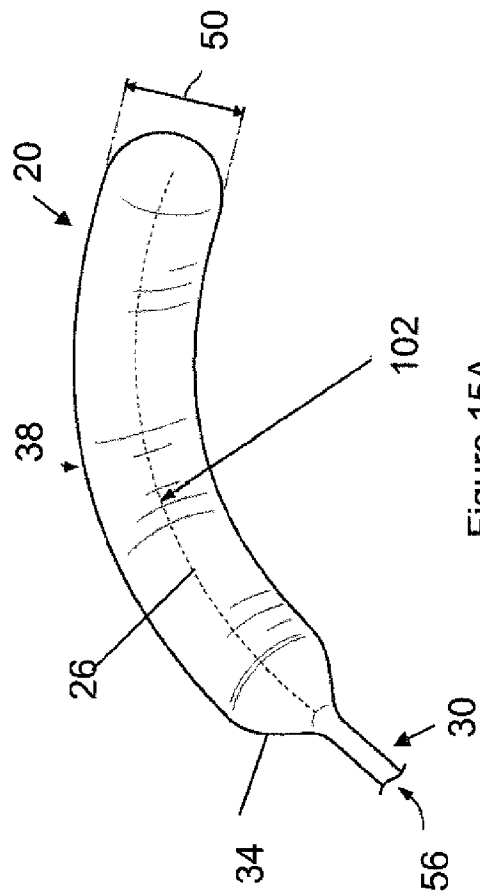


Figure 13C



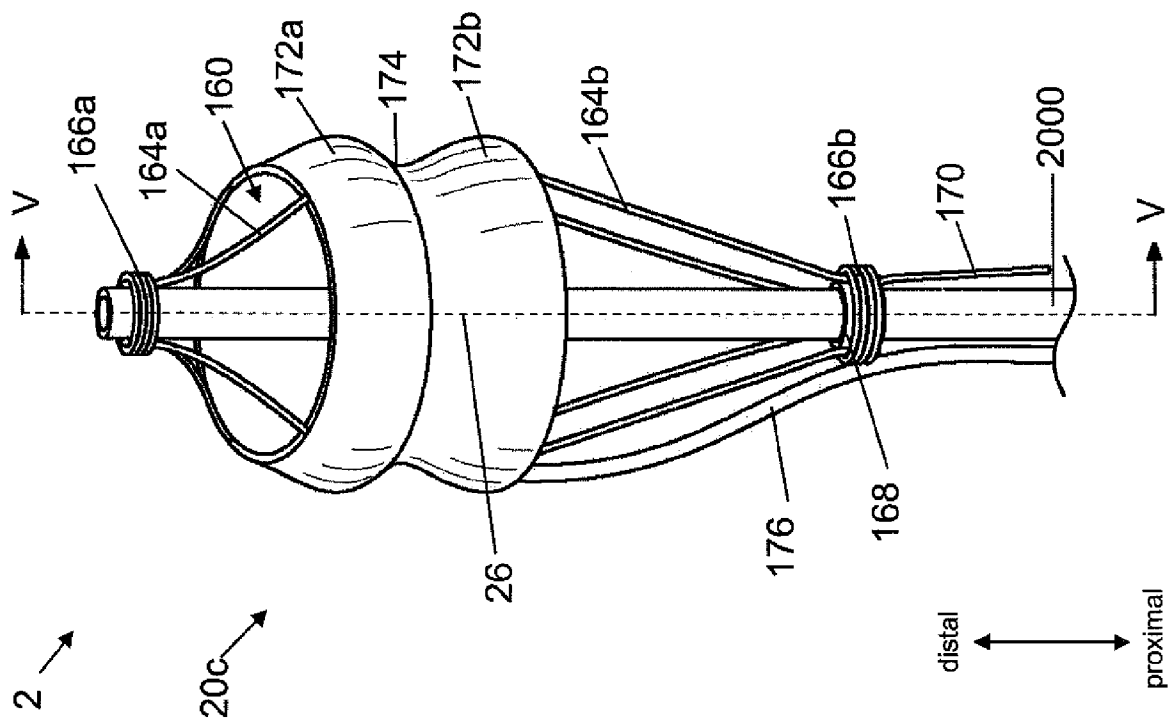


Figure 16A

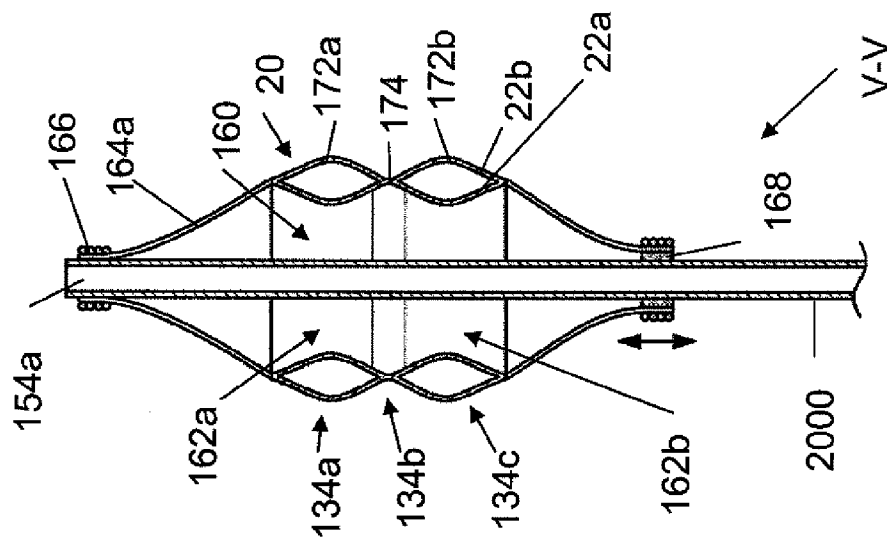


Figure 16B

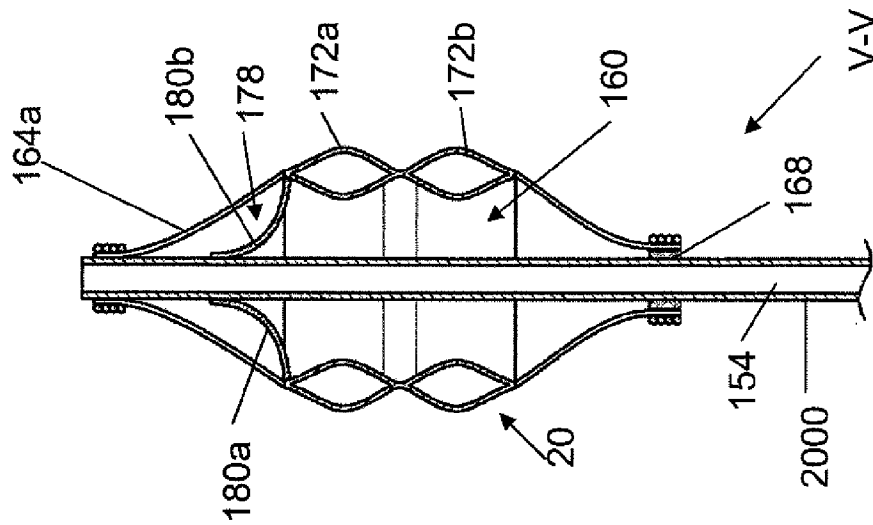
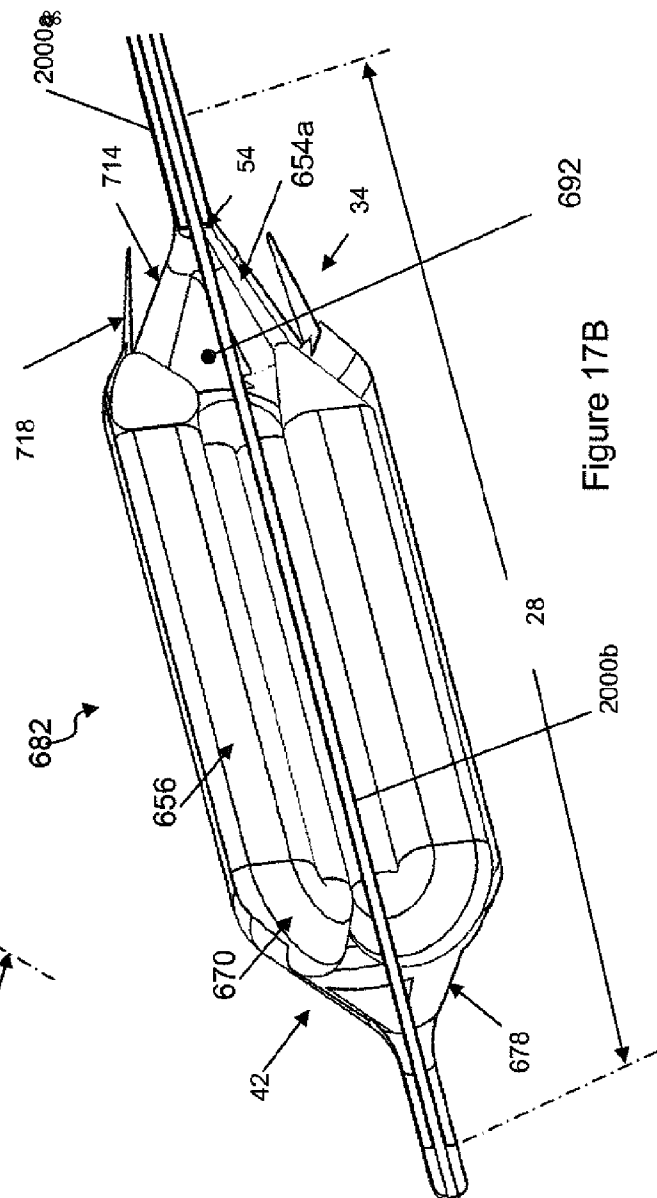
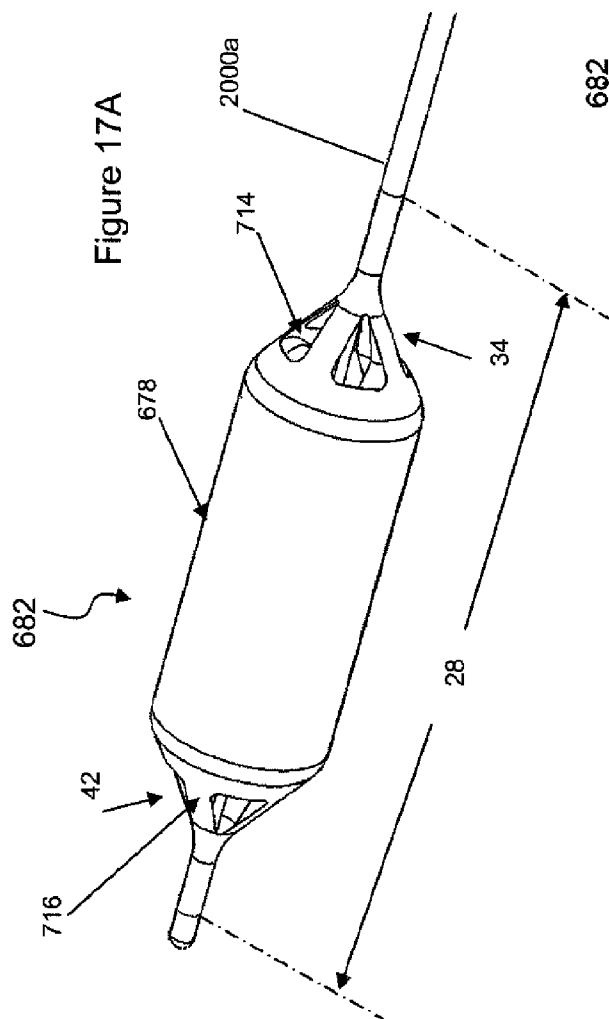
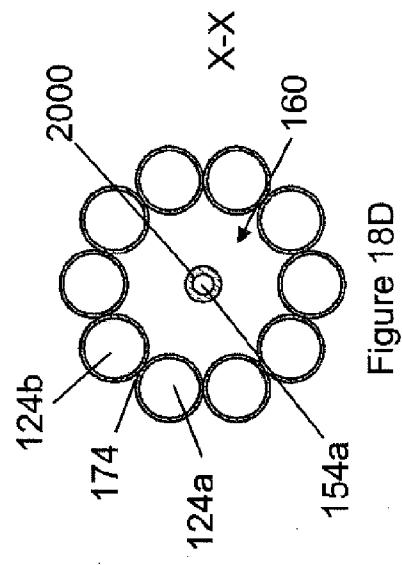
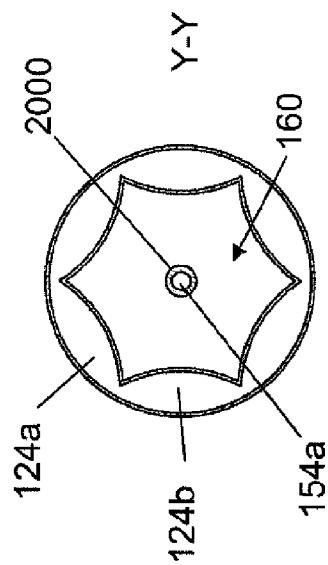
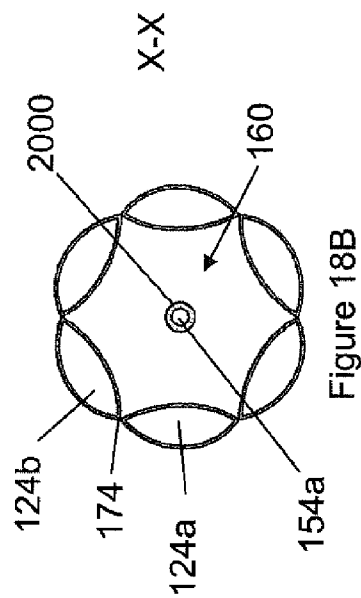
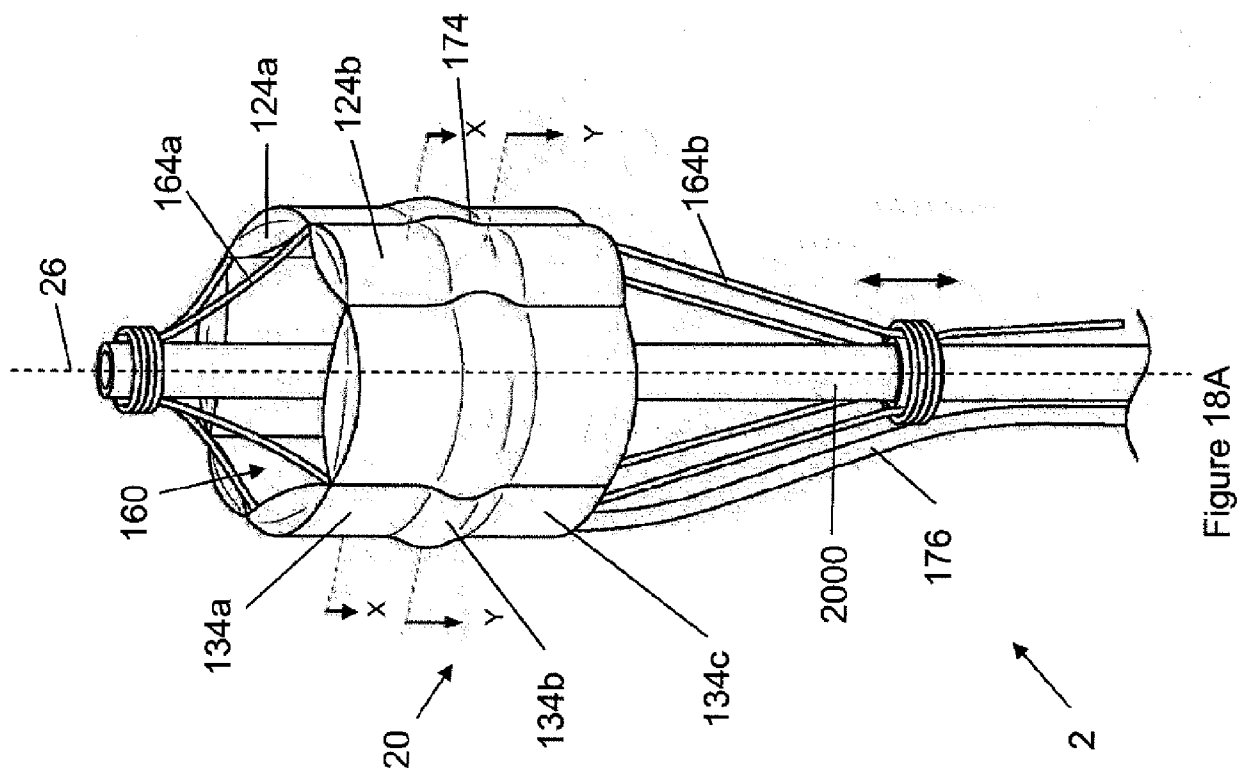


Figure 16C





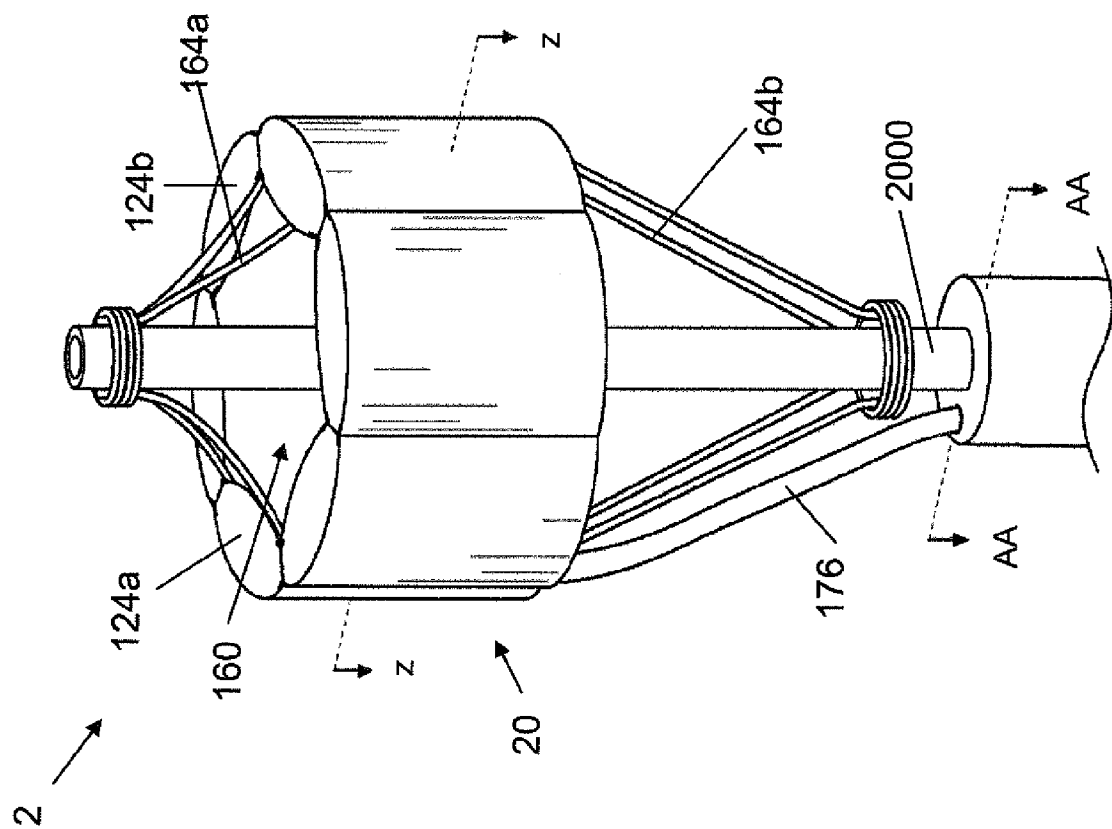


Figure 19A

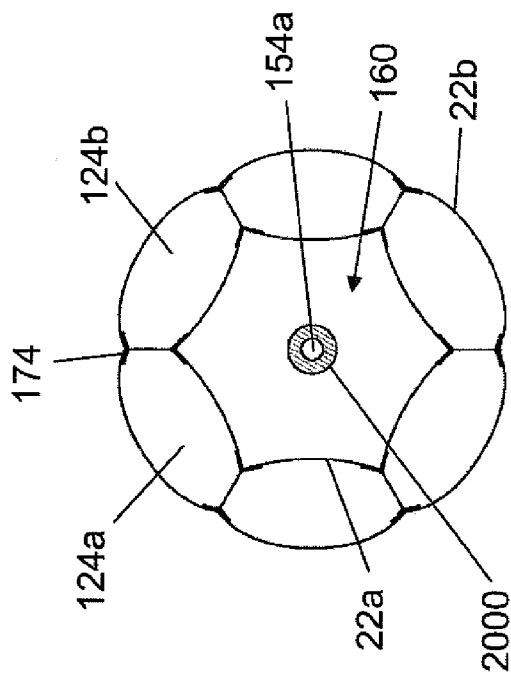


Figure 19B

Z-Z

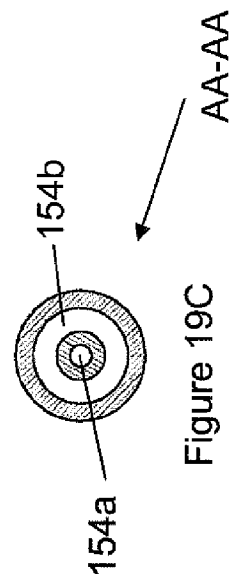
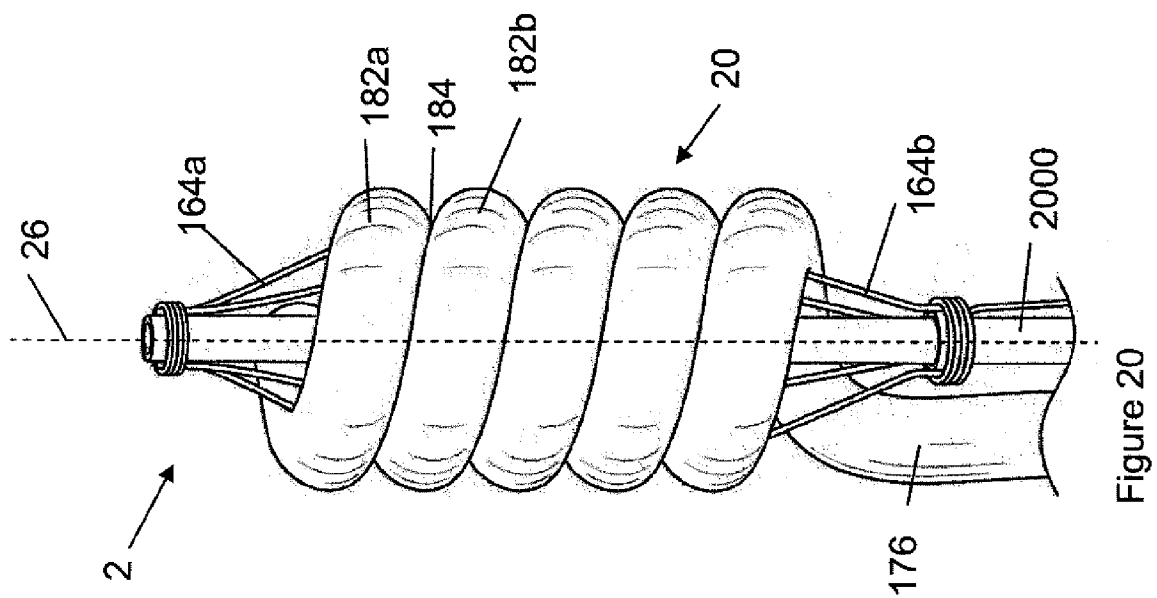
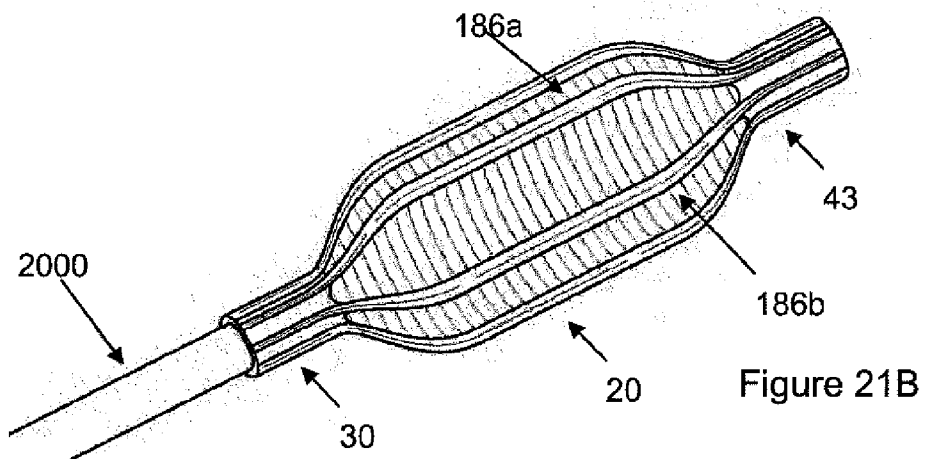
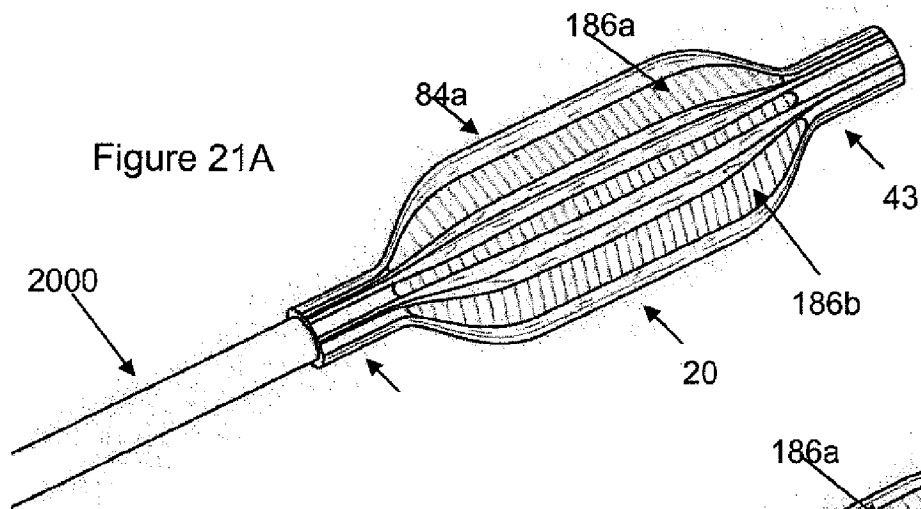
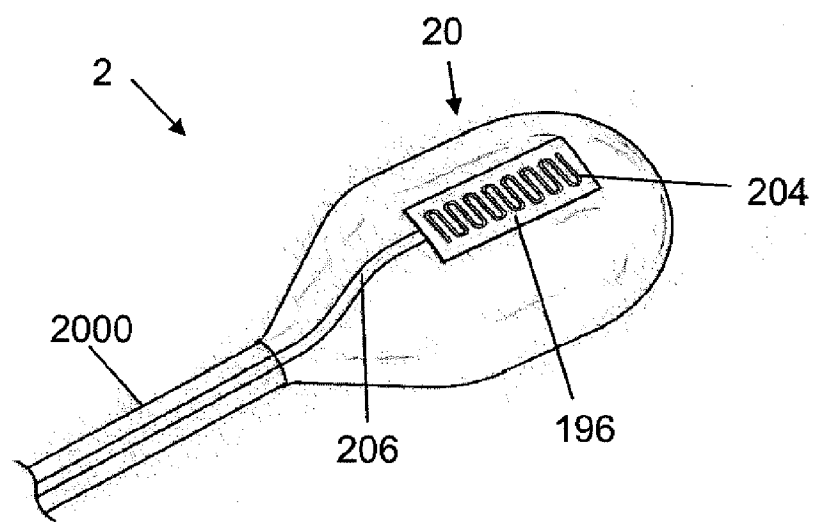
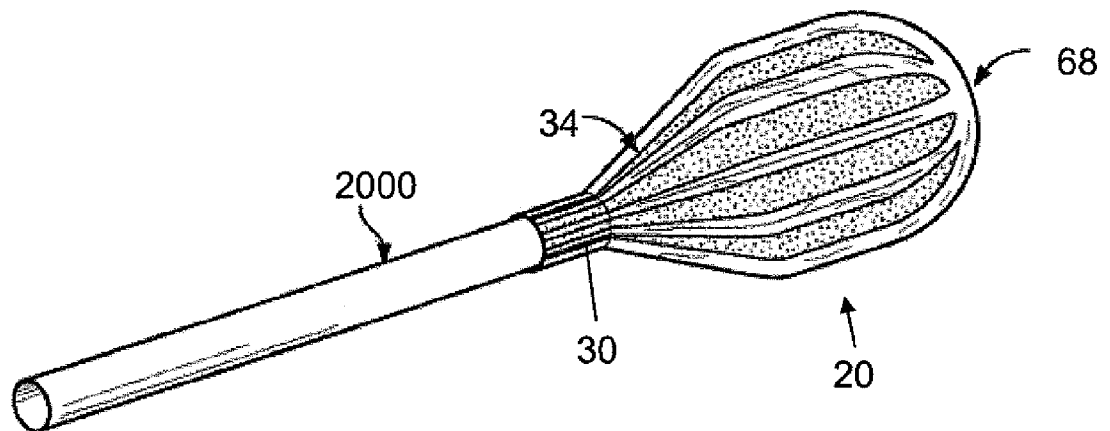
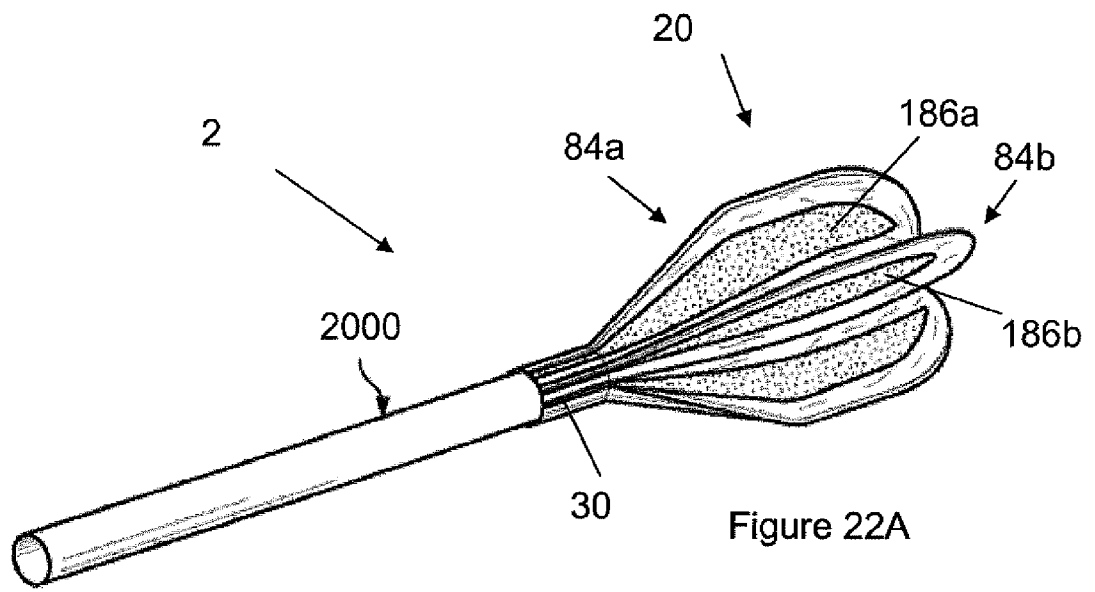


Figure 19C

AA-AA





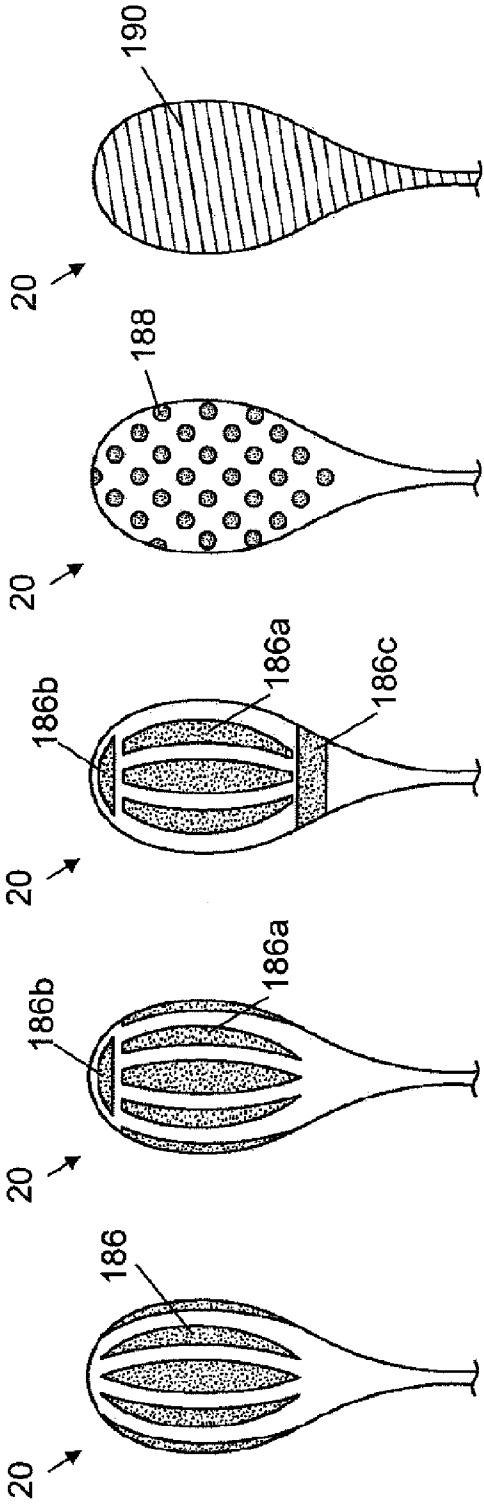


Figure 23E

Figure 23D

Figure 23C

Figure 23B

Figure 23A

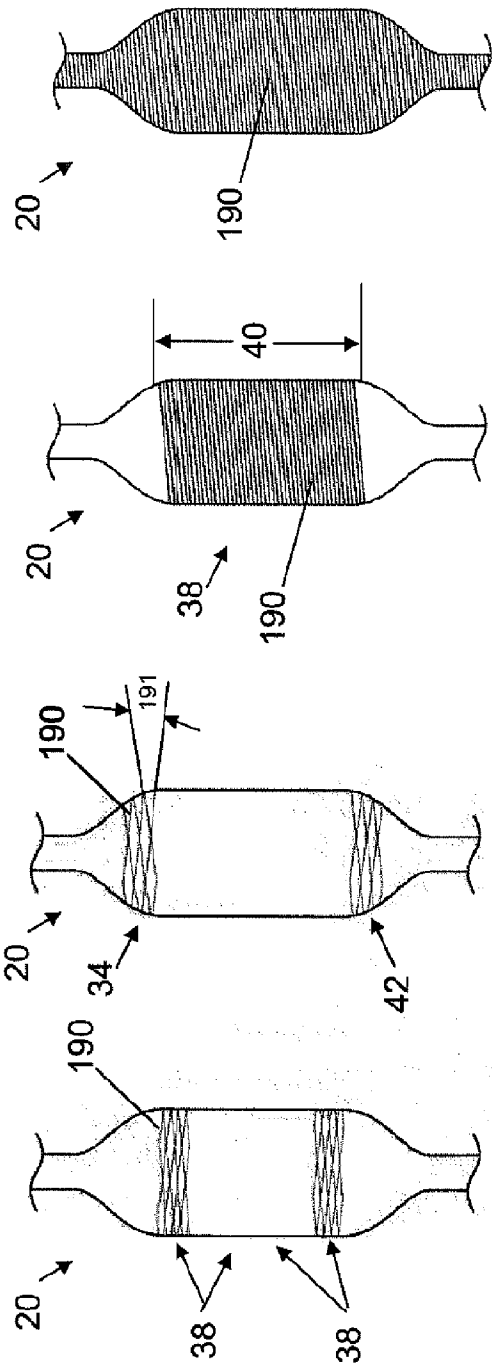
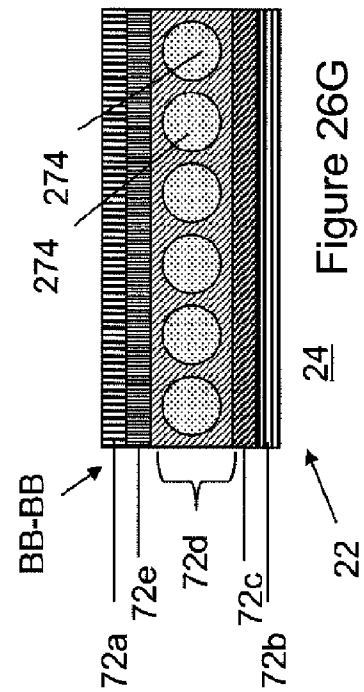
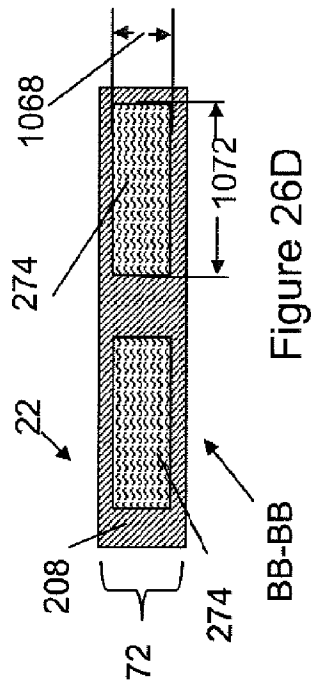
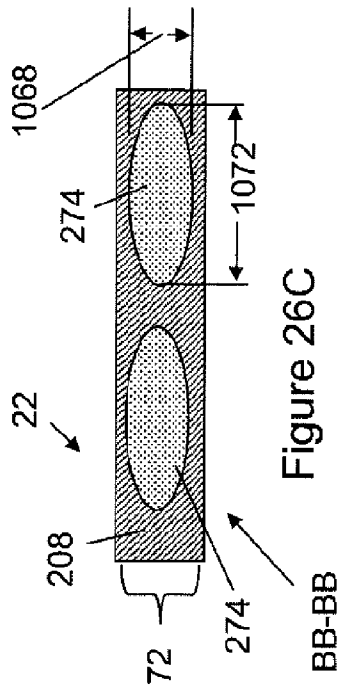
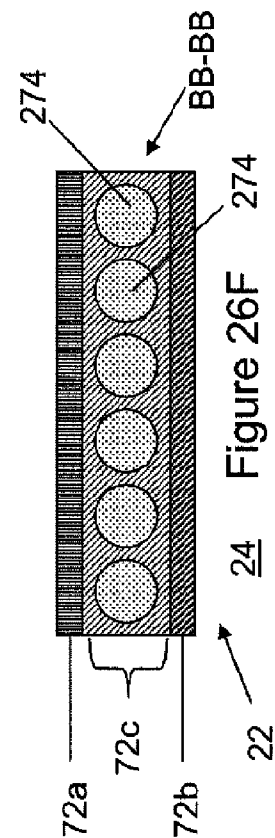
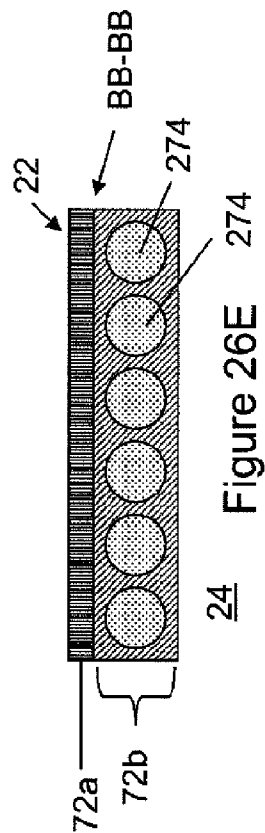
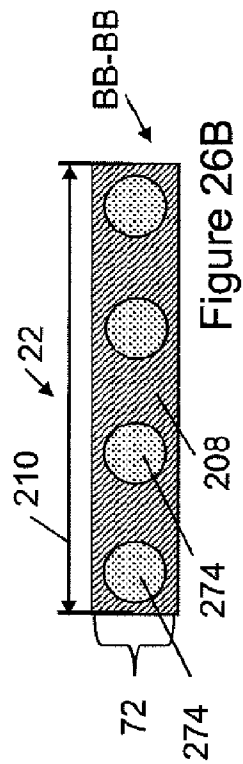
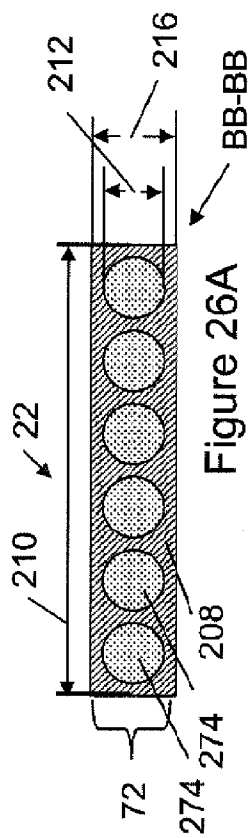


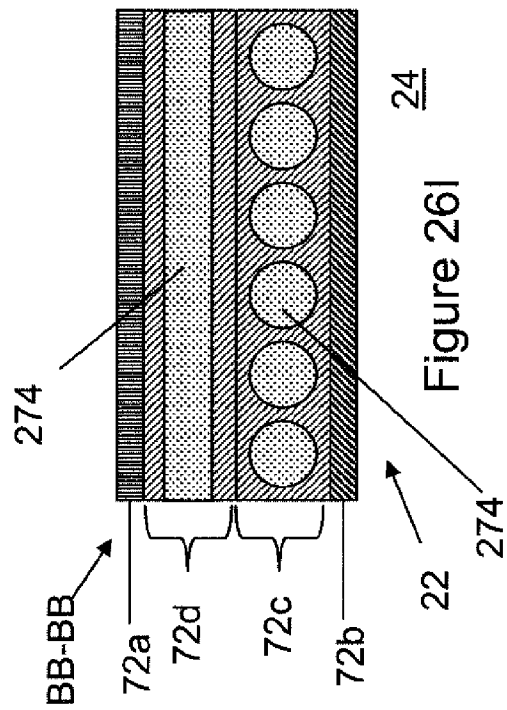
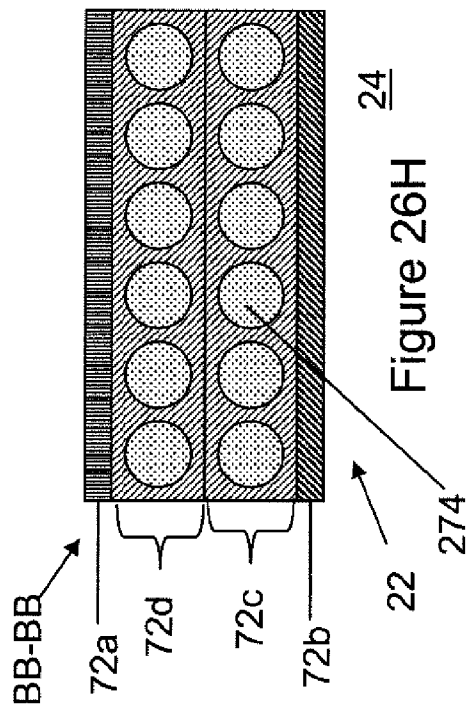
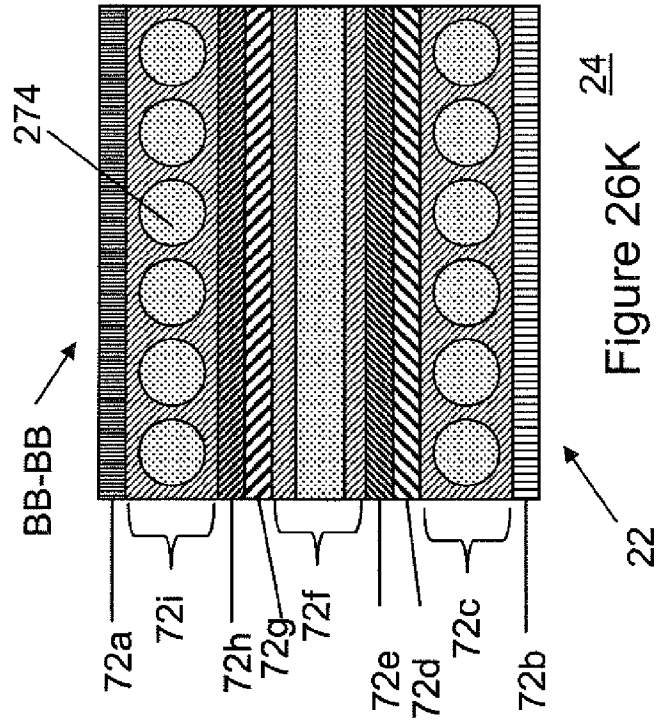
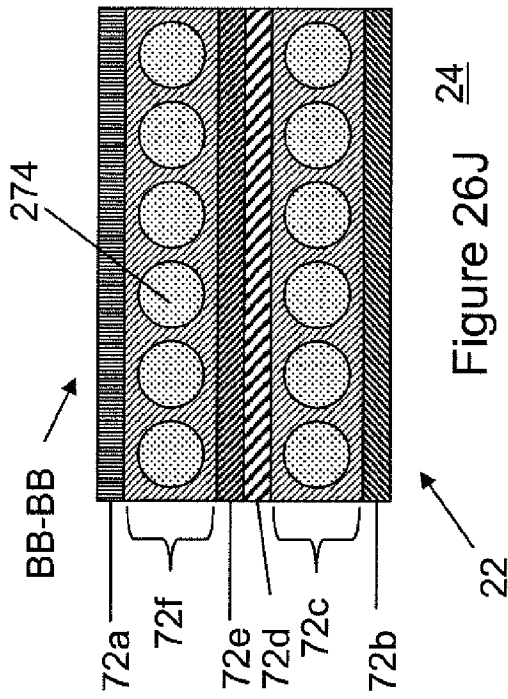
Figure 24D

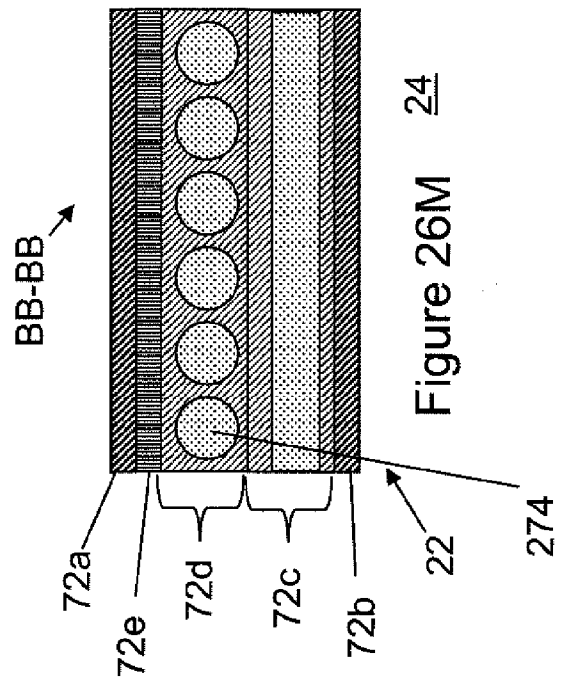
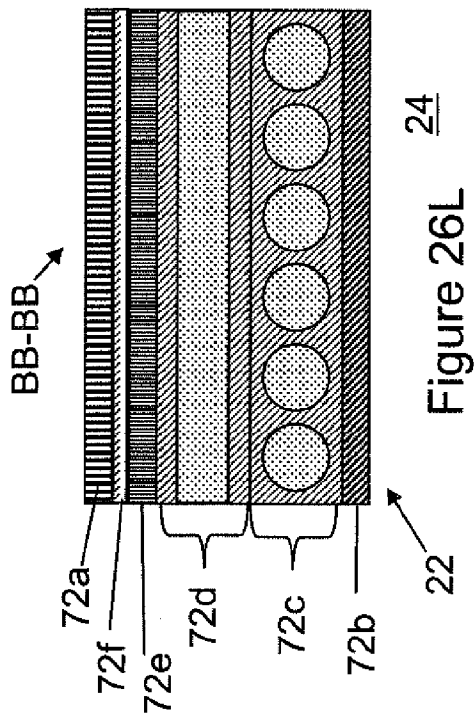
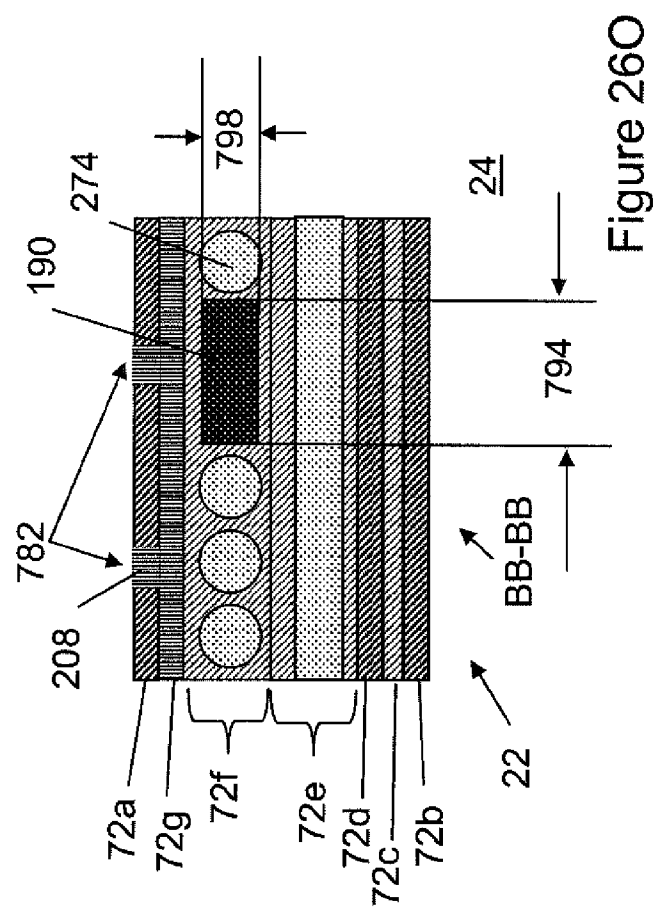
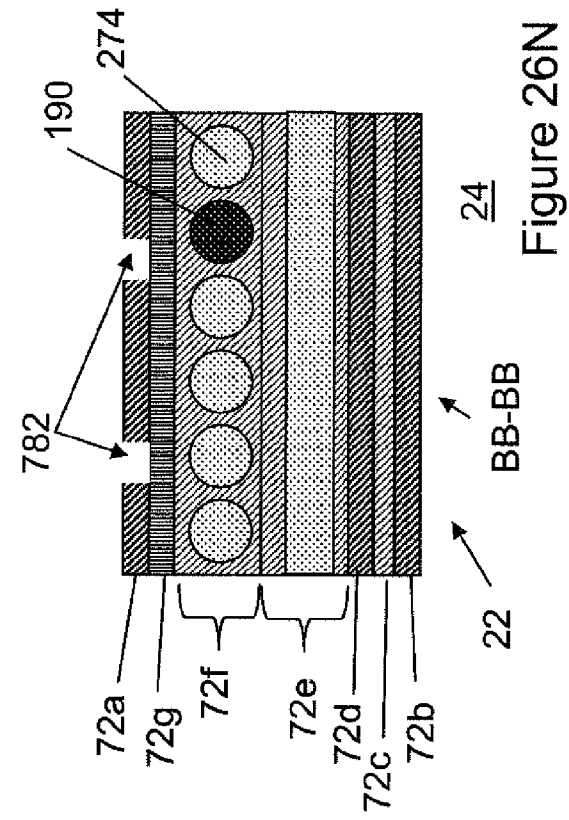
Figure 24C

Figure 24B

Figure 24A







Film Materials

Type	Sample Manufacturer or Supplier
Co-Polyamide	Deerfield Urethane, USA
Co-Polyester	Deerfield Urethane, USA
ECTFE	Saint-Gobain, France
FEP (Fluoroethylene-propylene)	DuPont, USA
Kapton	DuPont, USA
HDPE	Dow Chemical, USA
LDPE	Lyondell Chemical, USA
Mylar / PET (Polyethylene Terephthalate) / Polyester	DuPont, USA
Nylon	Honeywell, USA
PEEK	Victrex, UK
PEN (Polyethylene Naphthalate)	DuPont, USA
Tedlar (PVF)	DuPont, USA
Thermoplastic Polyurethane (TPU)	Deerfield Urethane, USA
Vectran (LCP (Liquid Crystal Polymer))	Hoechst-Celanes, USA
Solef	Solvay, Italy
Parylene	Para Tech Coating, USA

Figure 27

Reinforcement material

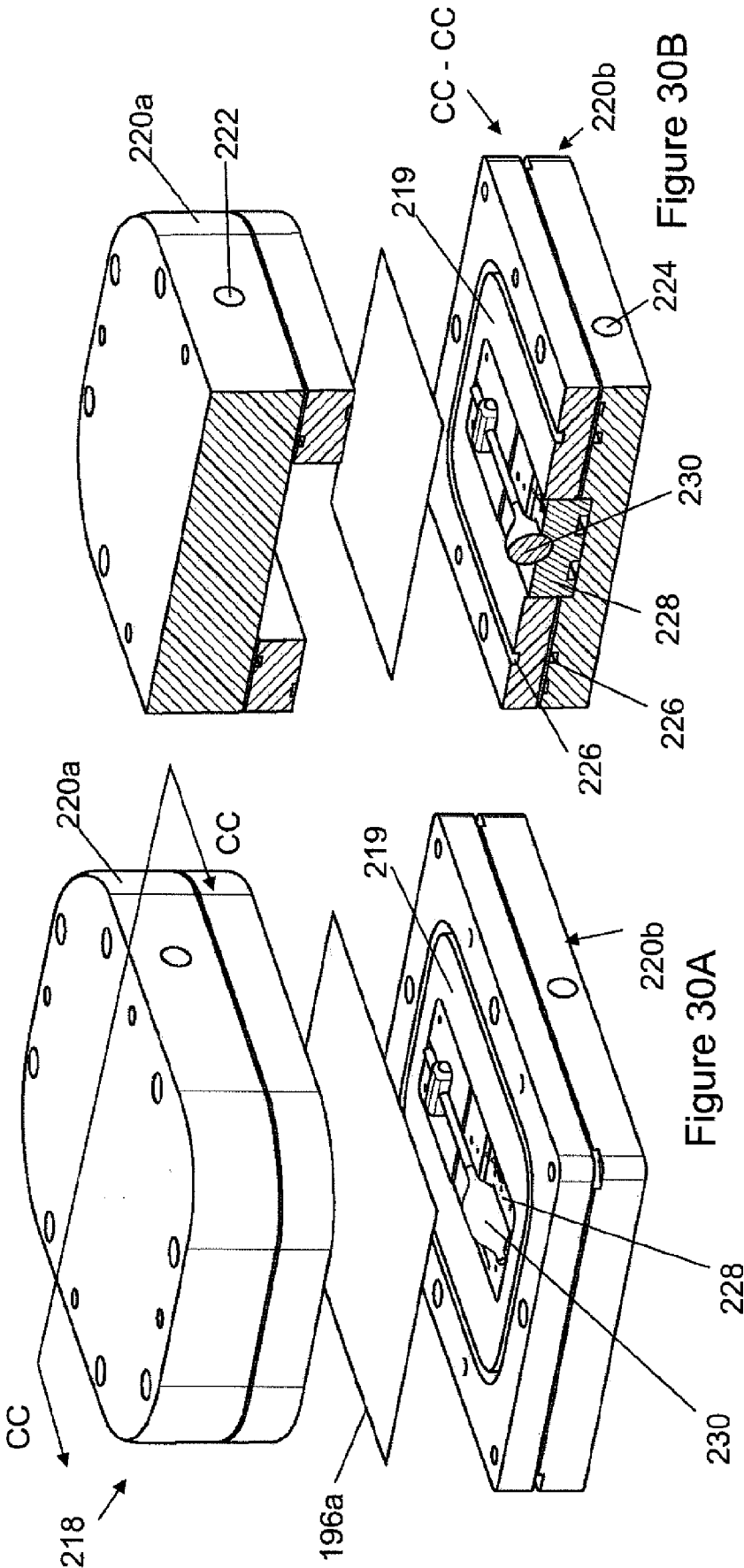
Type	Sample Manufacturer or Supplier
Vectran	Hoechst-Celanese, USA
PBO	Toyobo, Japan
Spectra	Allied Signal, USA
Conex	Teijin, Japan
Dyneema	DSM, Netherlands
Technora	Teijin, Japan
Dacron	DuPont, USA
Polyester	Hoechst-Celanese, USA
Combet	Allied Signal, USA
Nylon	DuPont, USA
PEEK	ICI-Fiberite, USA
PPS	Phillips Petroleum, USA
Boron Fiber	AVCO-Textron, USA
Ceramic Fiber	AVCO-Textron, USA
Kevlar	DuPont, USA
Inorganic Carbon/Carbon Fiber	Hercules Inc., USA
Inorganic Silicon/high strength fiberglass	Owens Corning Fiber, USA
Organic Polymer/Aramid	DuPont, USA
Twaron	Teijin, Japan
Tungsten and its alloys	California Fine Wire, USA
Molybdenum and its alloys	California Fine Wire, USA
Stainless Steel (302, 304, 316, 316L and other alloys)	California Fine Wire, USA
Nickel/cobalt alloys	California Fine Wire, USA
Titanium and its alloys	California Fine Wire, USA
Nitinol alloys	NDC, USA

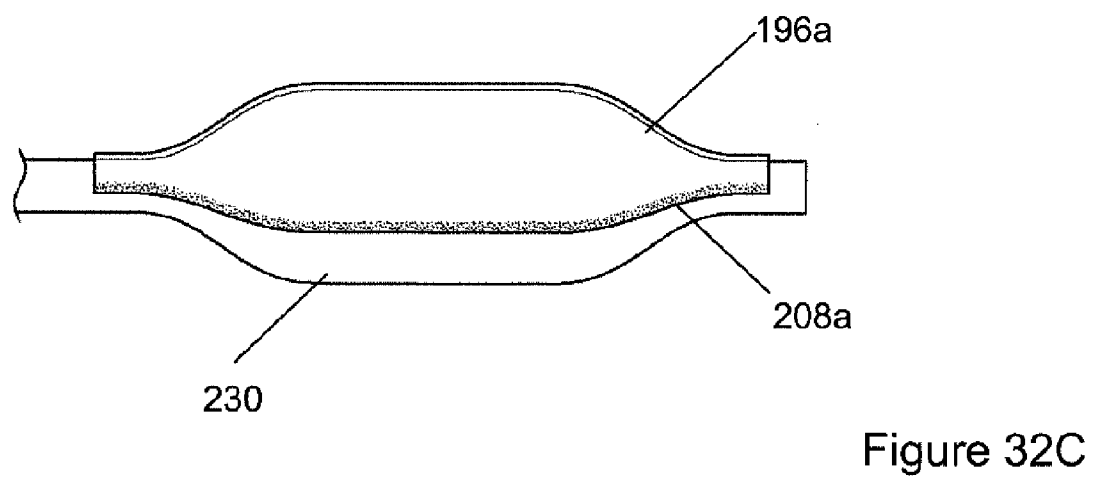
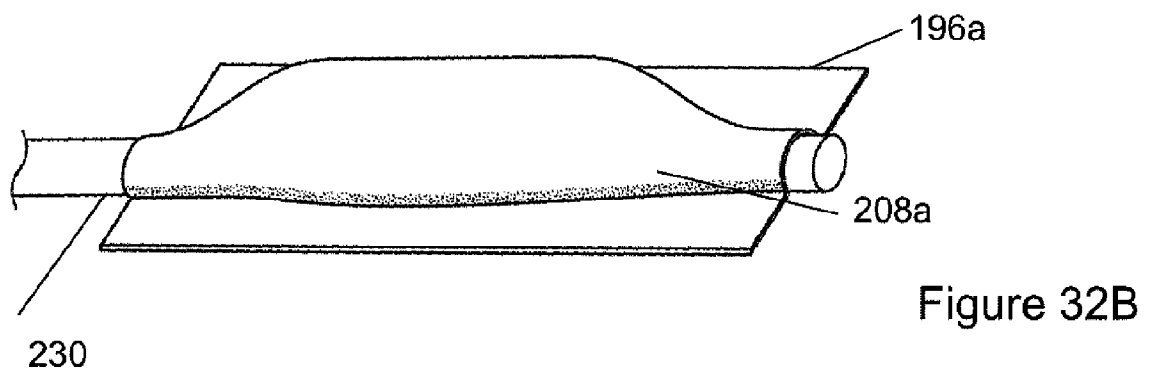
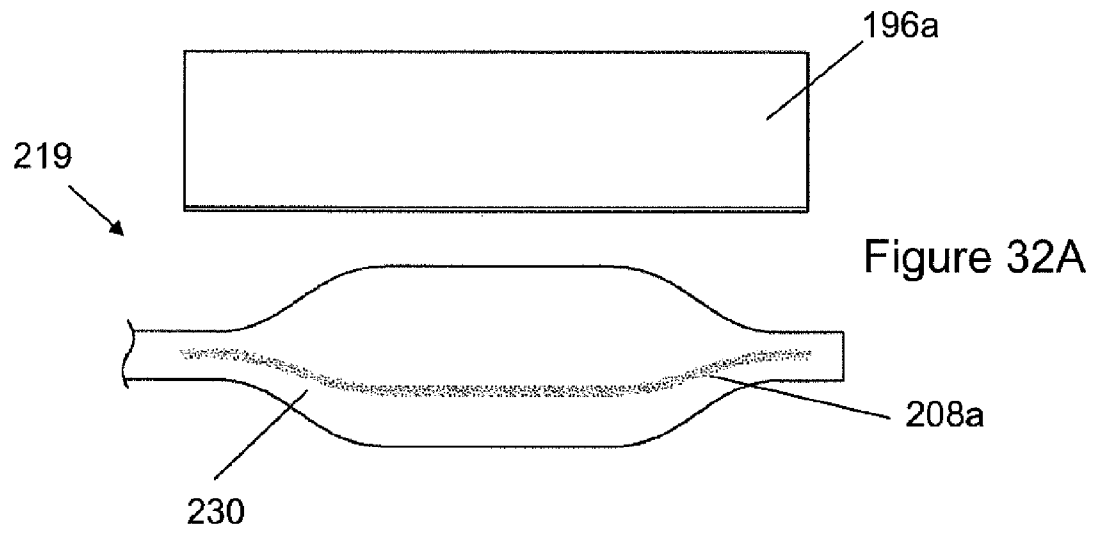
Figure 28

Adhesive and Matrix Materials

Type	Sample Manufacturer or Supplier
Urethanes	Hysol, USA
Polyesters	Thiokol, USA
Silicones	Dow Chemical, USA
Polypropylene	Honam Petrochemical, South Korea
Polyolefins	INEOS, UK
ULDPE, VLDPE, LDPE	ExxonMobil, USA
Nylon	Ashley Polymers, USA
Epoxies	Hysol, USA
Pebax	Arkema, USA
Tefzel	Dupont, USA
EVA	Dupont, USA
Solef	Solvay, Italy
Parylene	Para Tech Coating, USA

Figure 29





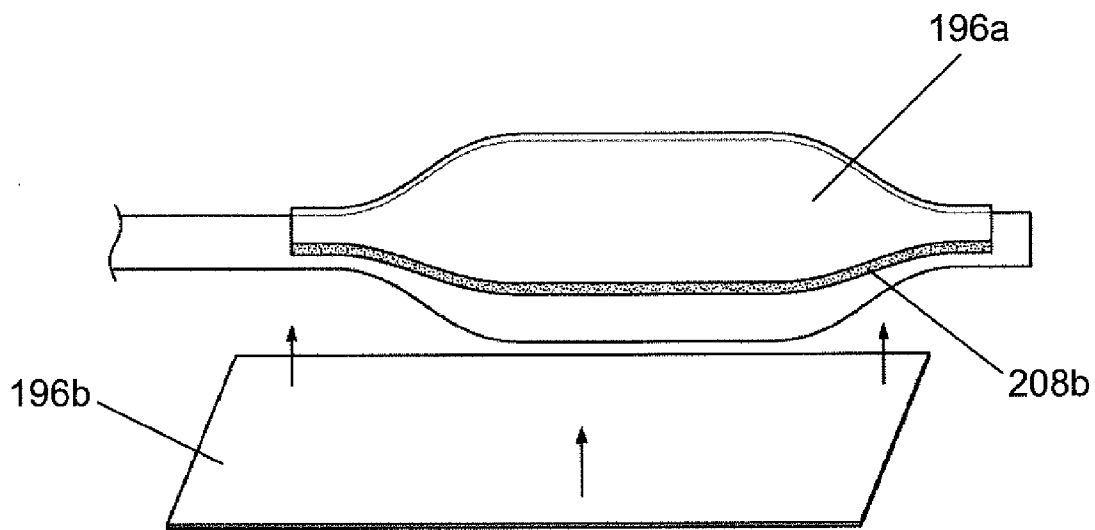


Figure 32D

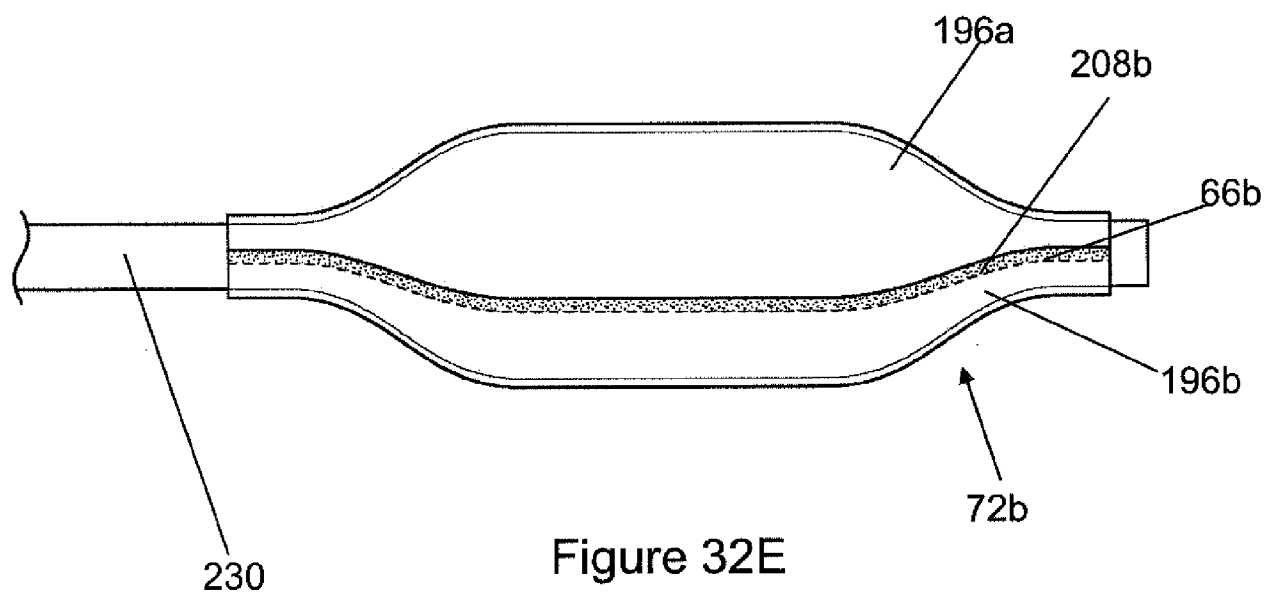
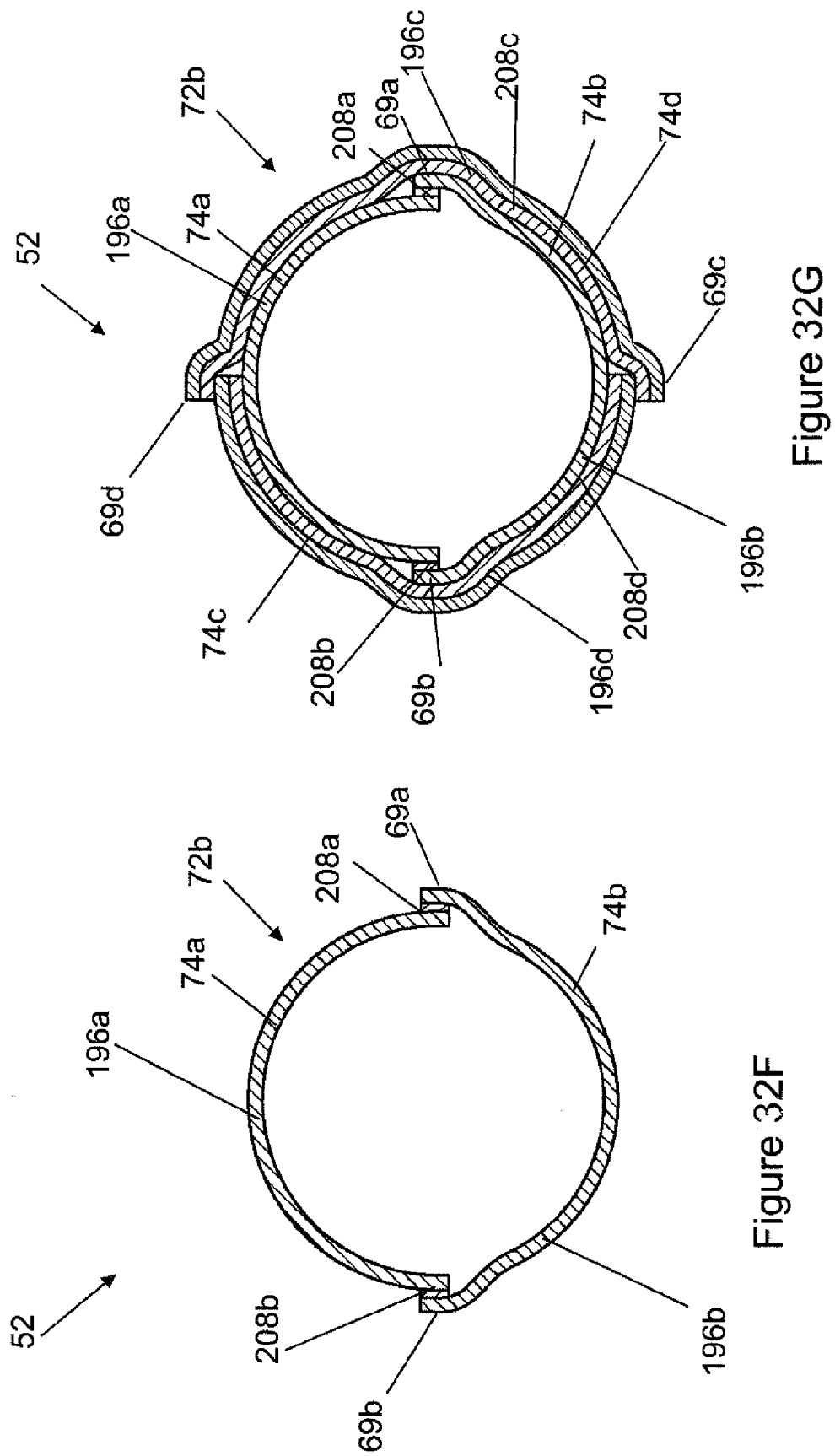


Figure 32E



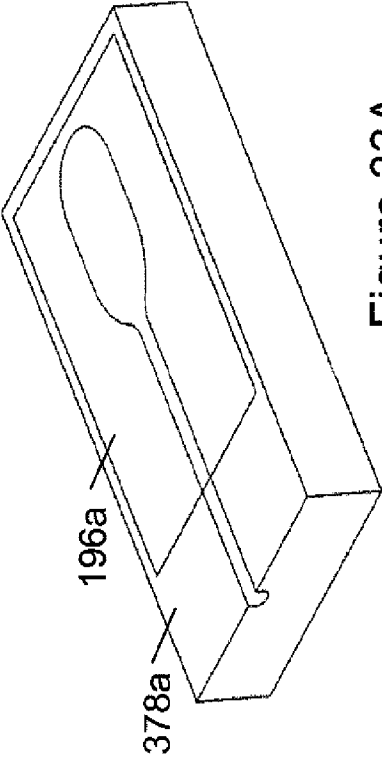


Figure 33A

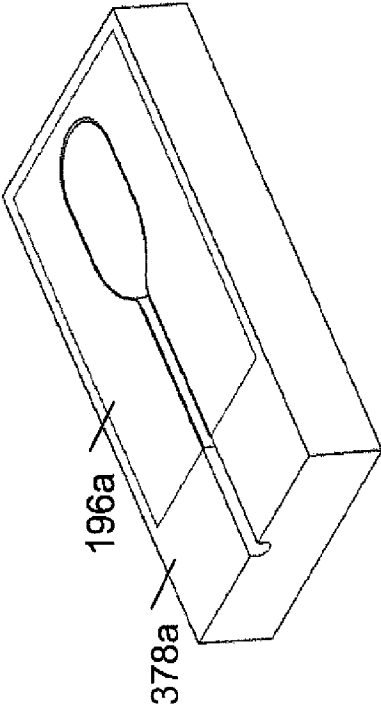


Figure 33B

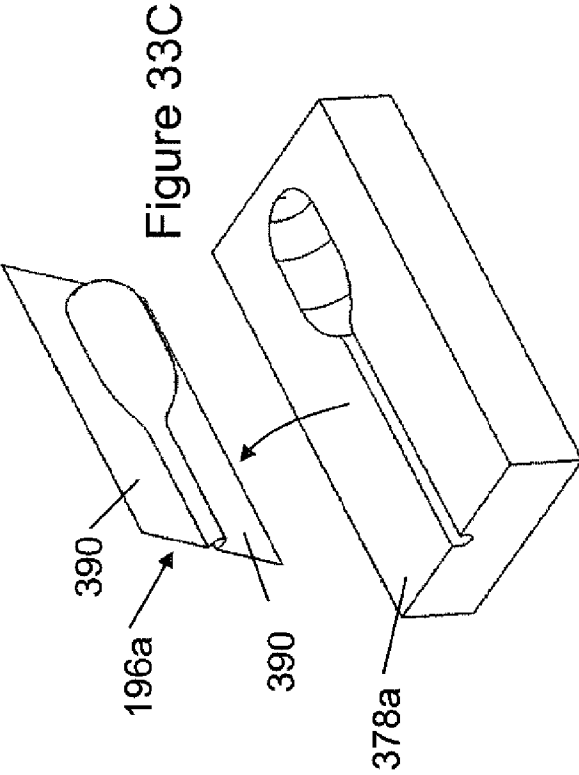


Figure 33C

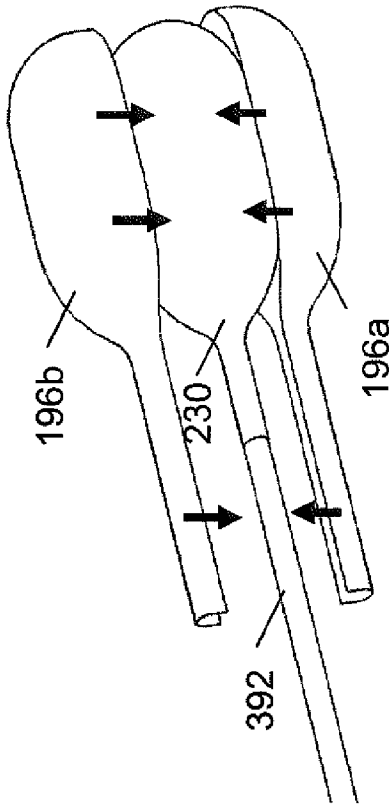
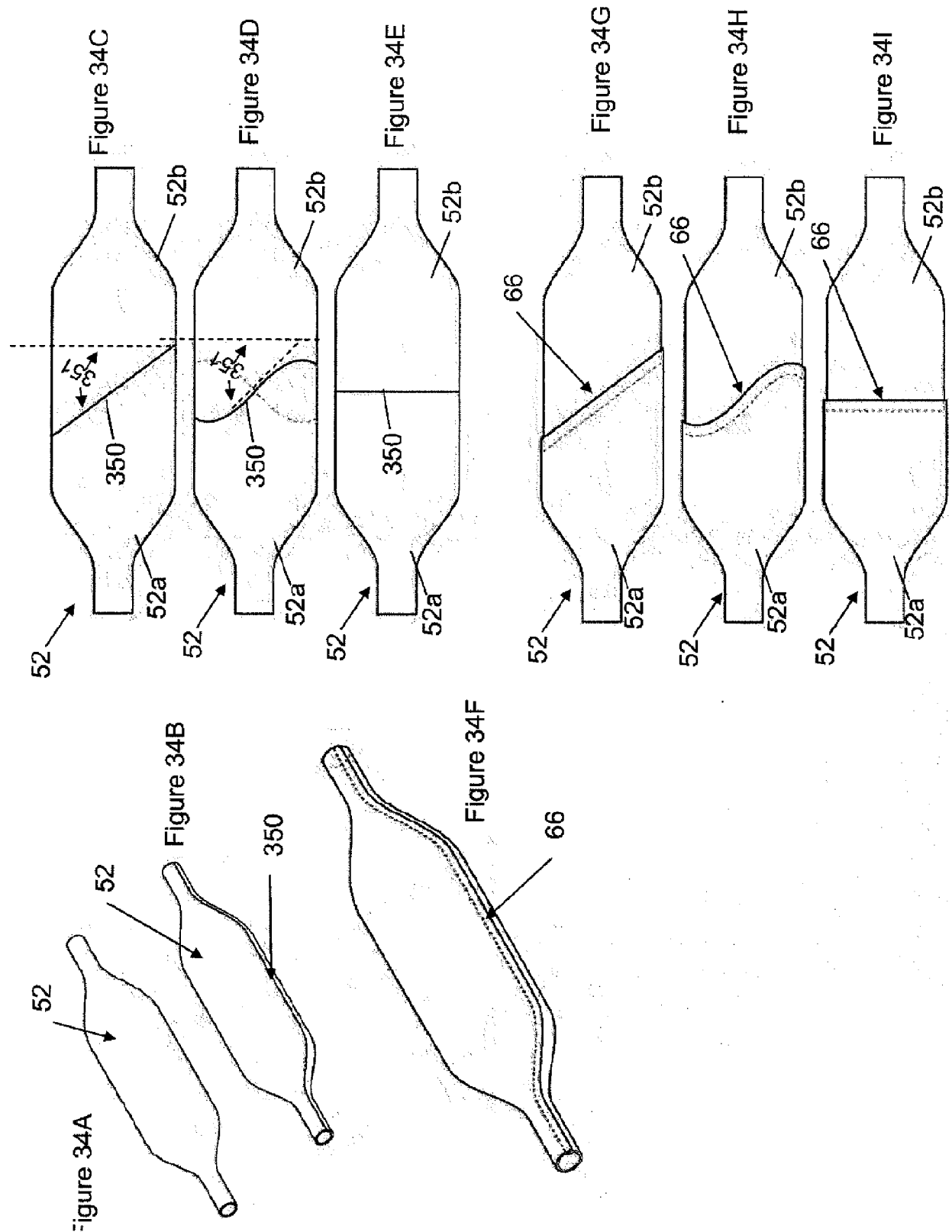


Figure 33D



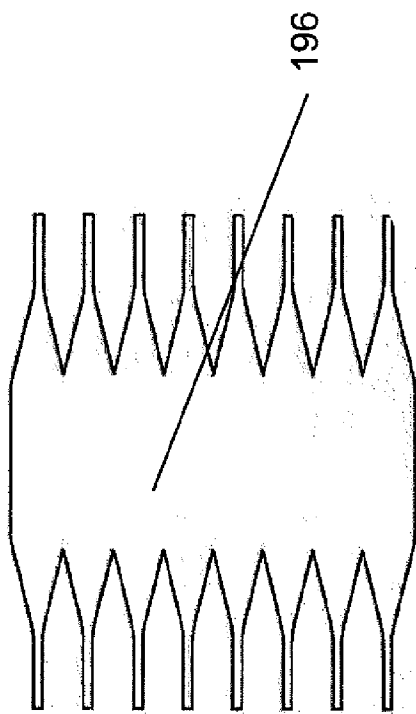


Figure 35

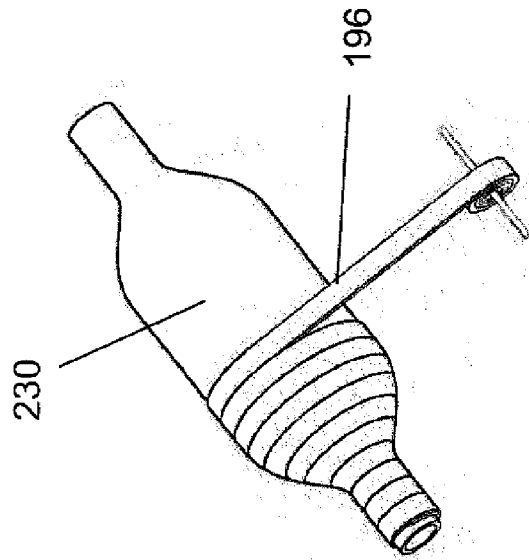


Figure 37

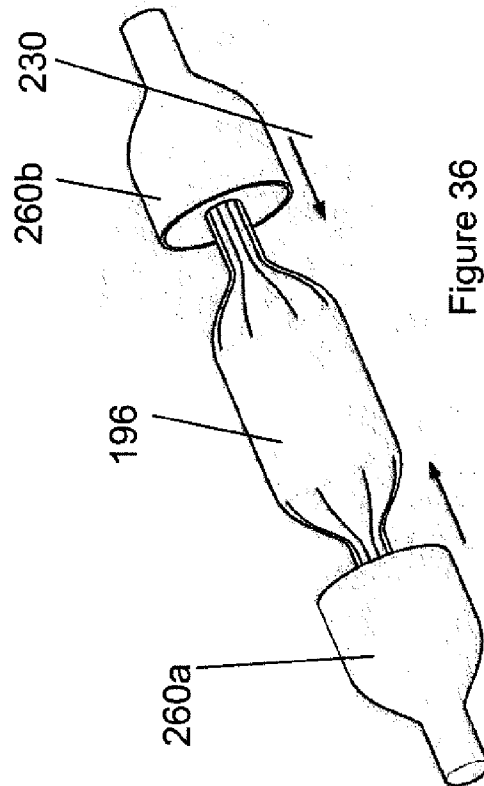


Figure 36

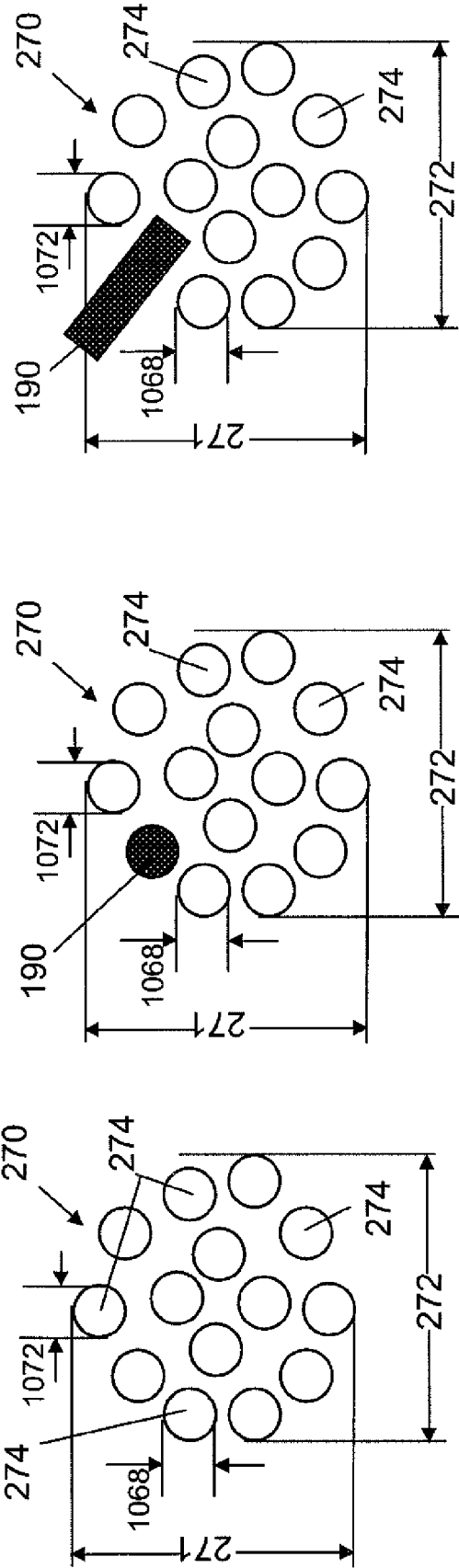


Figure 38C

Figure 38B

Figure 38A

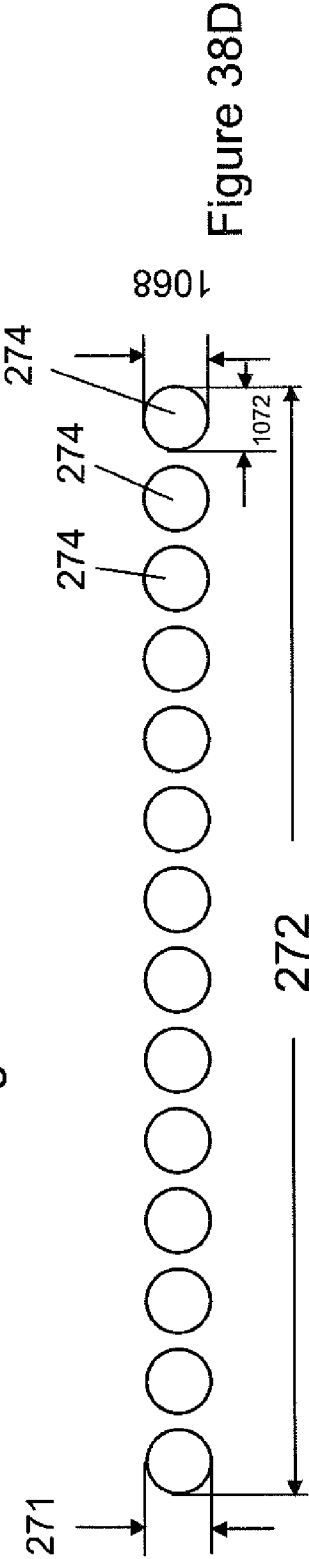


Figure 38D

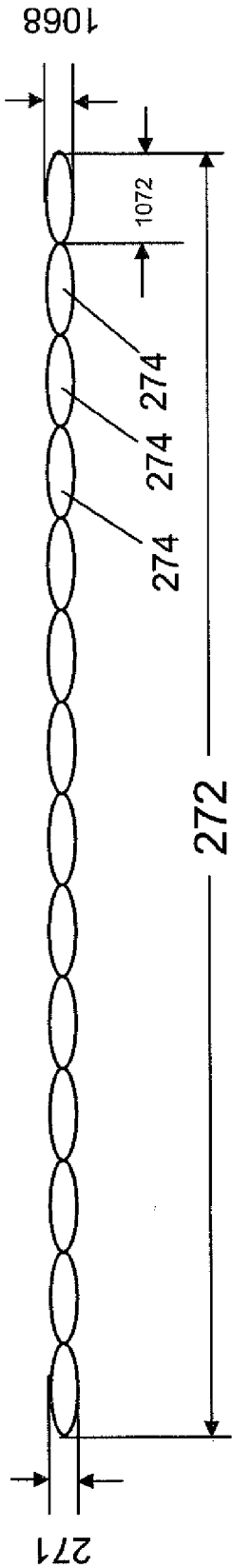
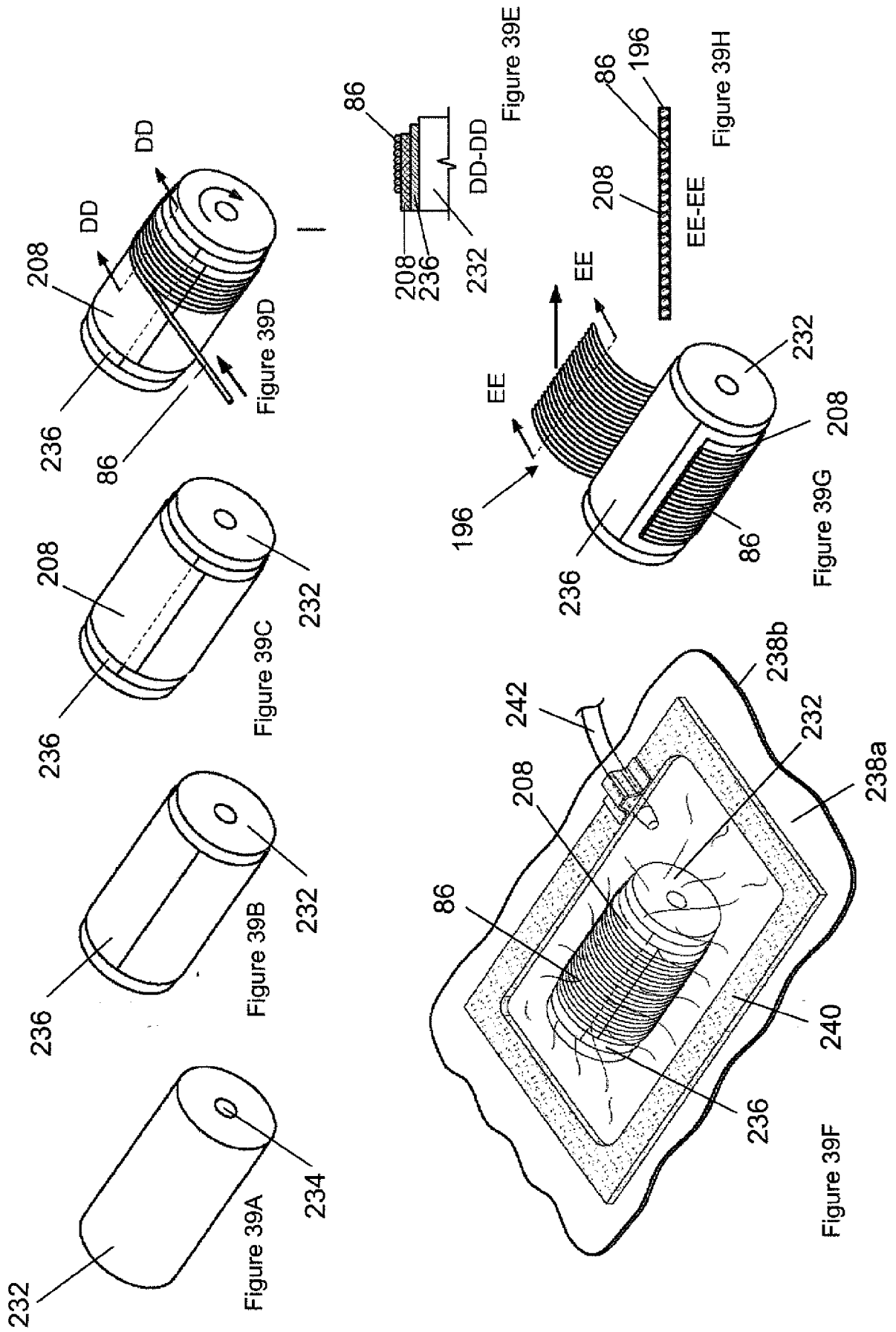


Figure 38E



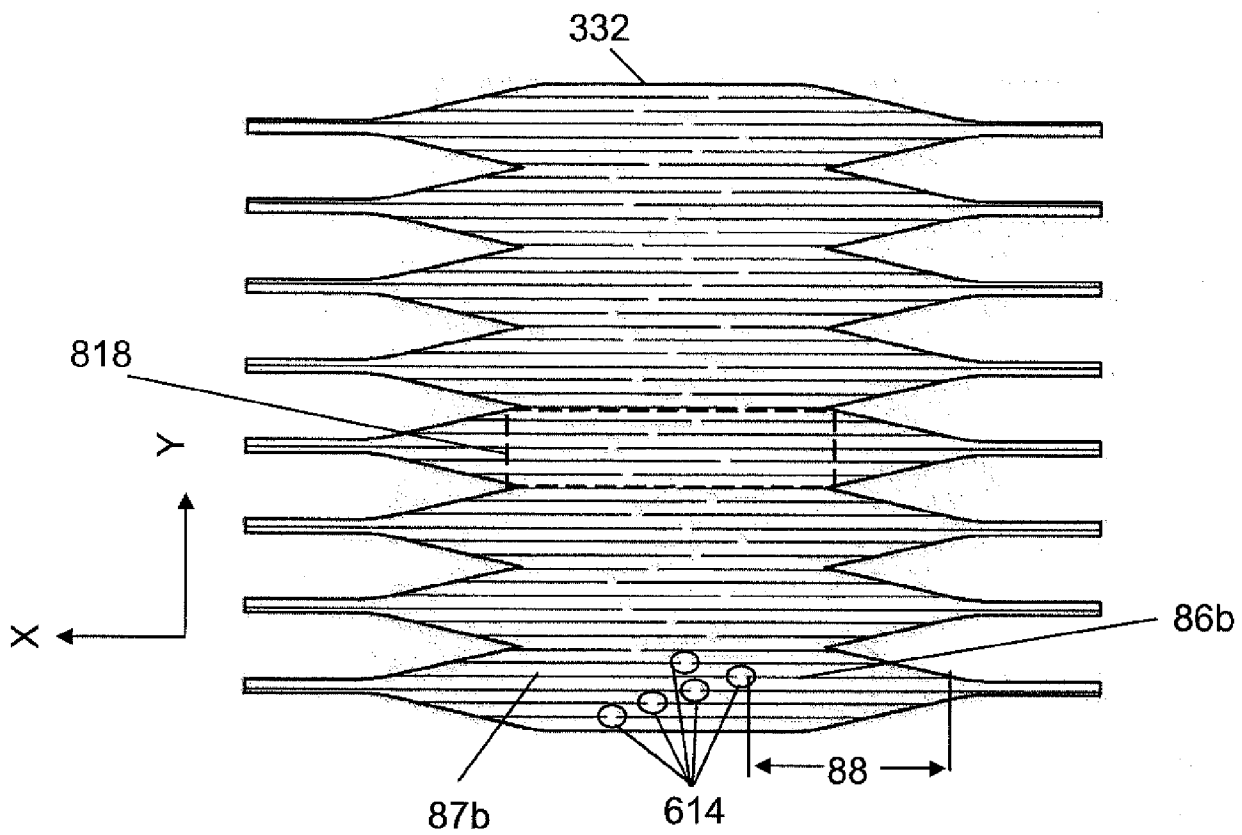


Figure 40B

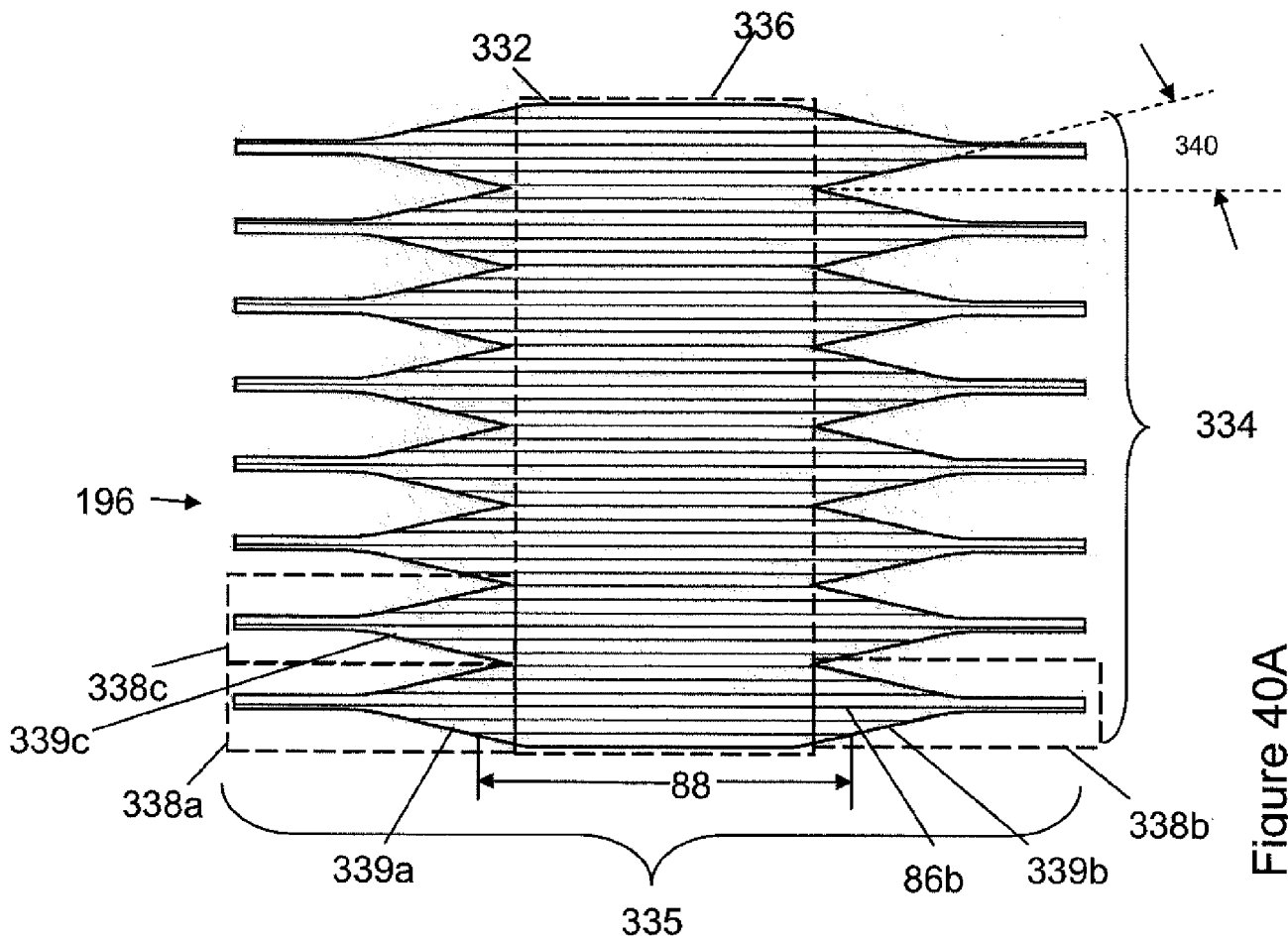


Figure 40A

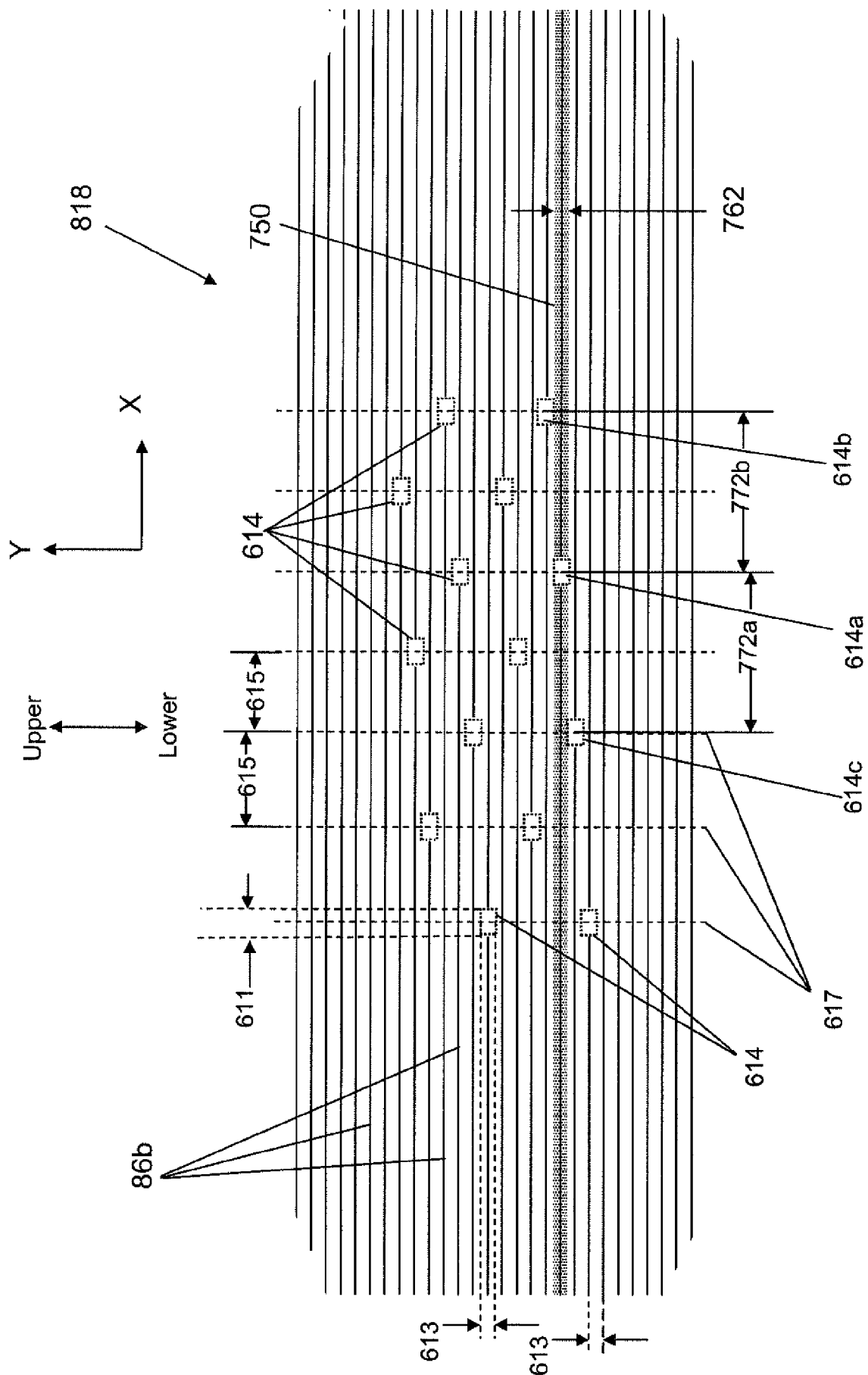
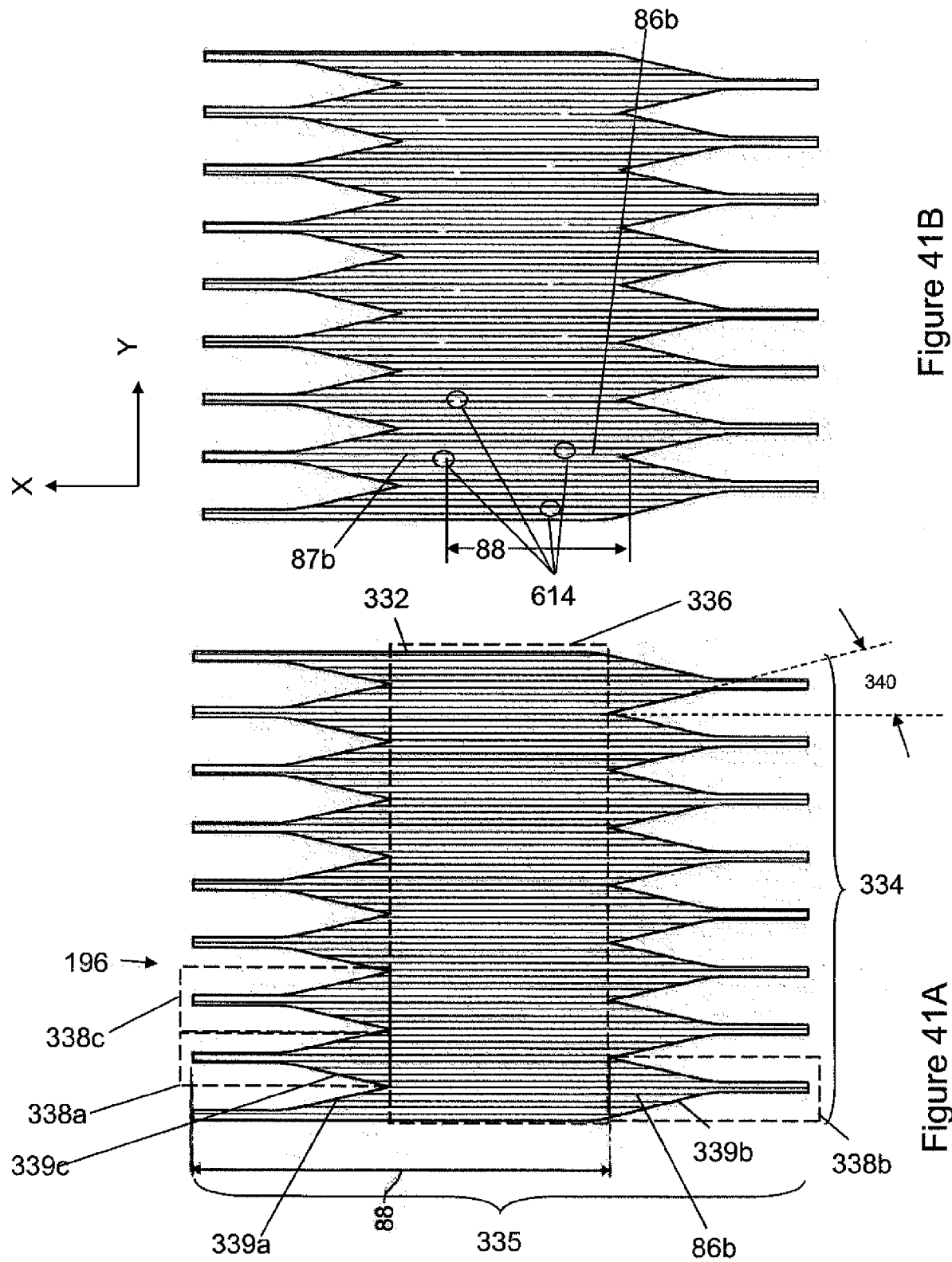


Figure 40C



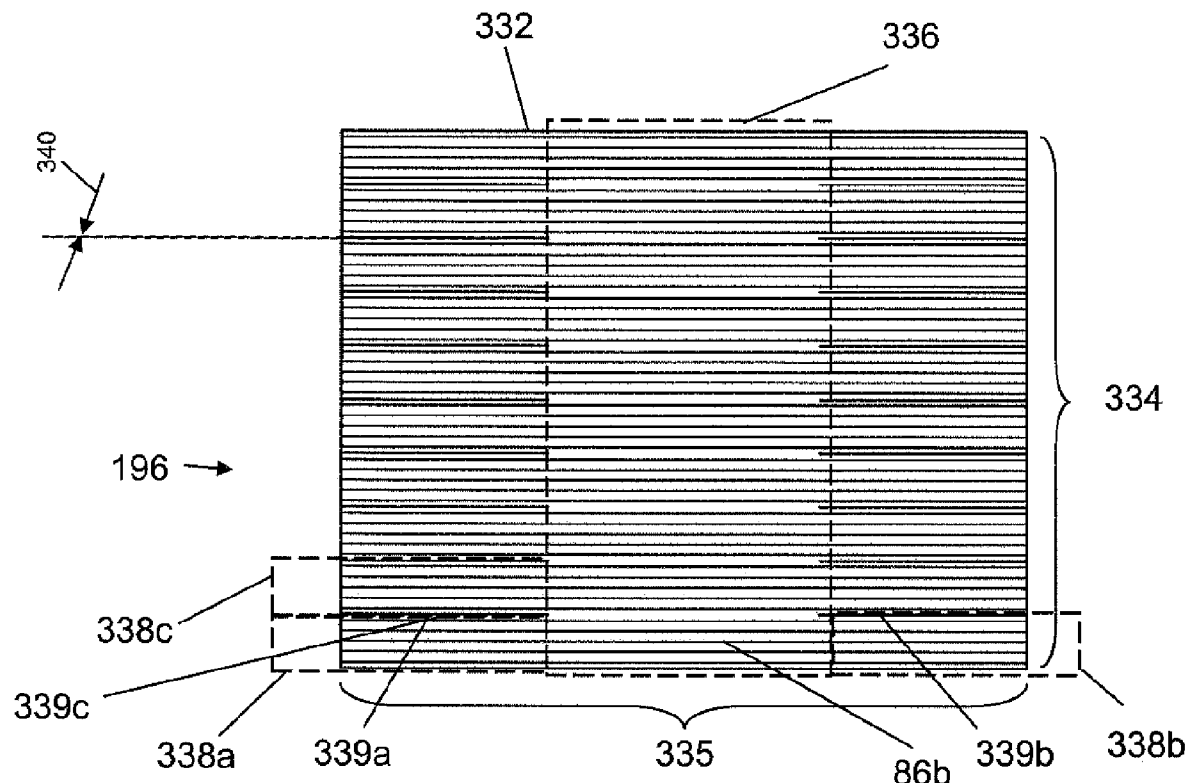


Figure 42B

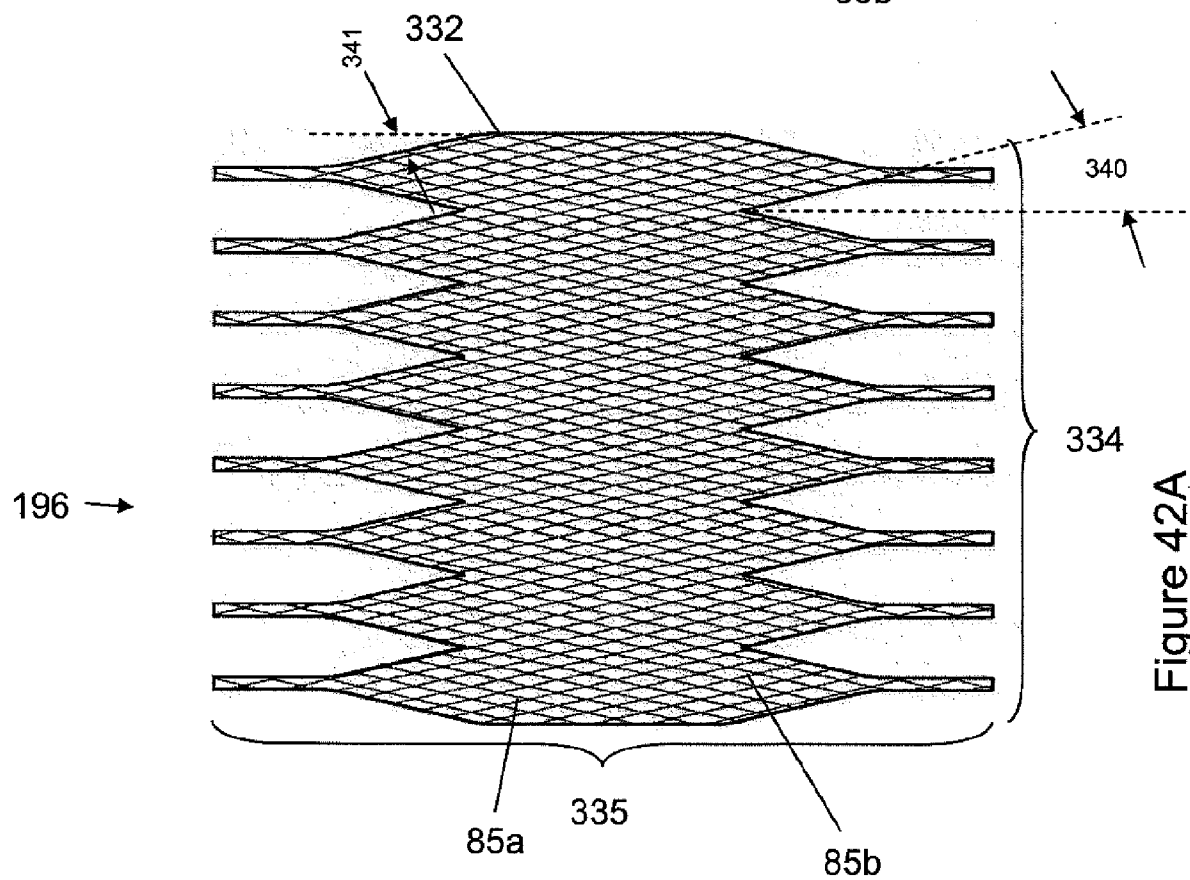


Figure 42A

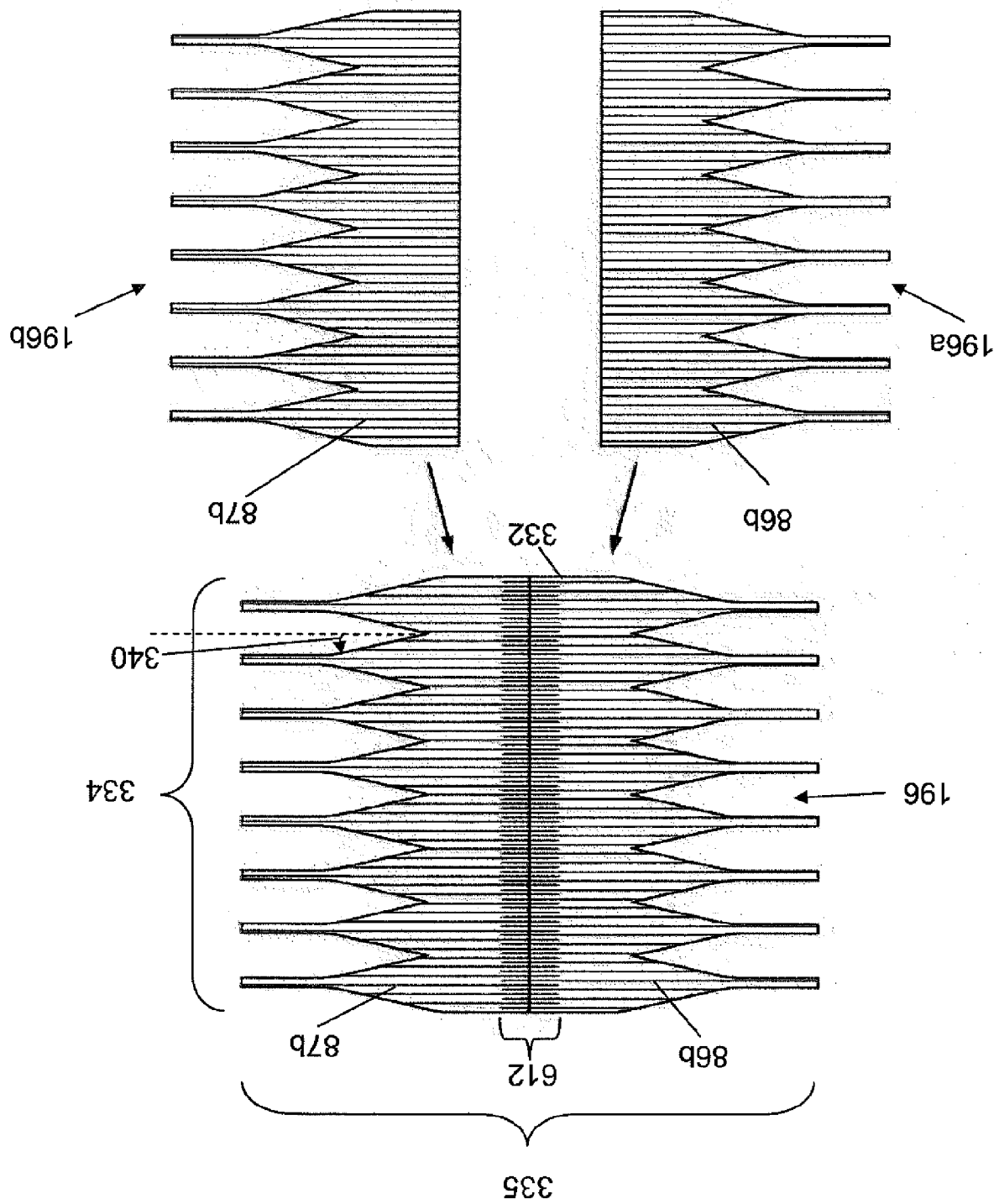


Figure 43B

Figure 43A

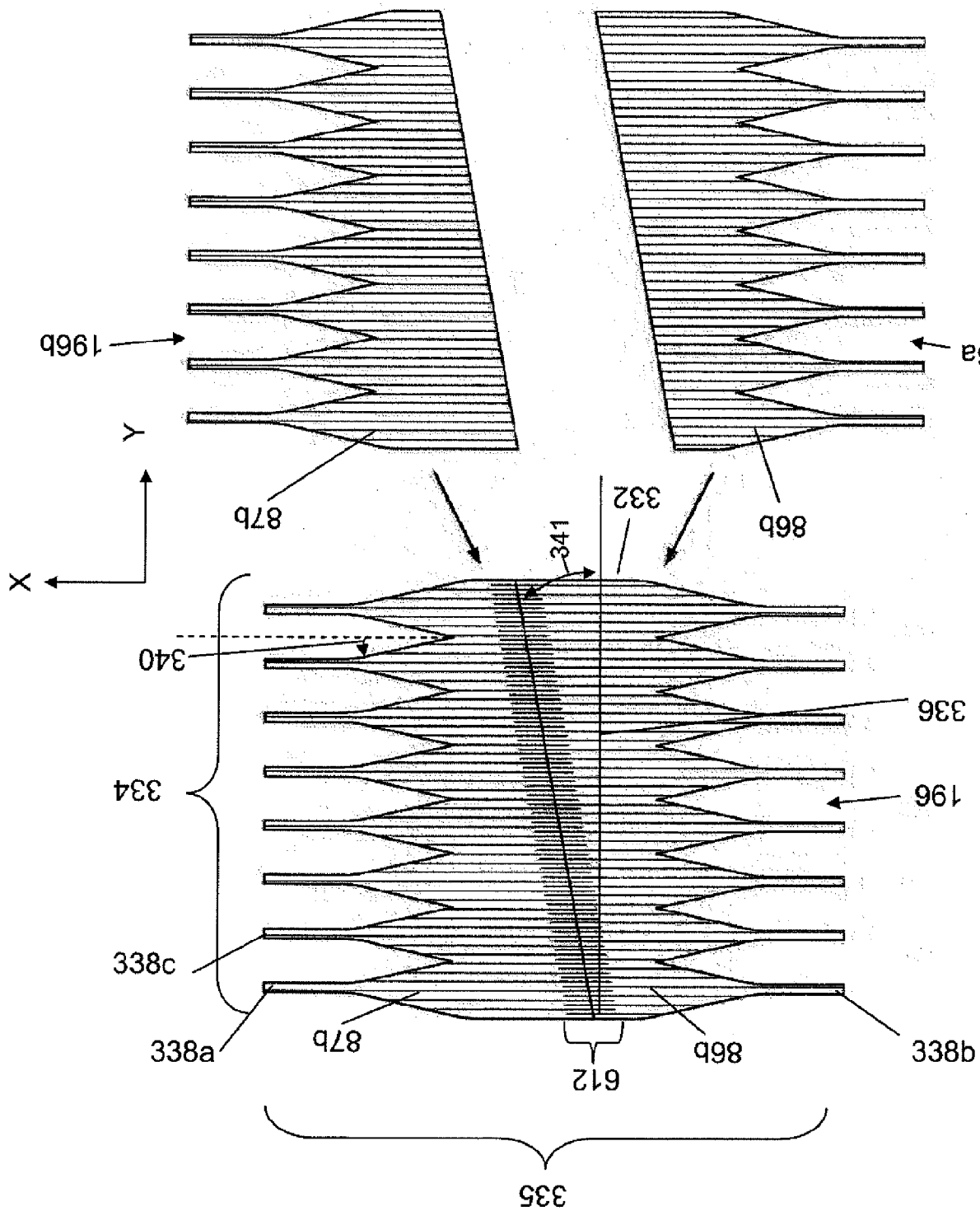


Figure 43C

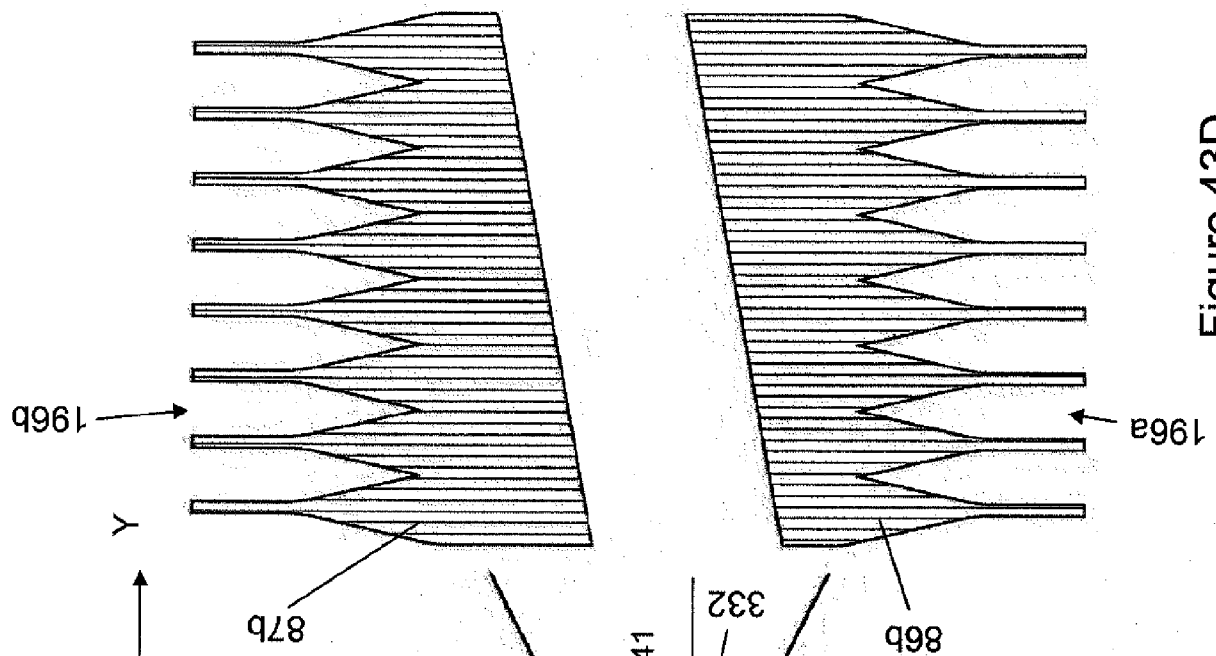


Figure 43D

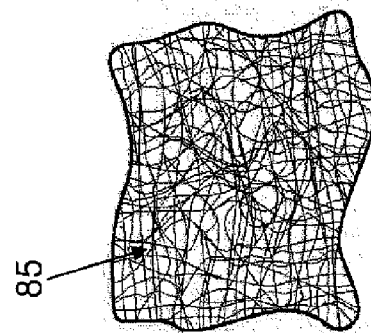
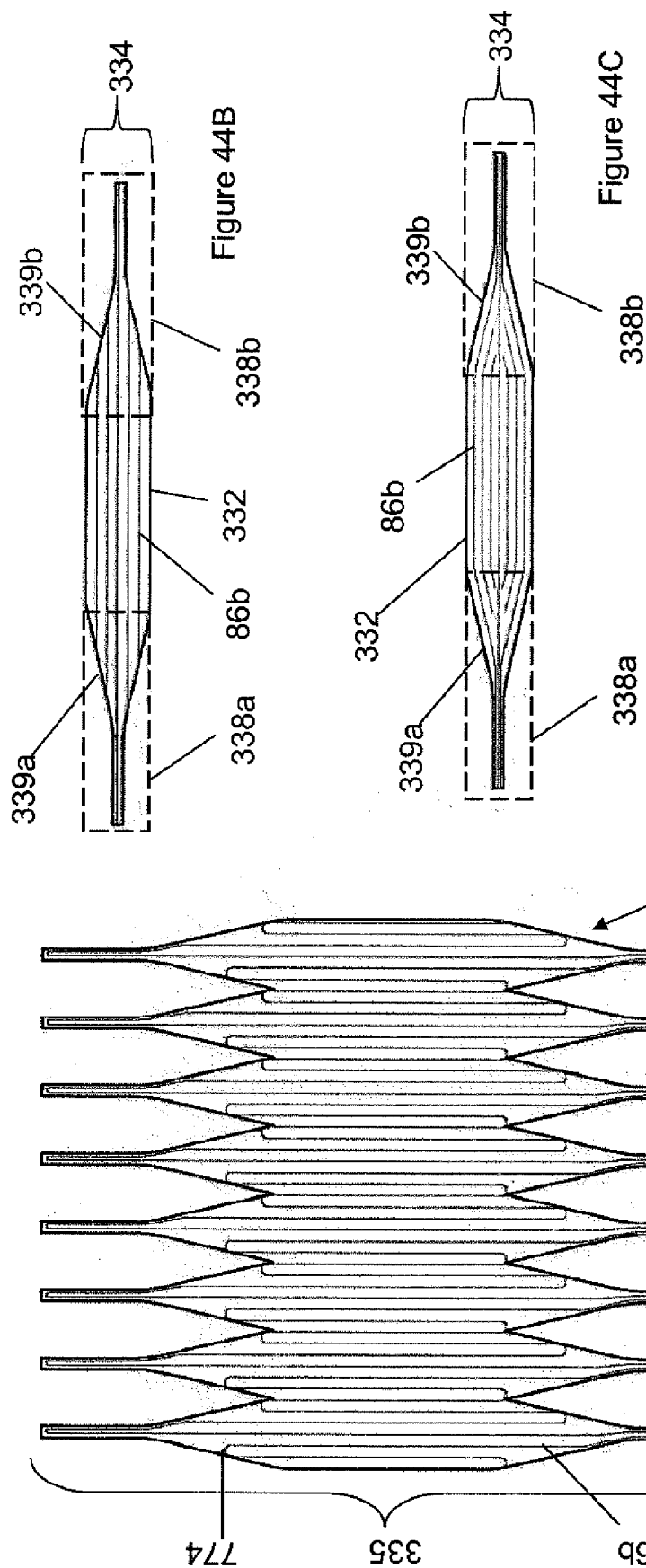


Figure 44F

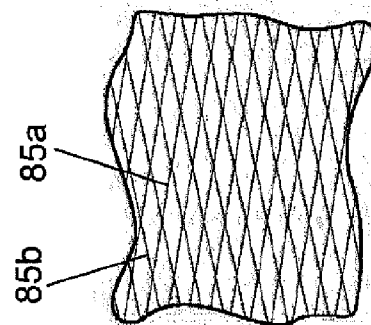


Figure 44E

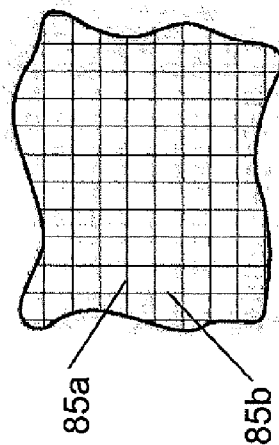


Figure 44D

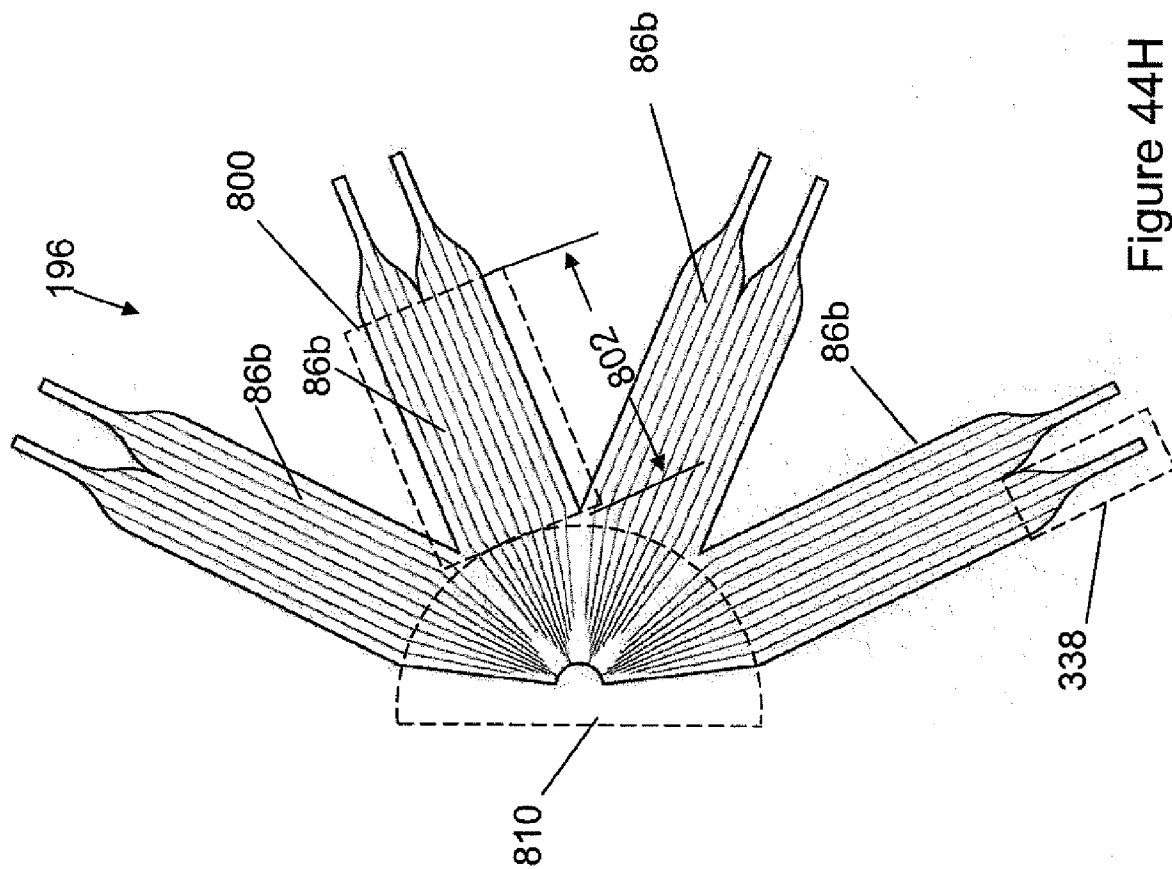


Figure 44H

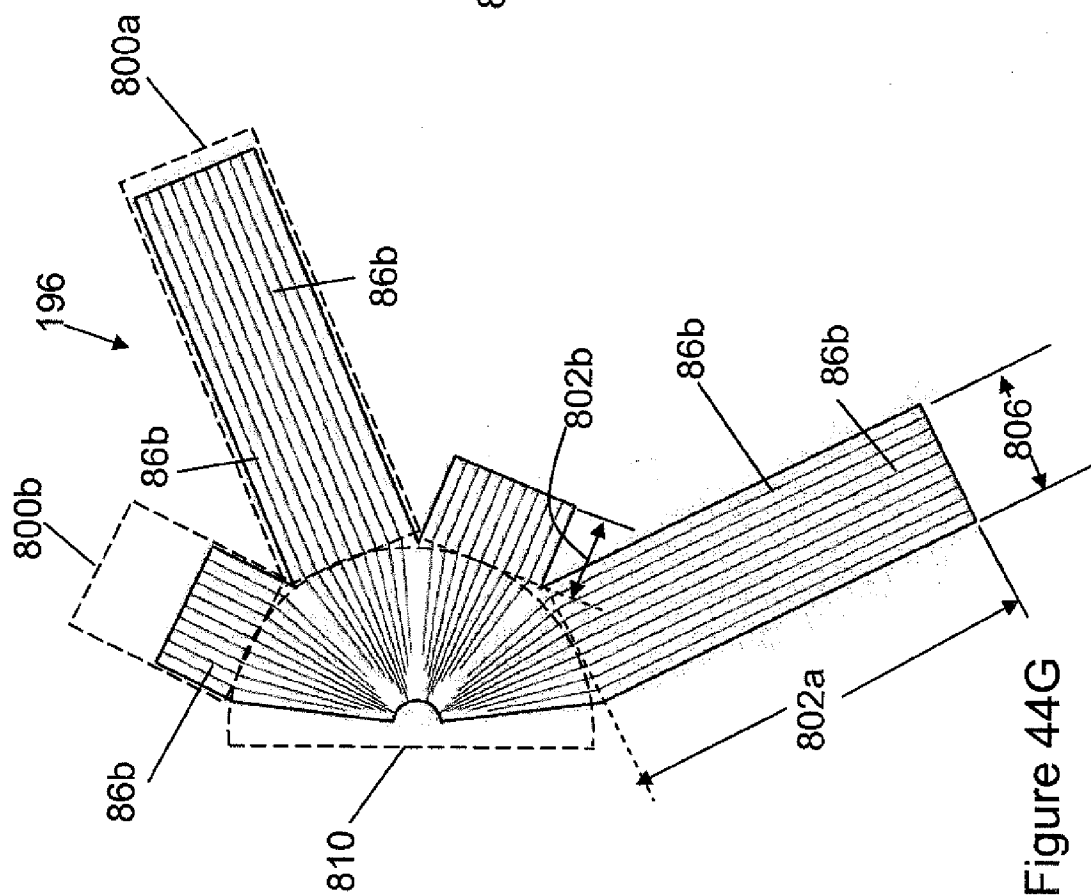


Figure 44G

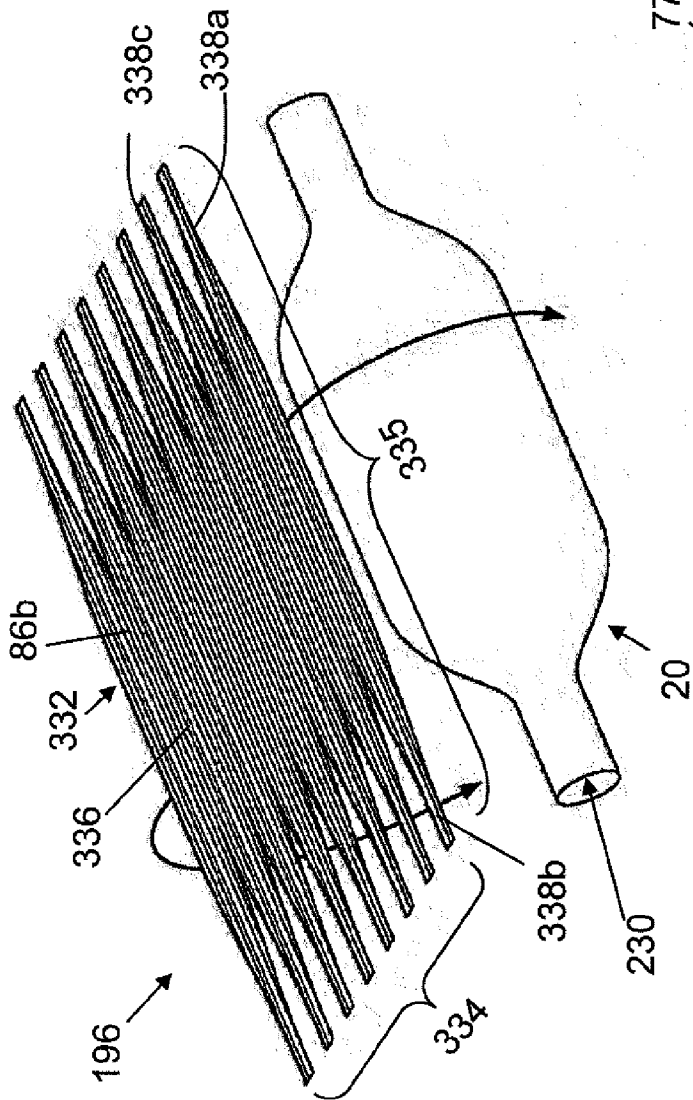


Figure 45A

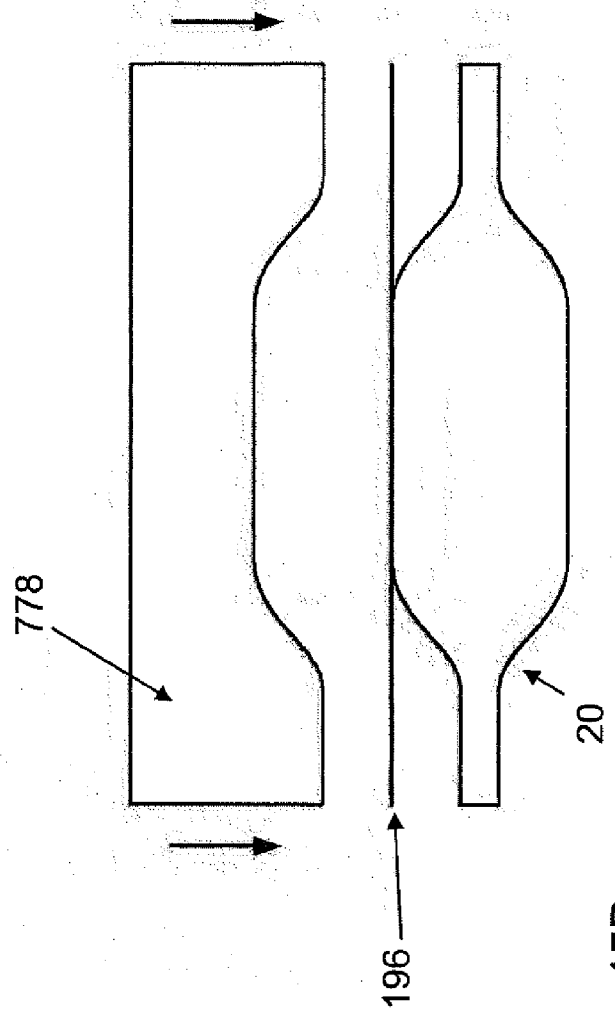
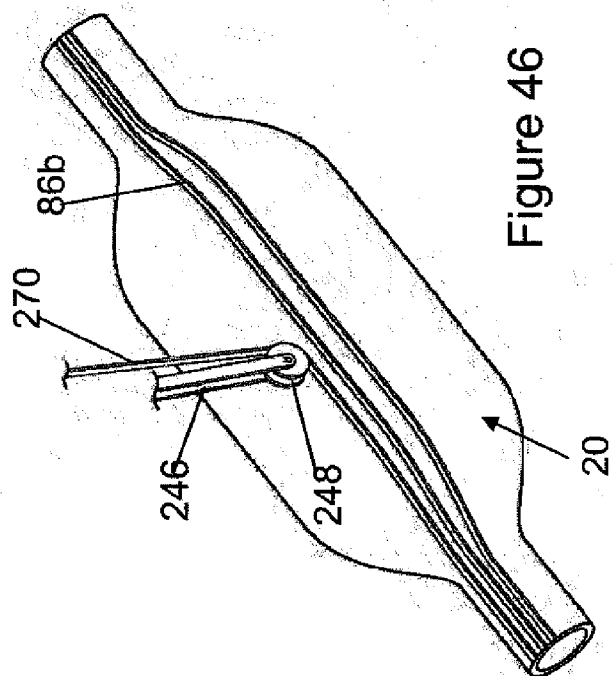
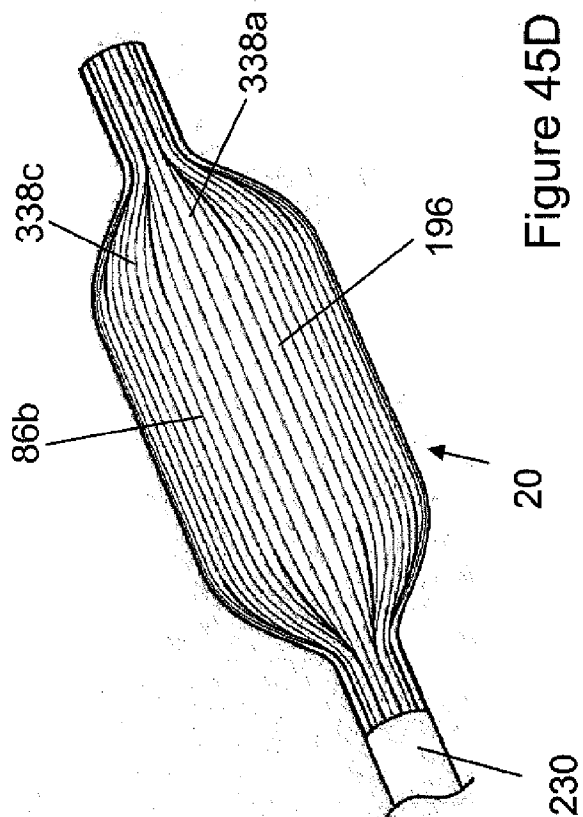
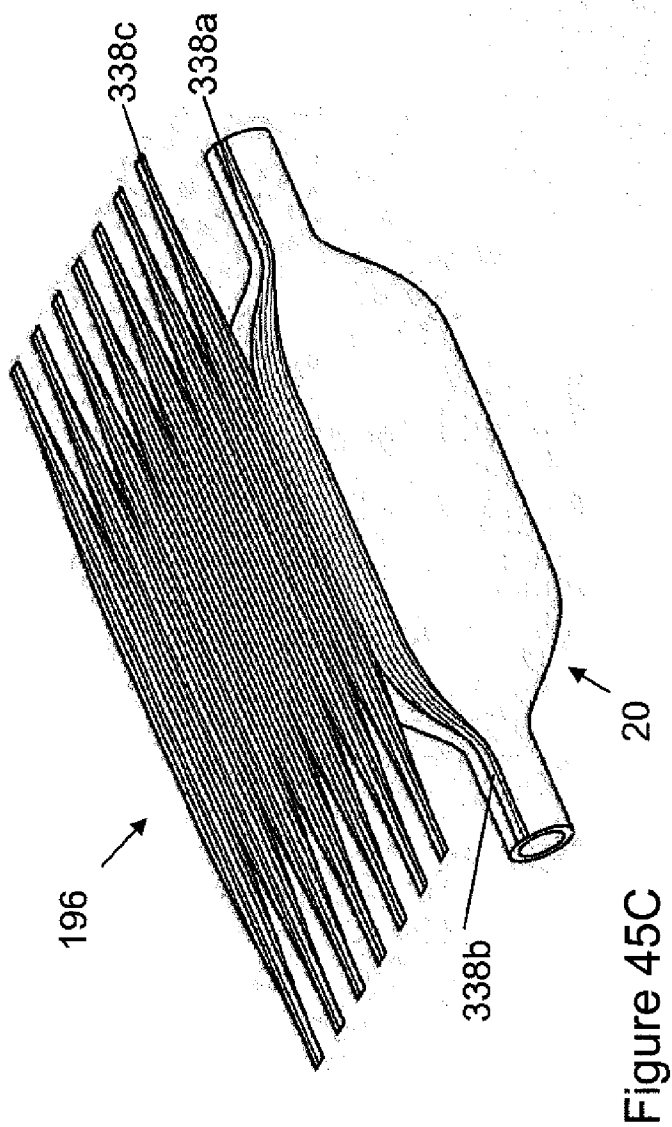


Figure 45B



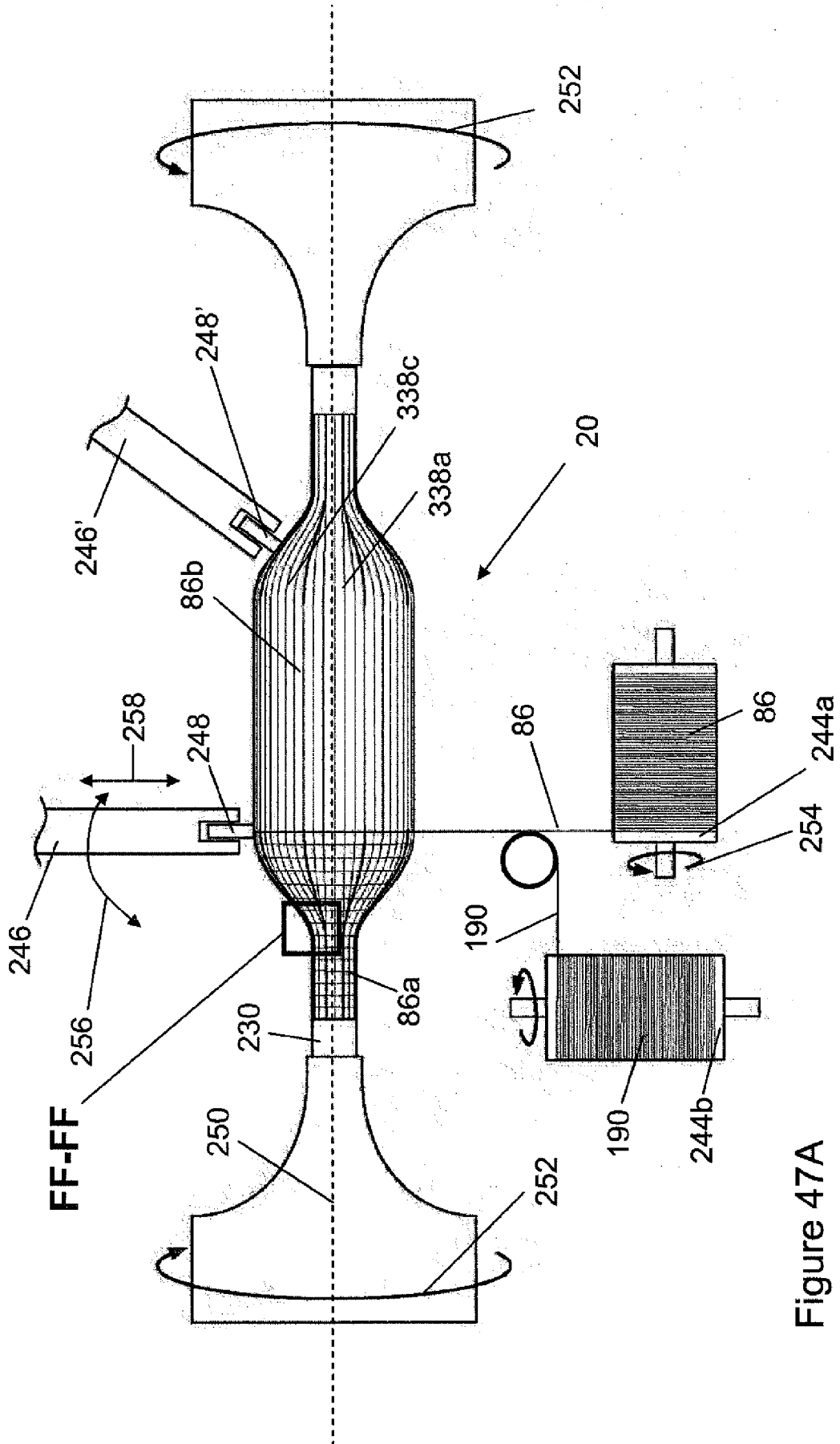


Figure 47A

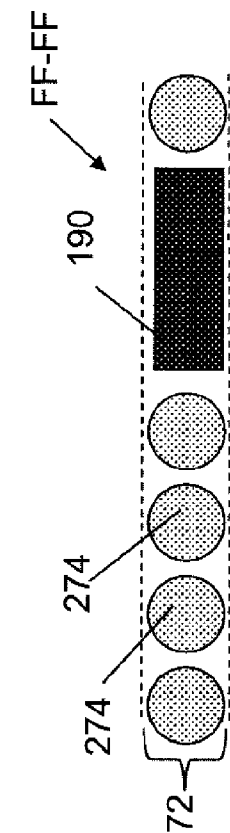


Figure 47B

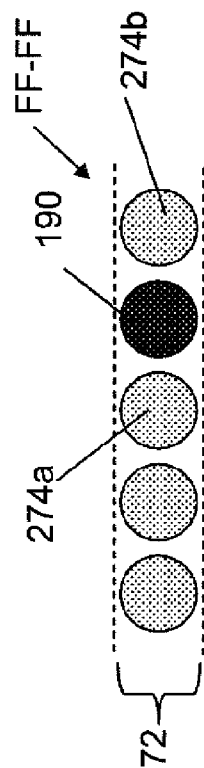


Figure 47C

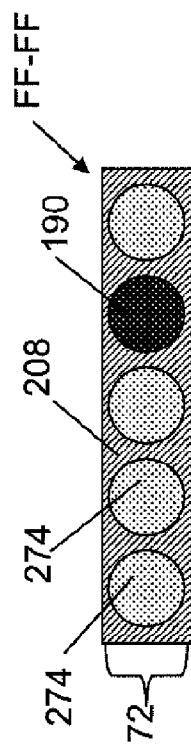


Figure 47D

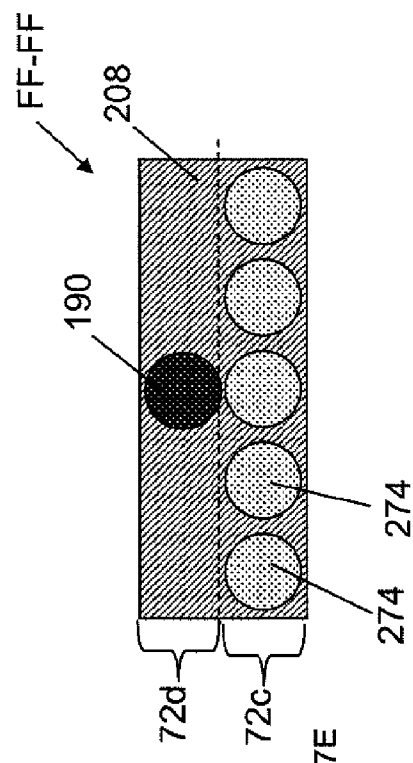


Figure 47E

Figure 47F

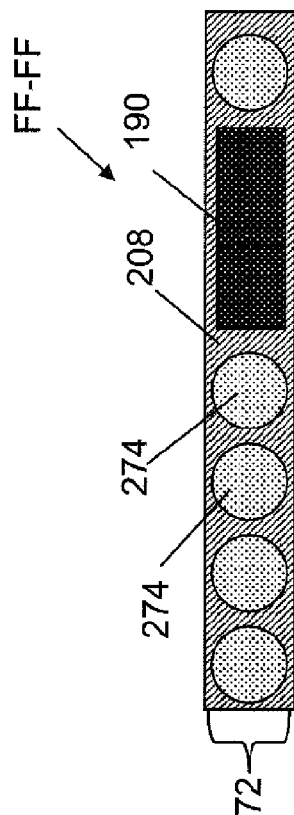


Figure 47G

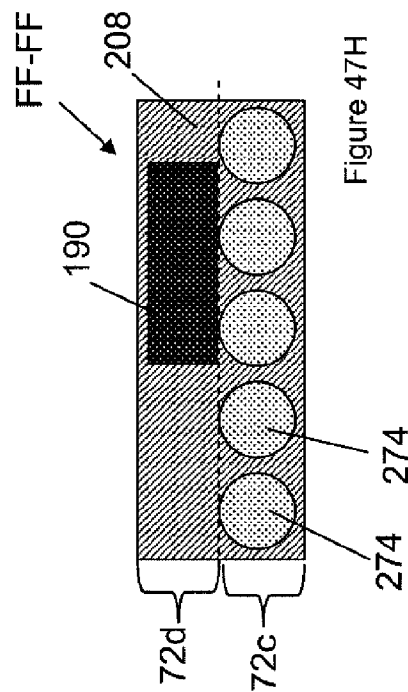
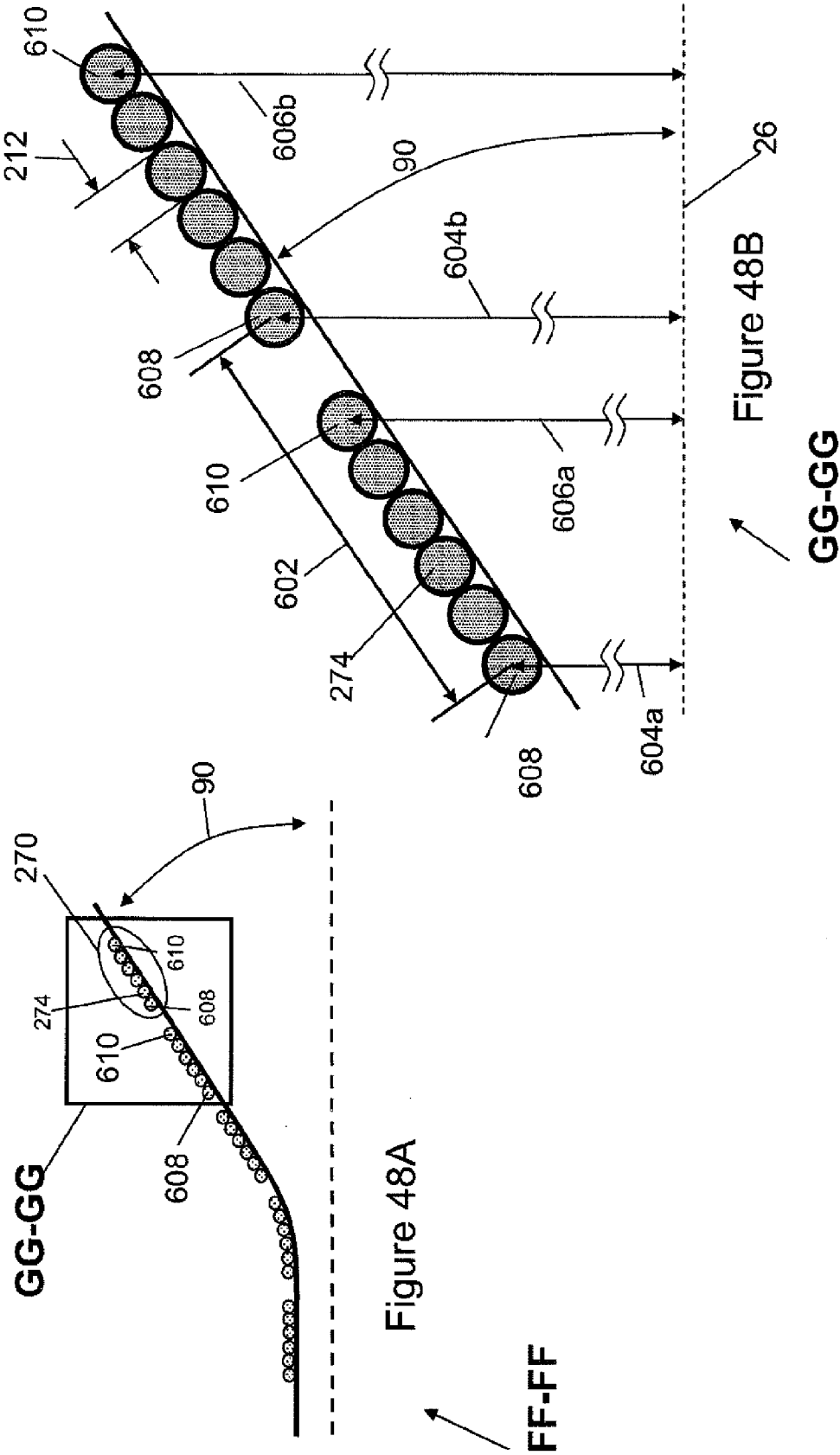


Figure 47H



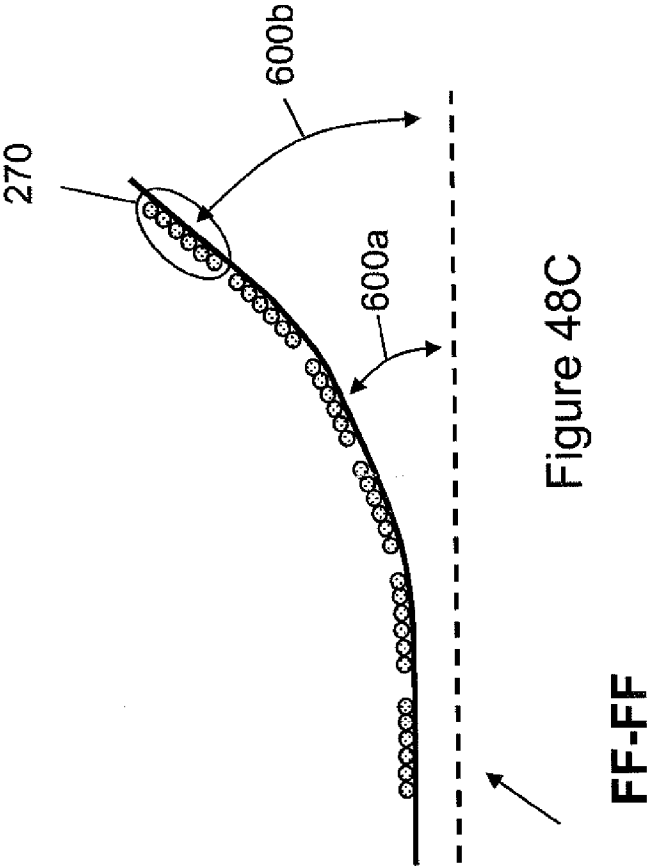


Figure 48C

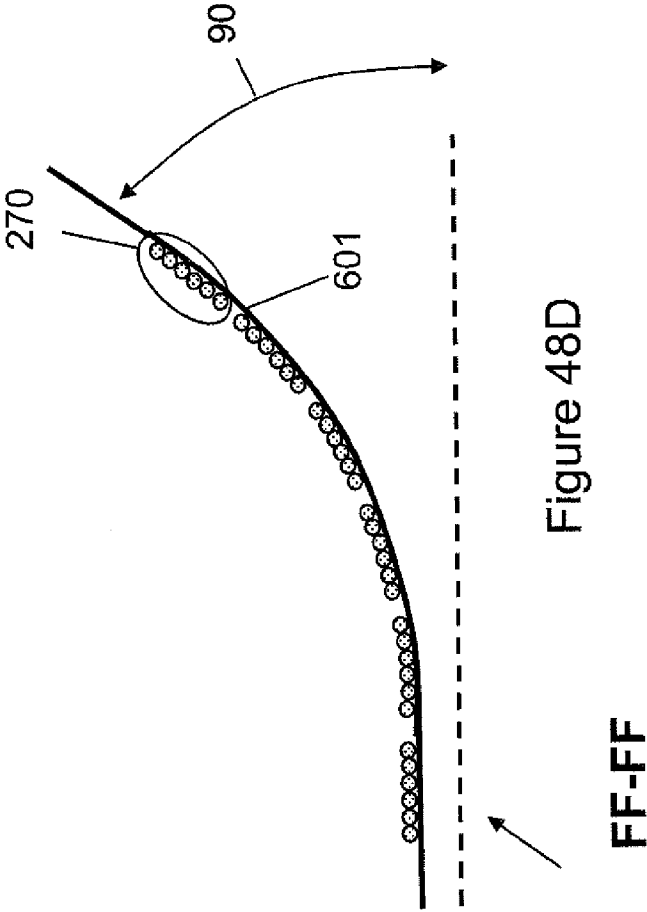


Figure 48D

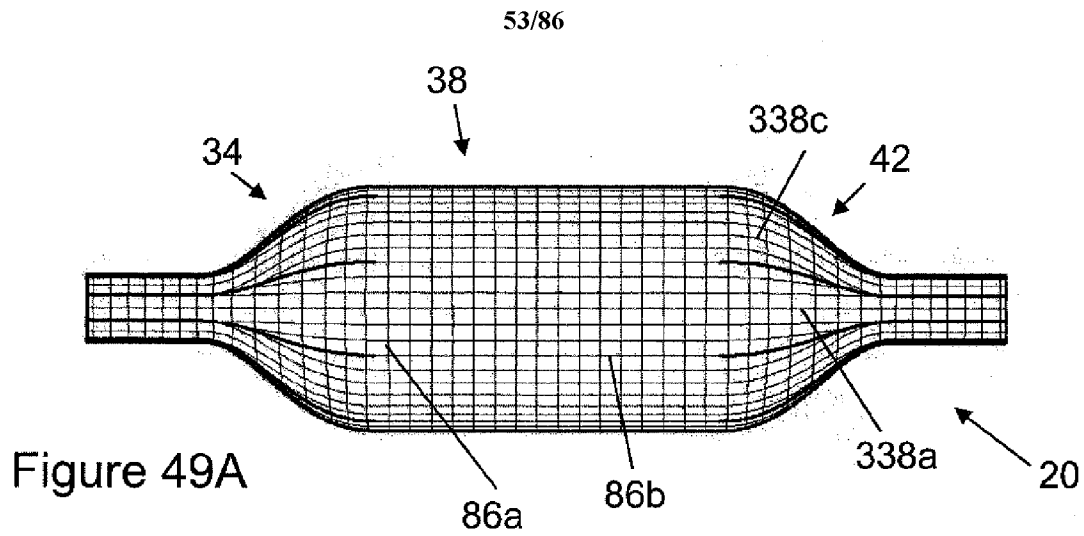


Figure 49A

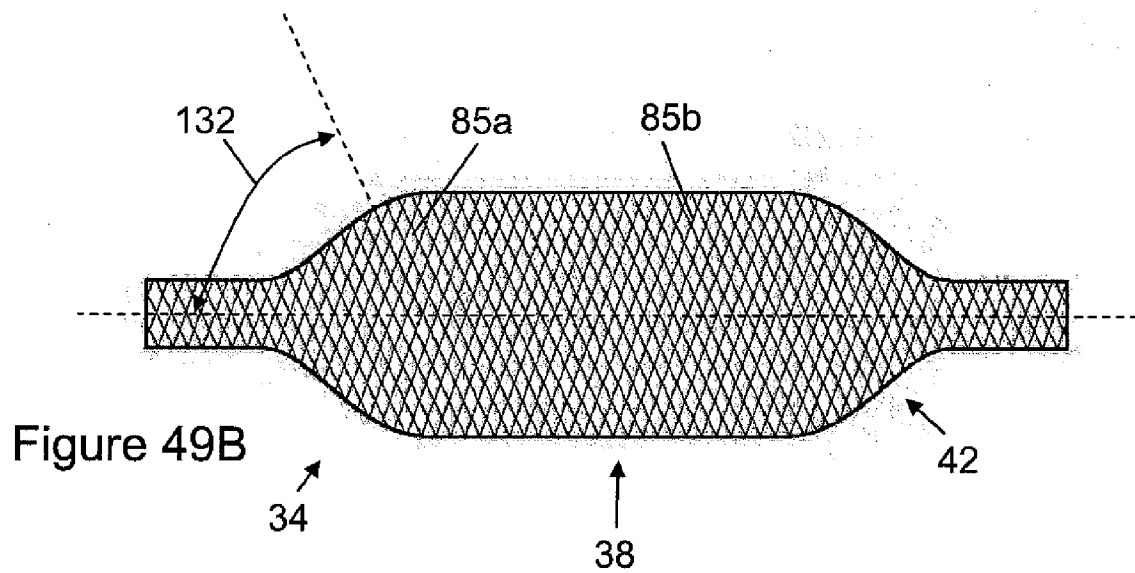


Figure 49B

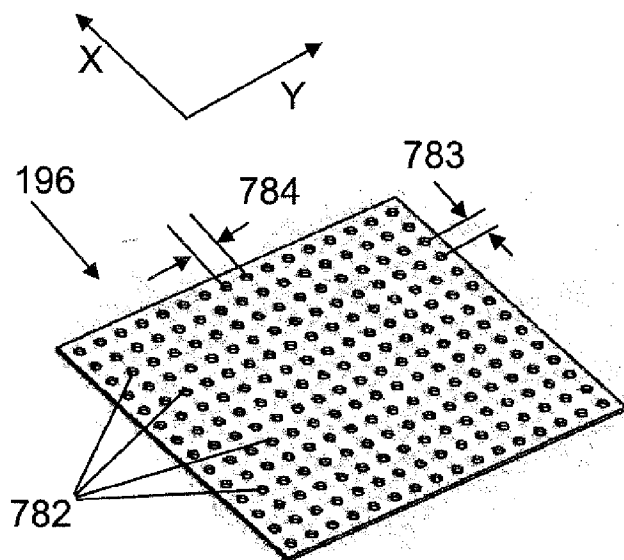


Figure 50A

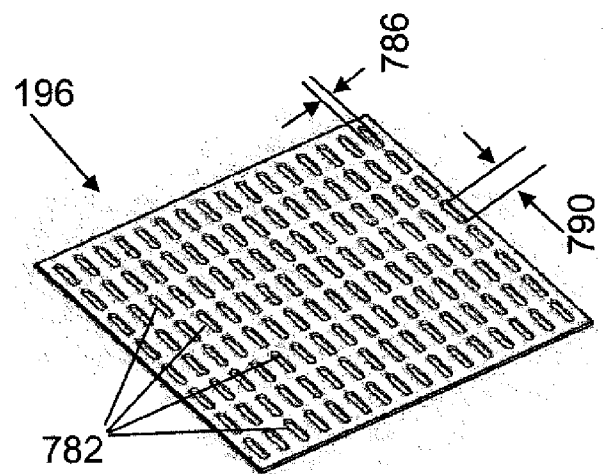
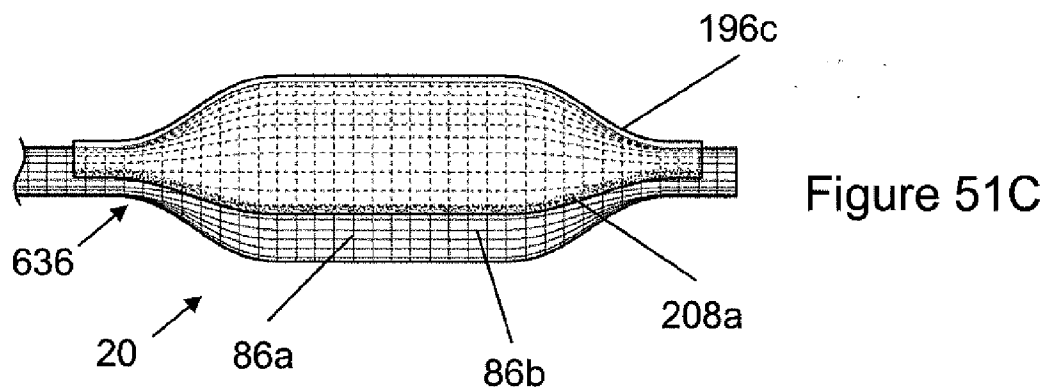
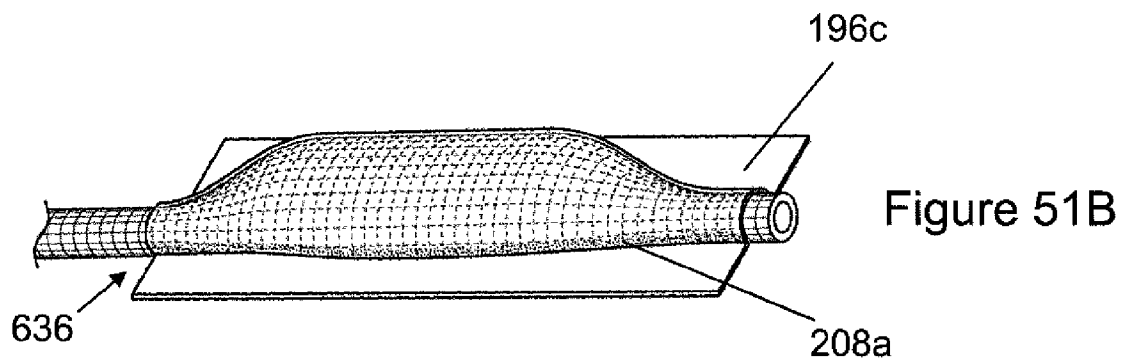
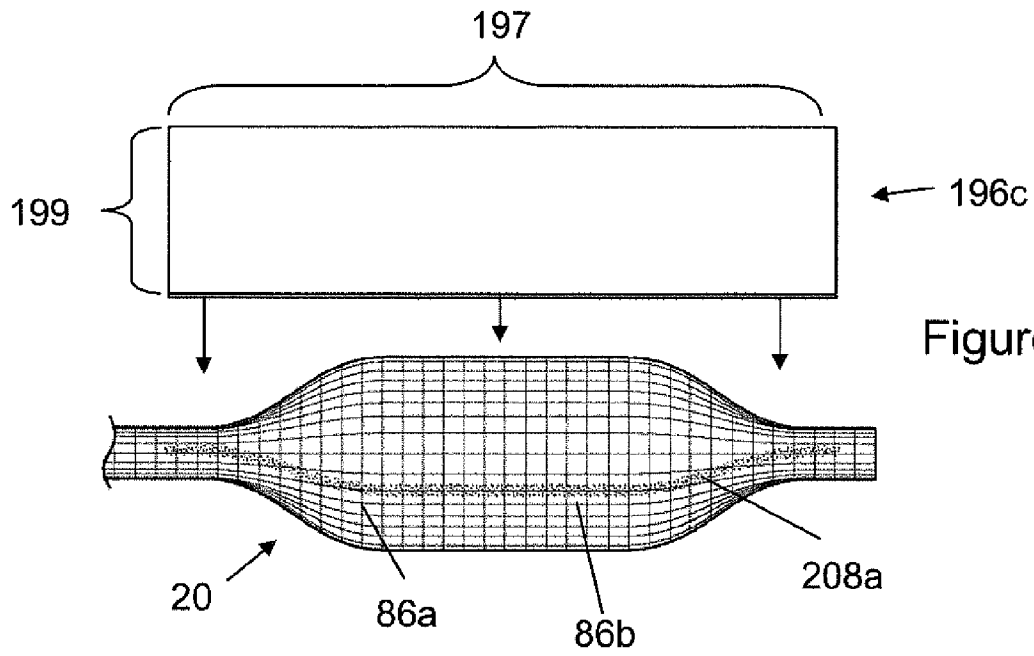


Figure 50B

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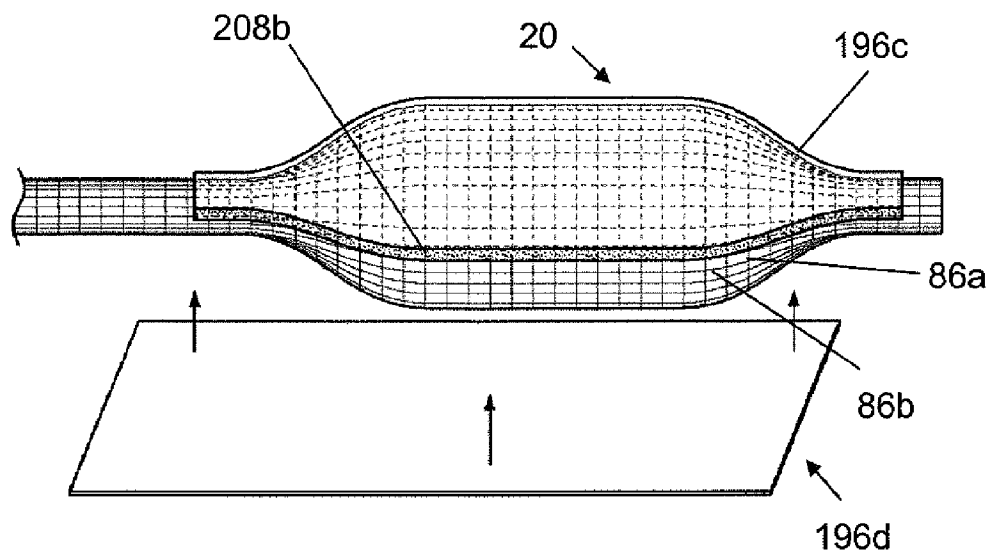


Figure 51D

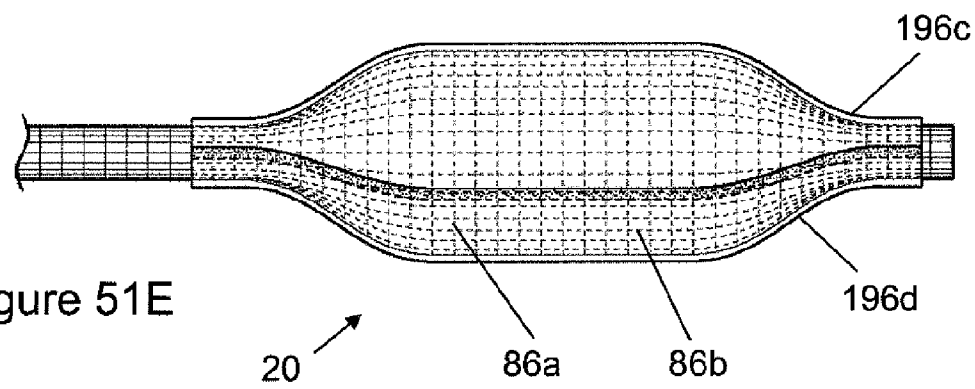


Figure 51E

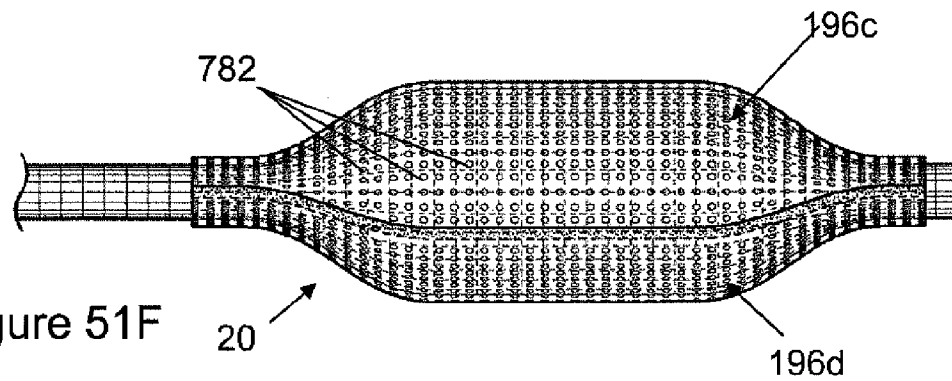


Figure 51F

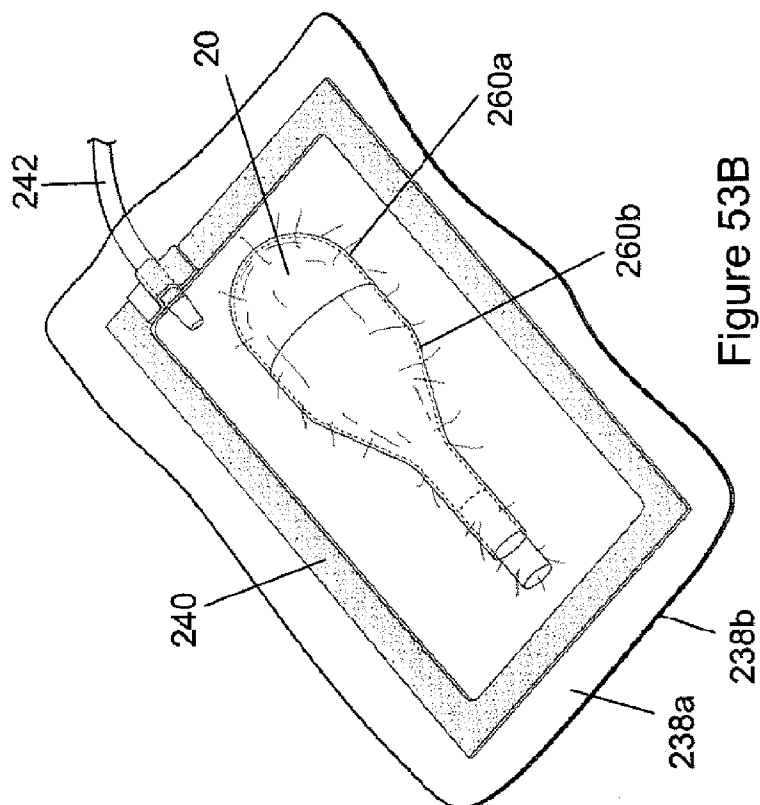


Figure 53B

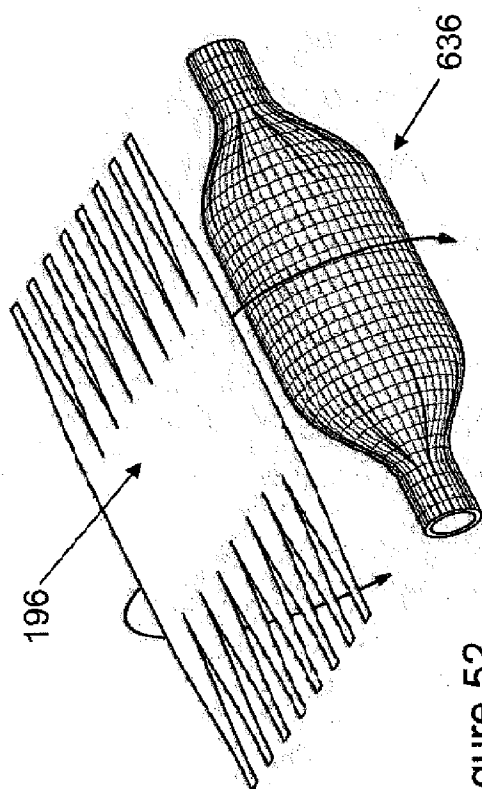


Figure 52

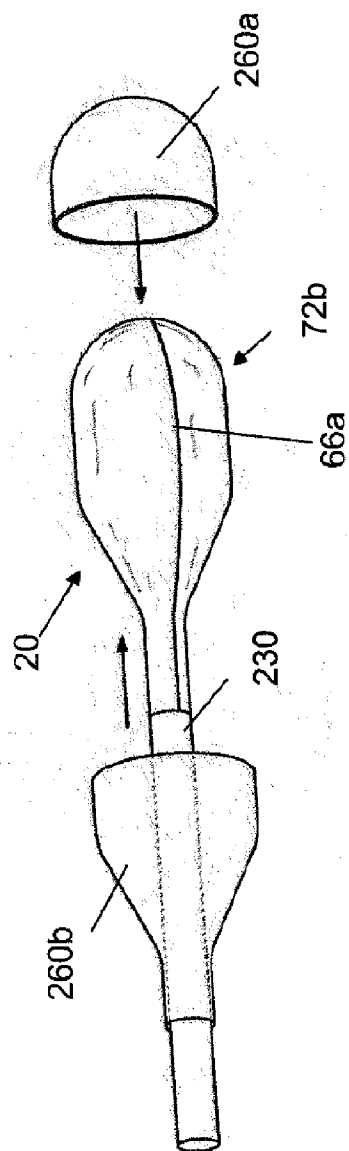


Figure 53A

Figure 55A

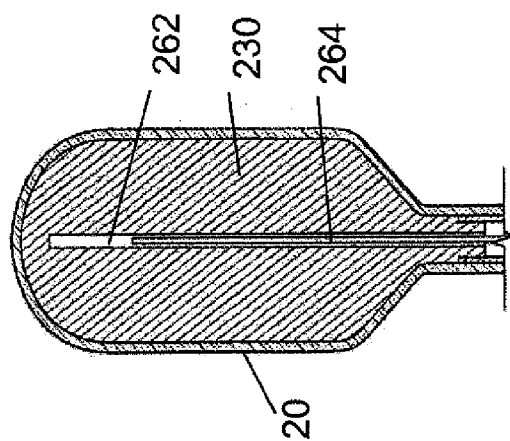
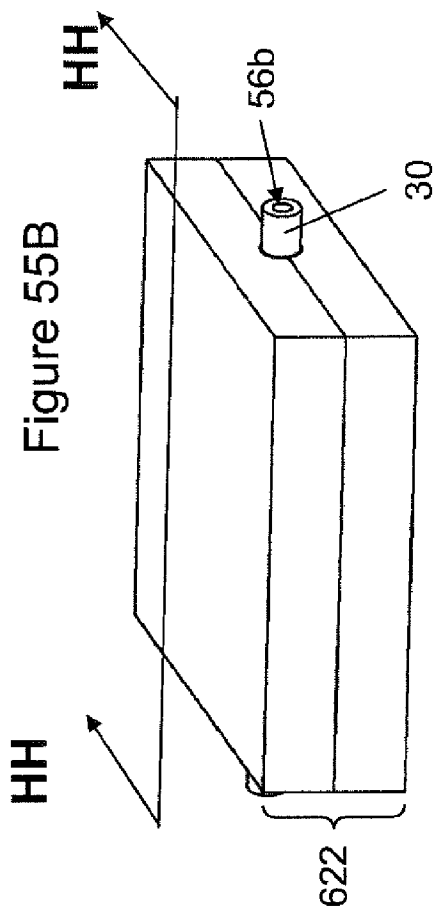
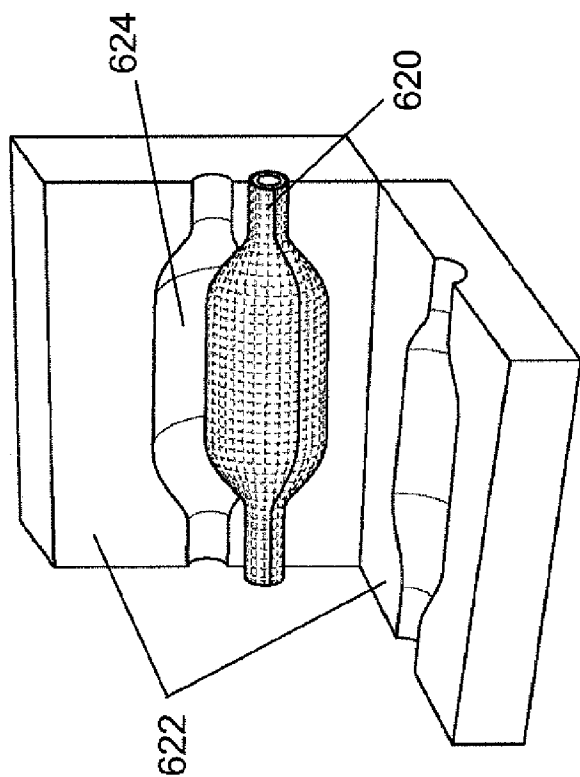
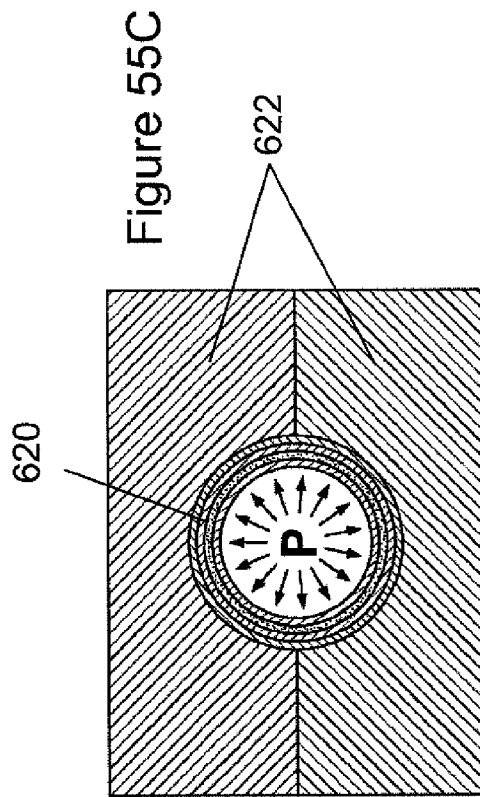


Figure 54



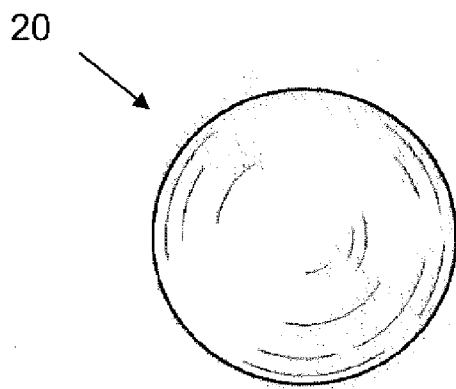


Figure 56A

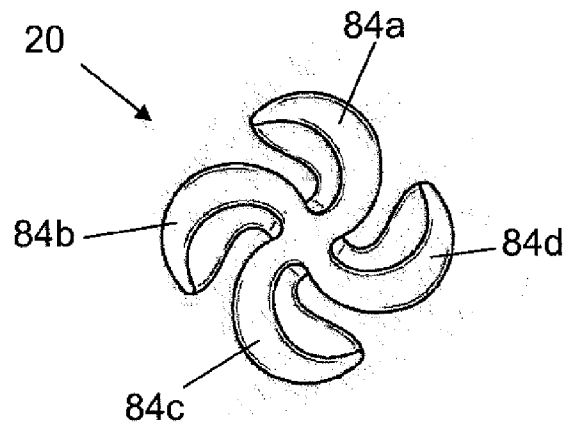


Figure 56C

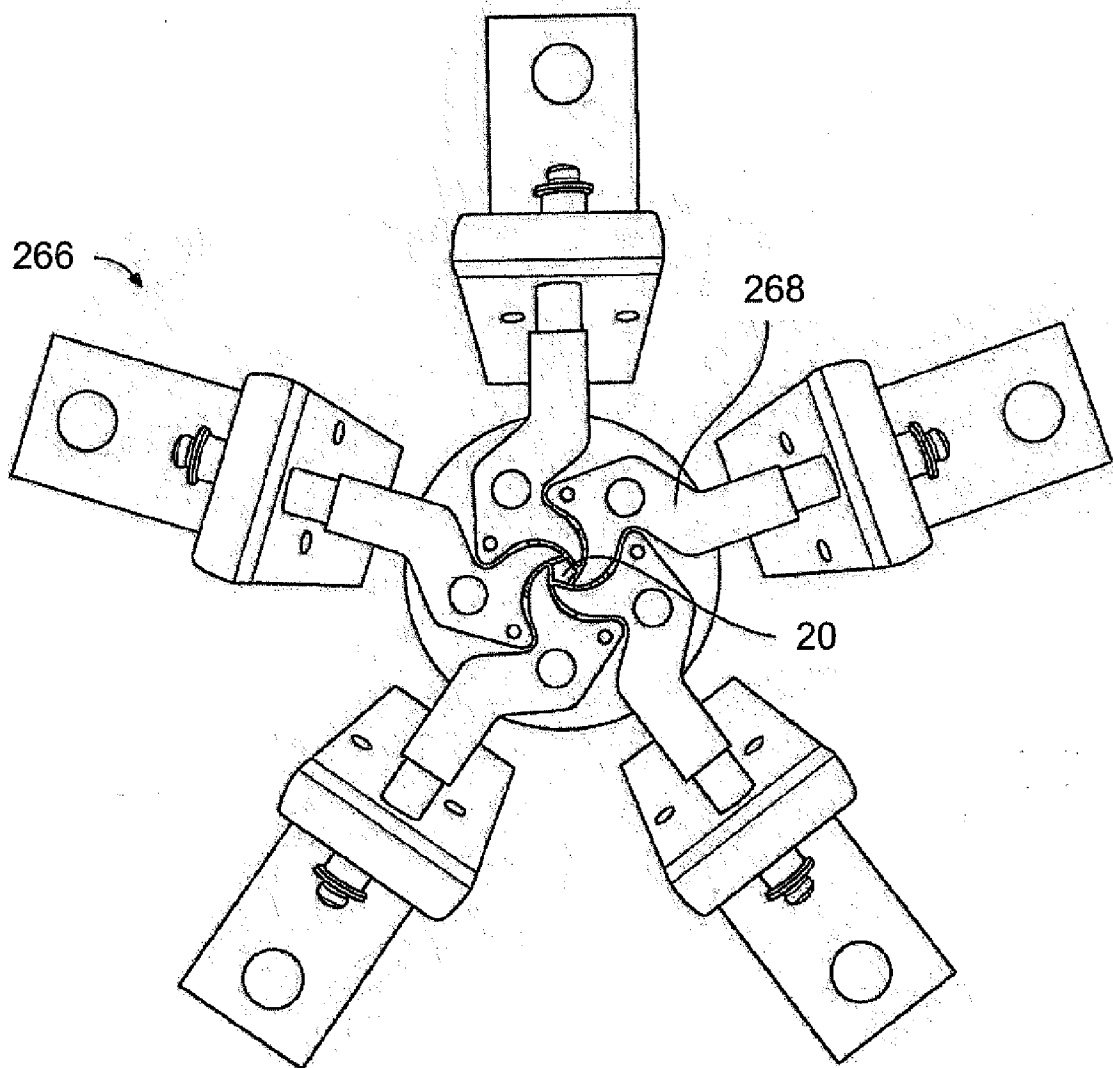


Figure 56B

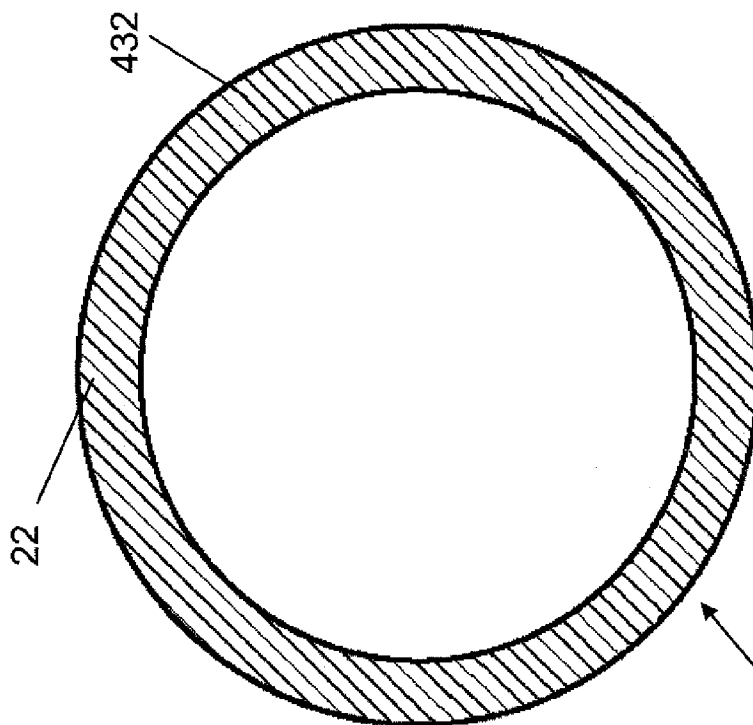


Figure 57A

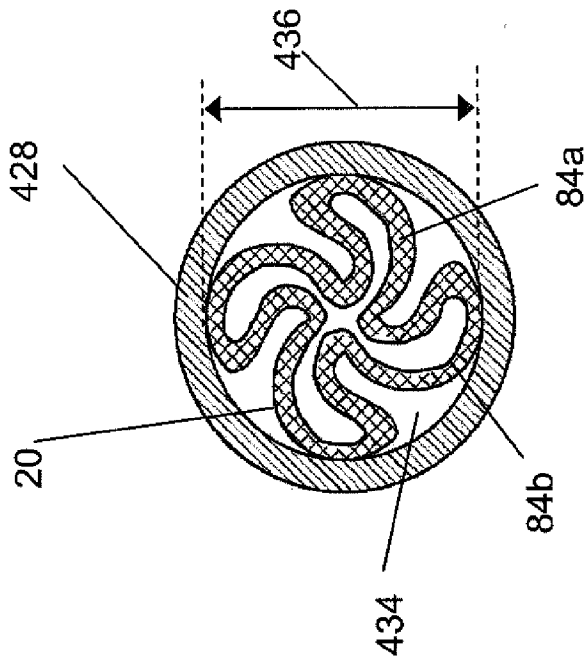


Figure 57B

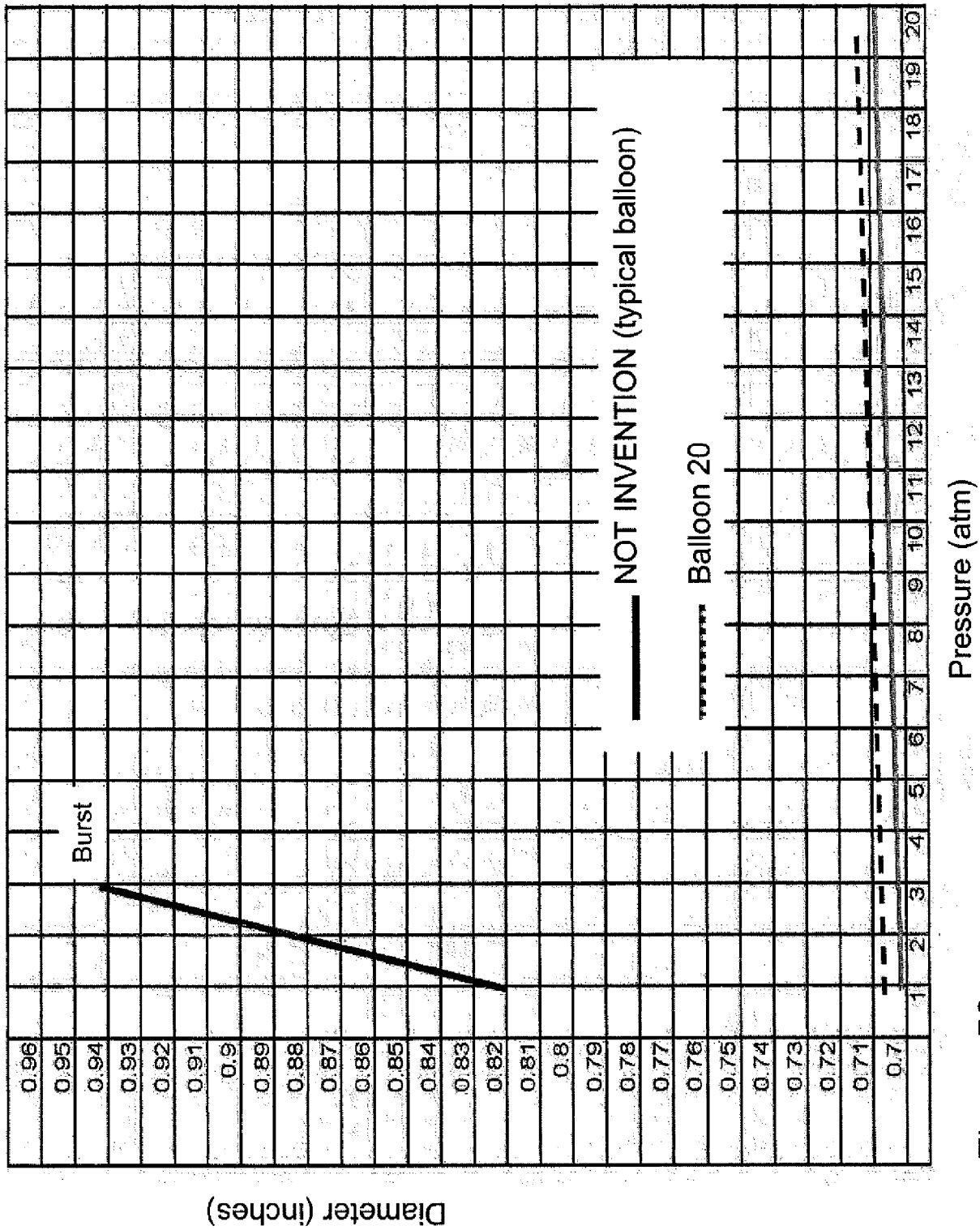


Figure 58

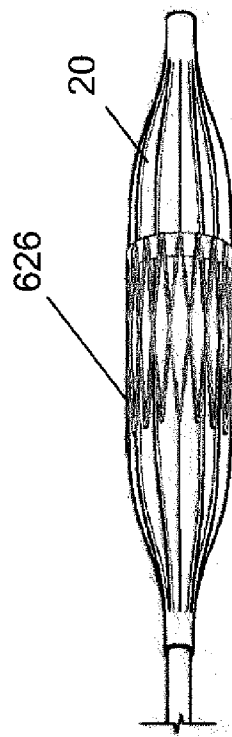


Figure 62A

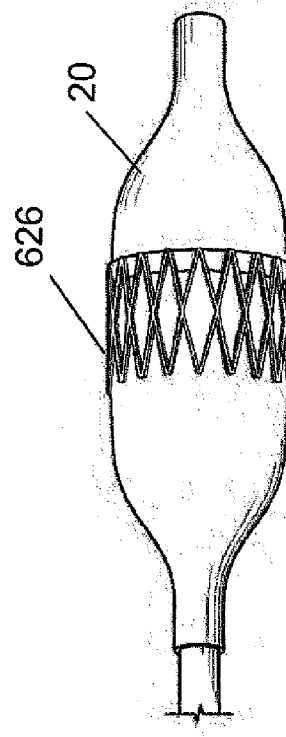


Figure 62B

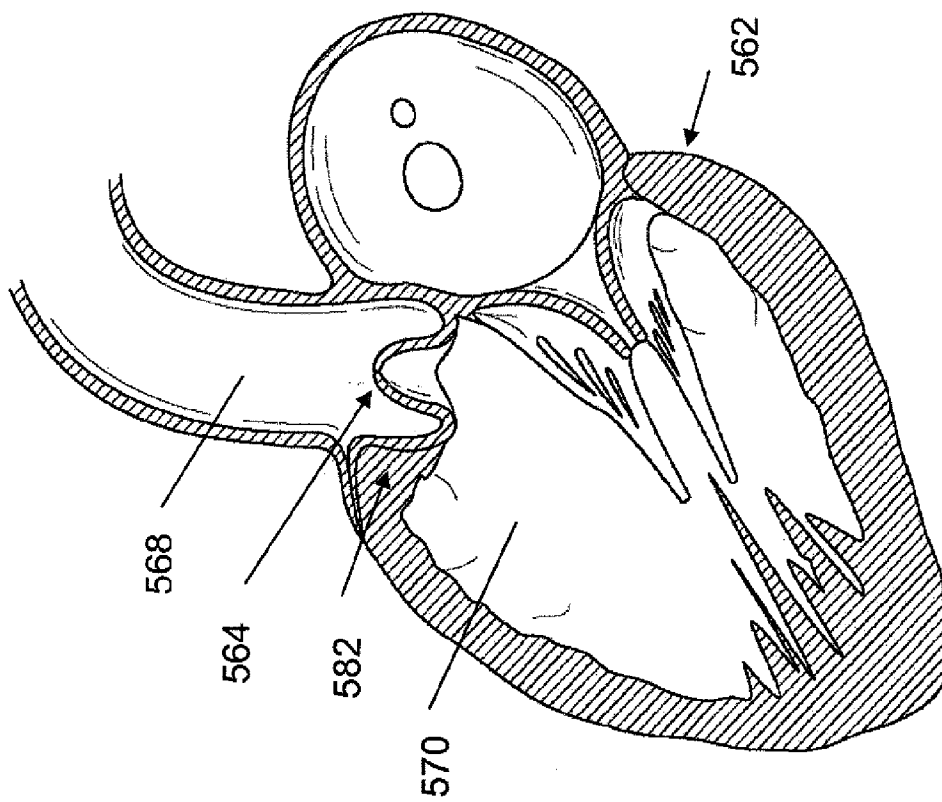


Figure 61

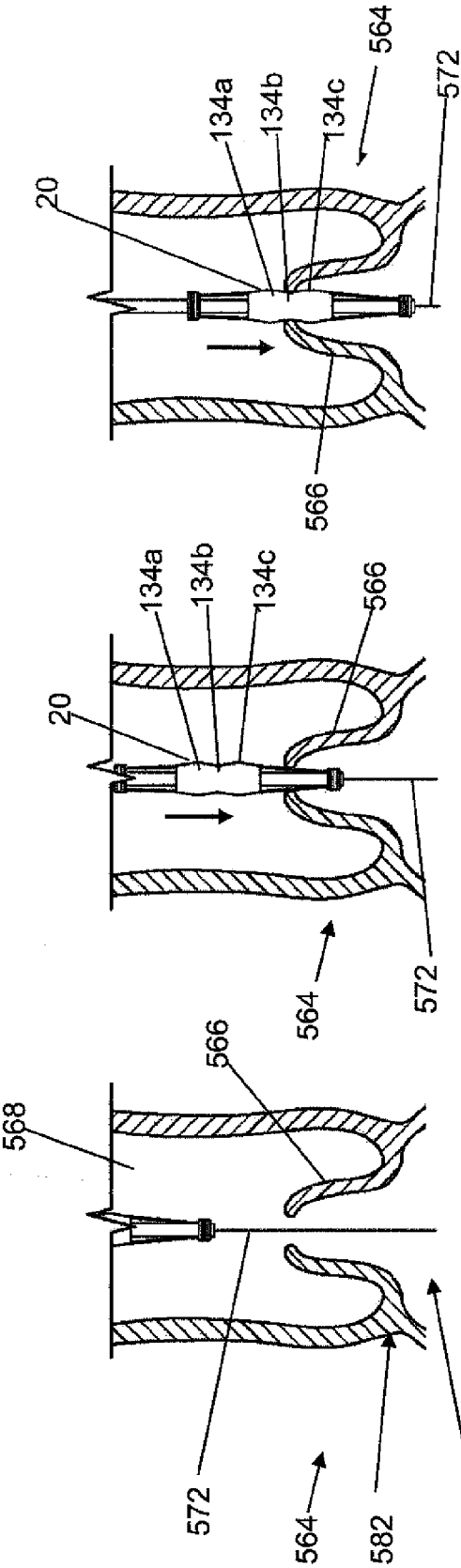


Figure 63A

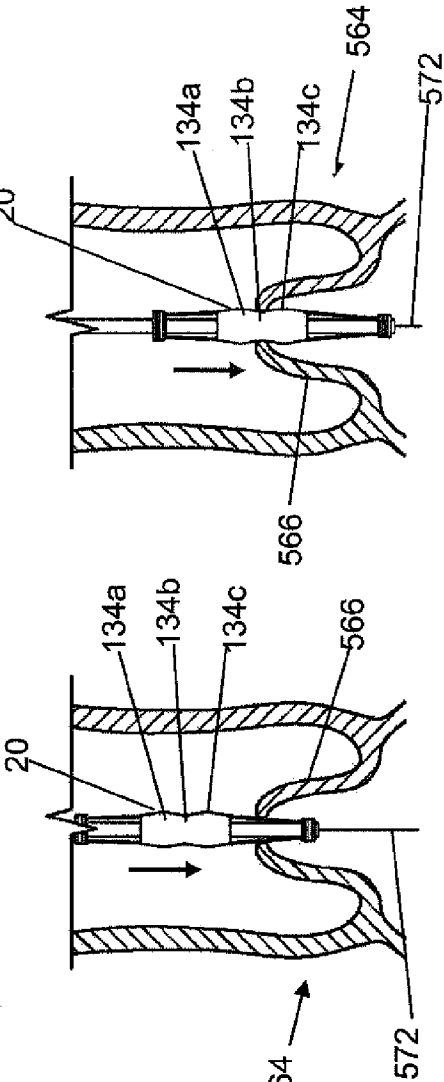


Figure 63B

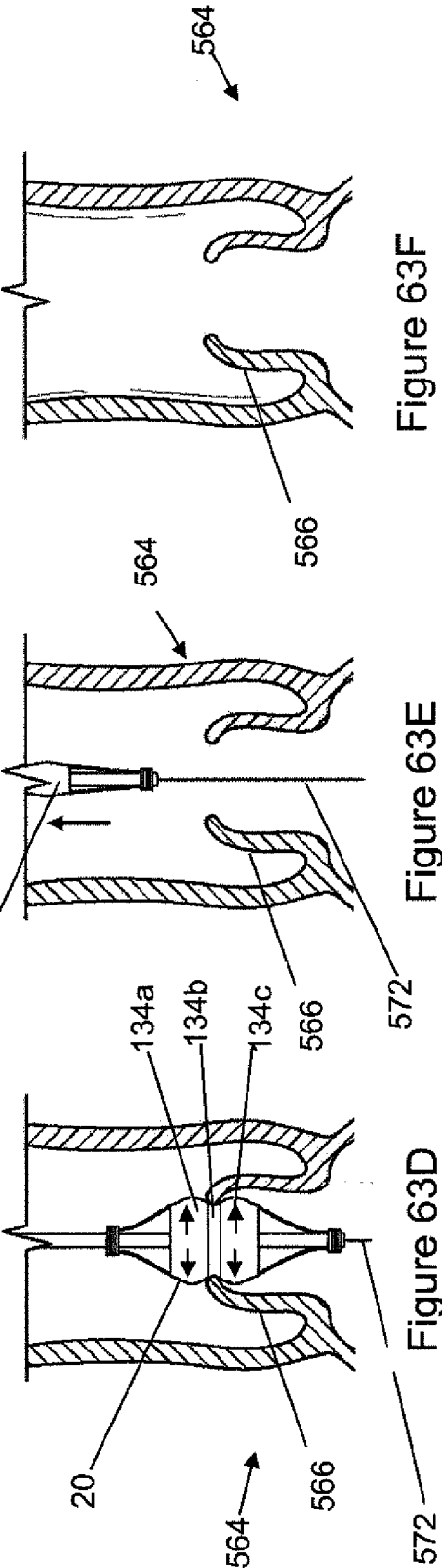


Figure 63C

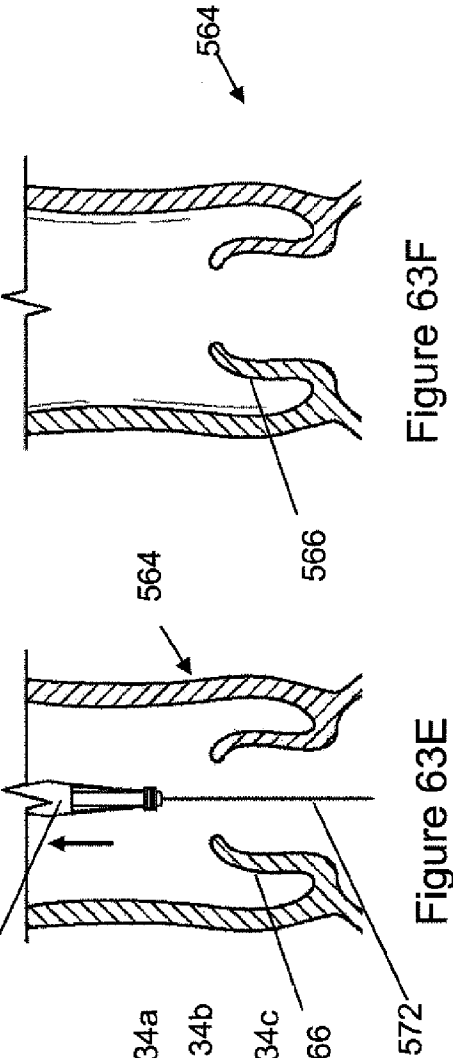


Figure 63D

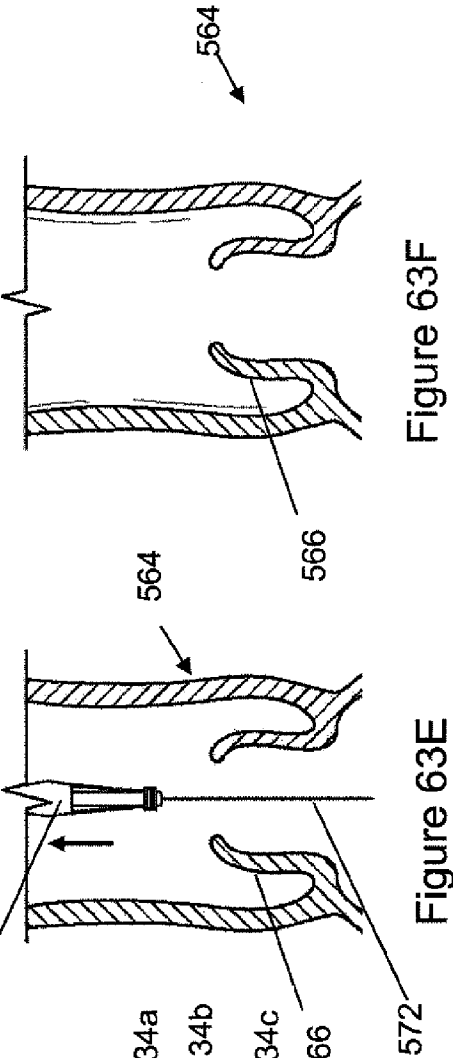


Figure 63E

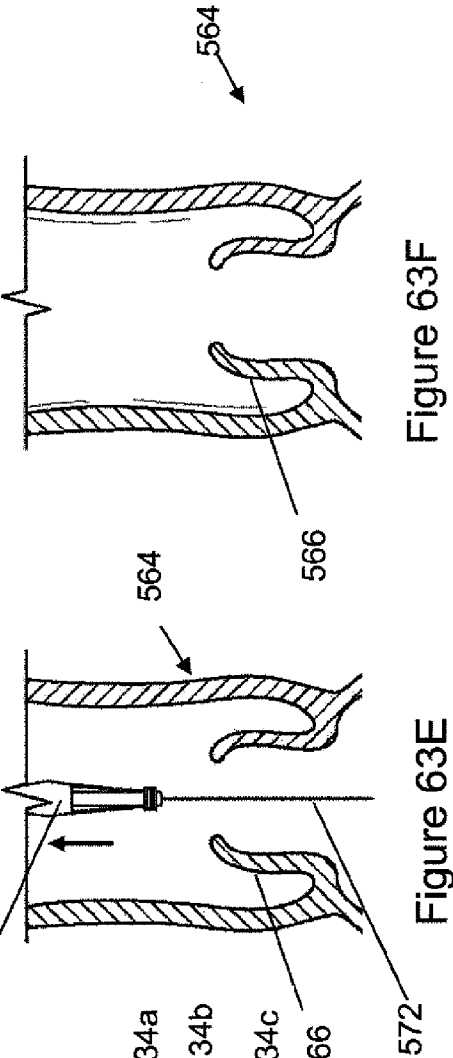


Figure 63F

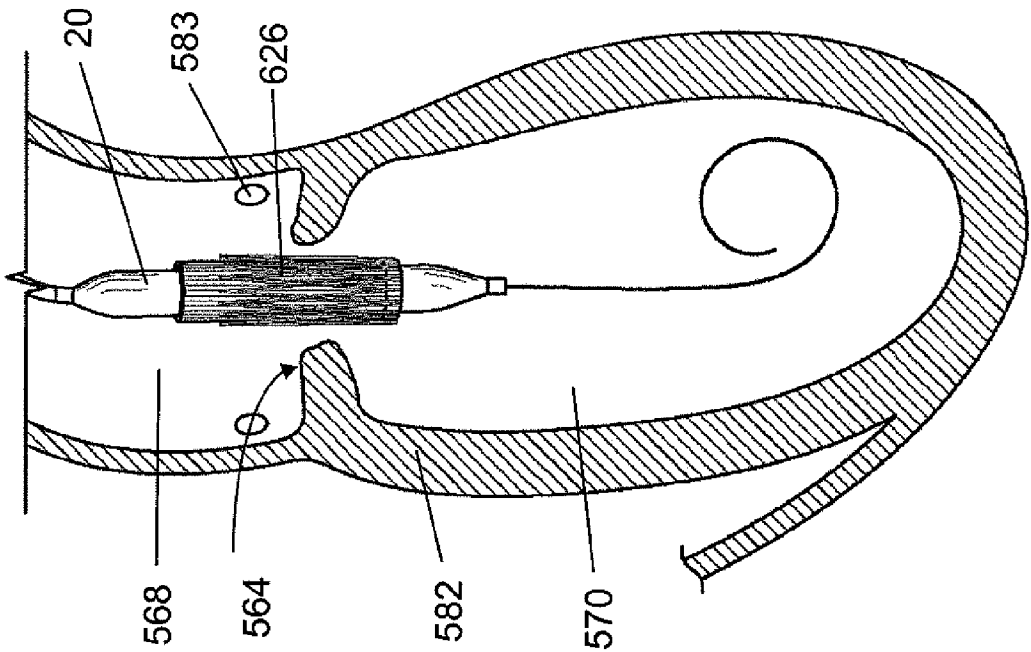


Figure 64B

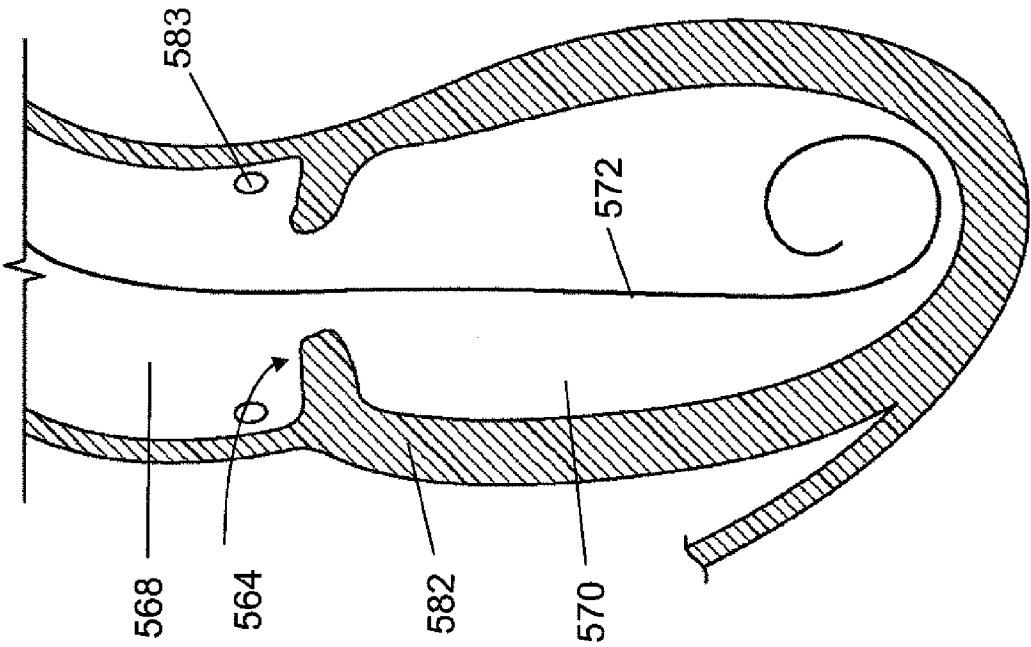


Figure 64A

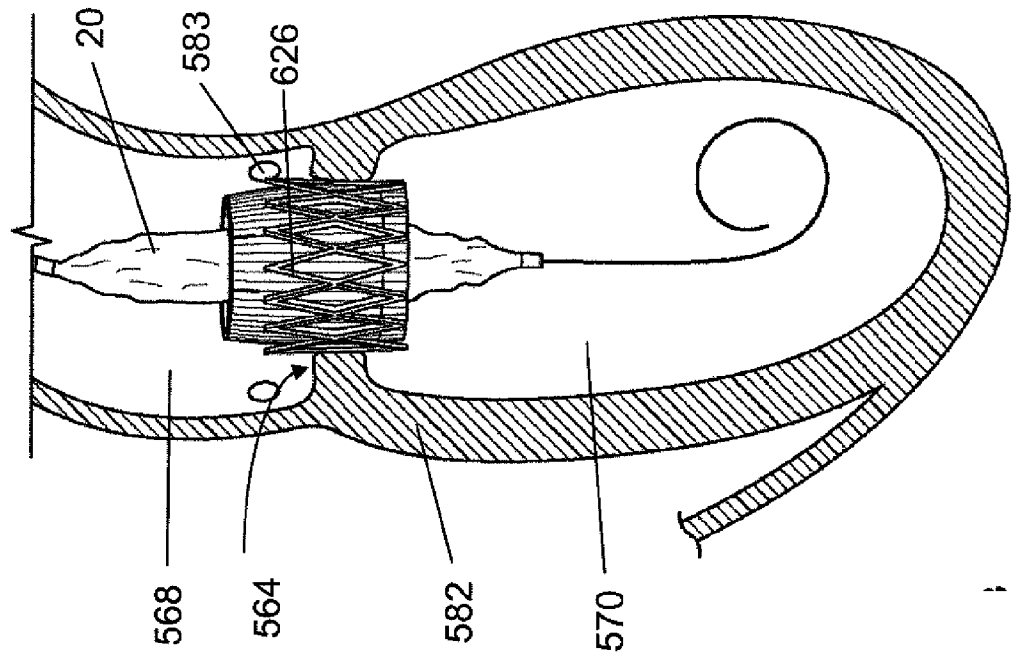


Figure 64D

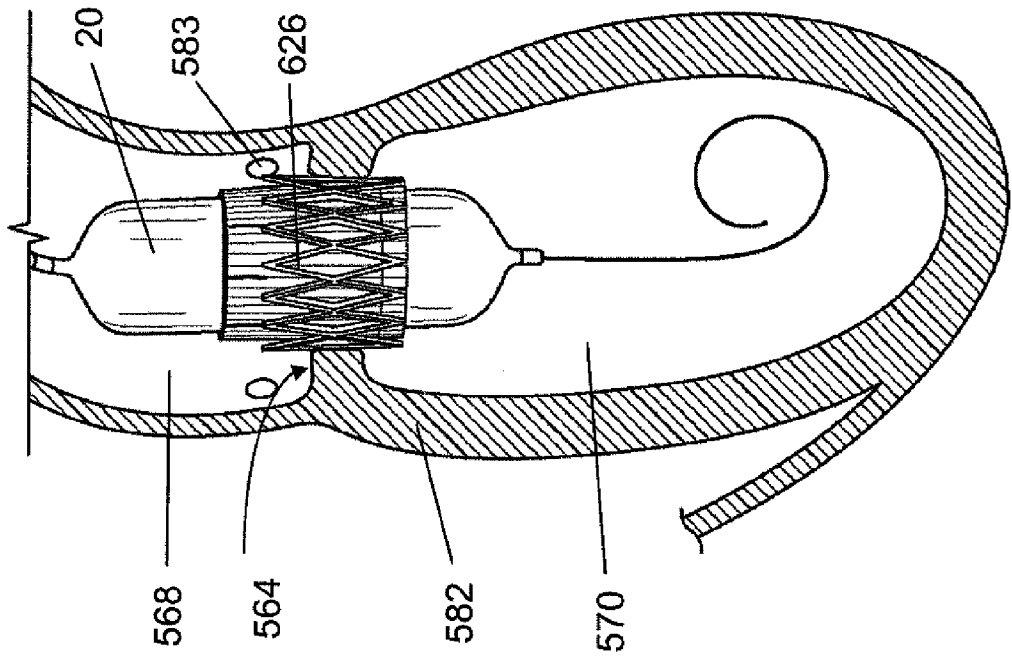


Figure 64C

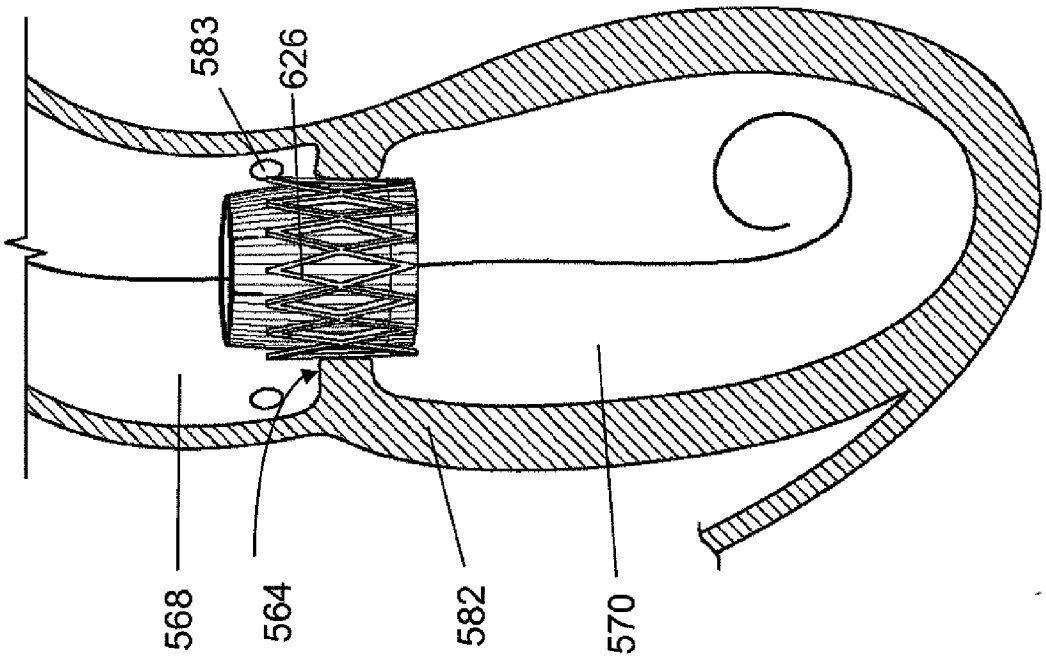


Figure 64F

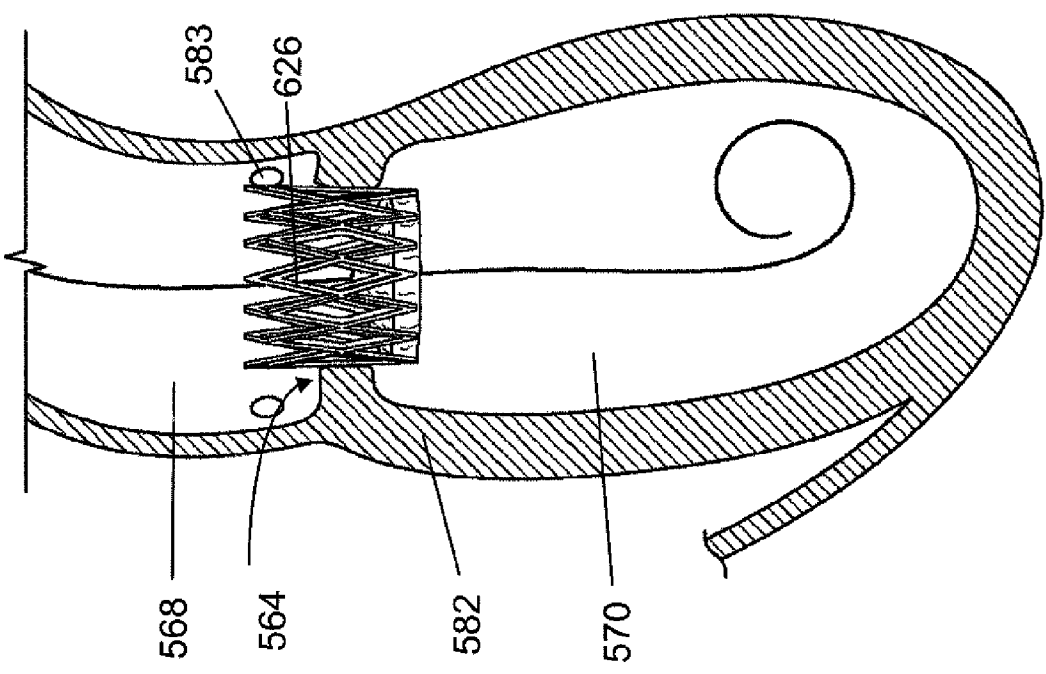
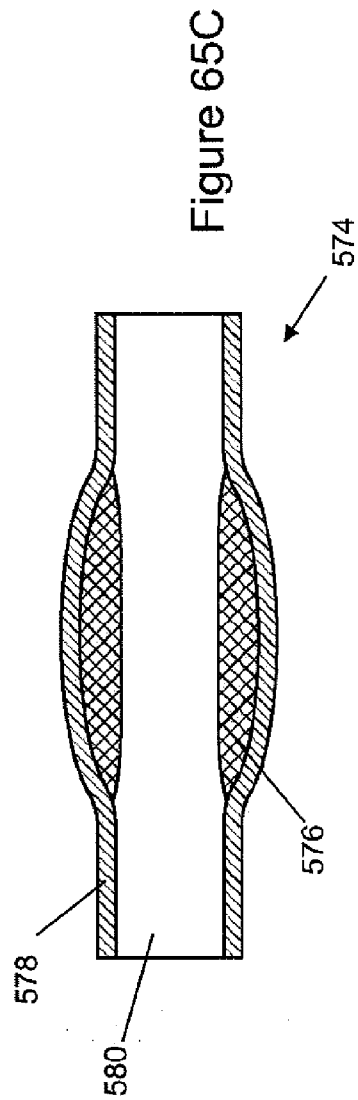
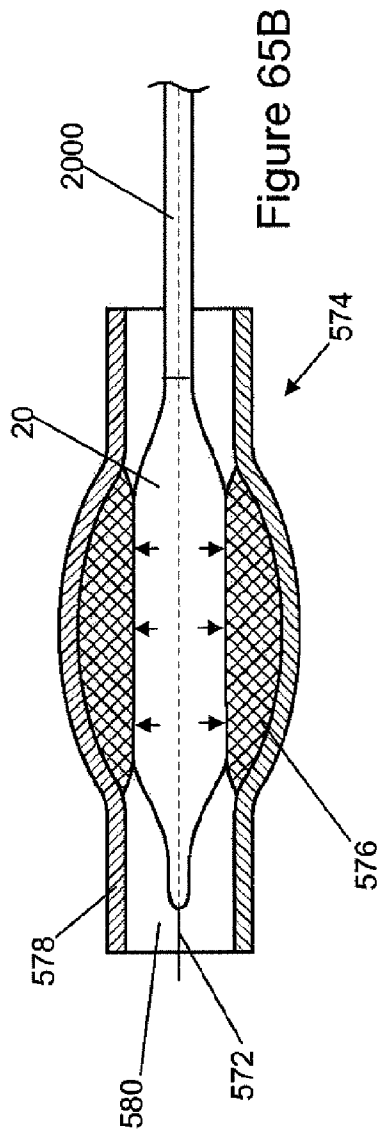
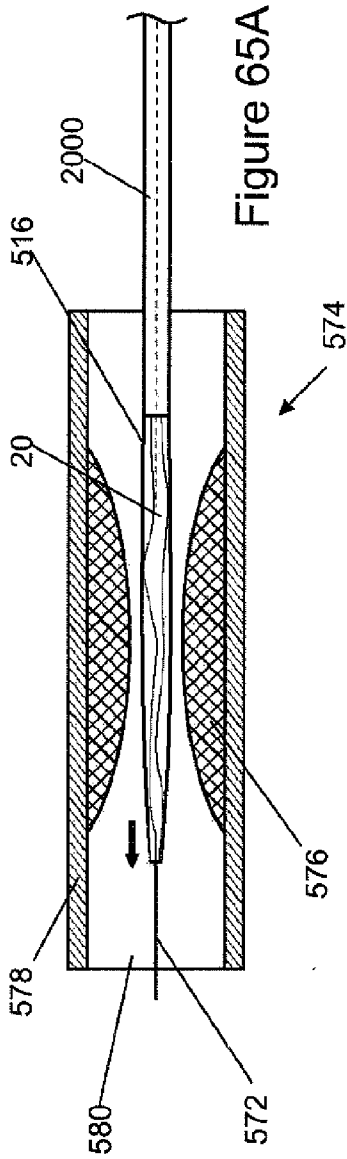


Figure 64E



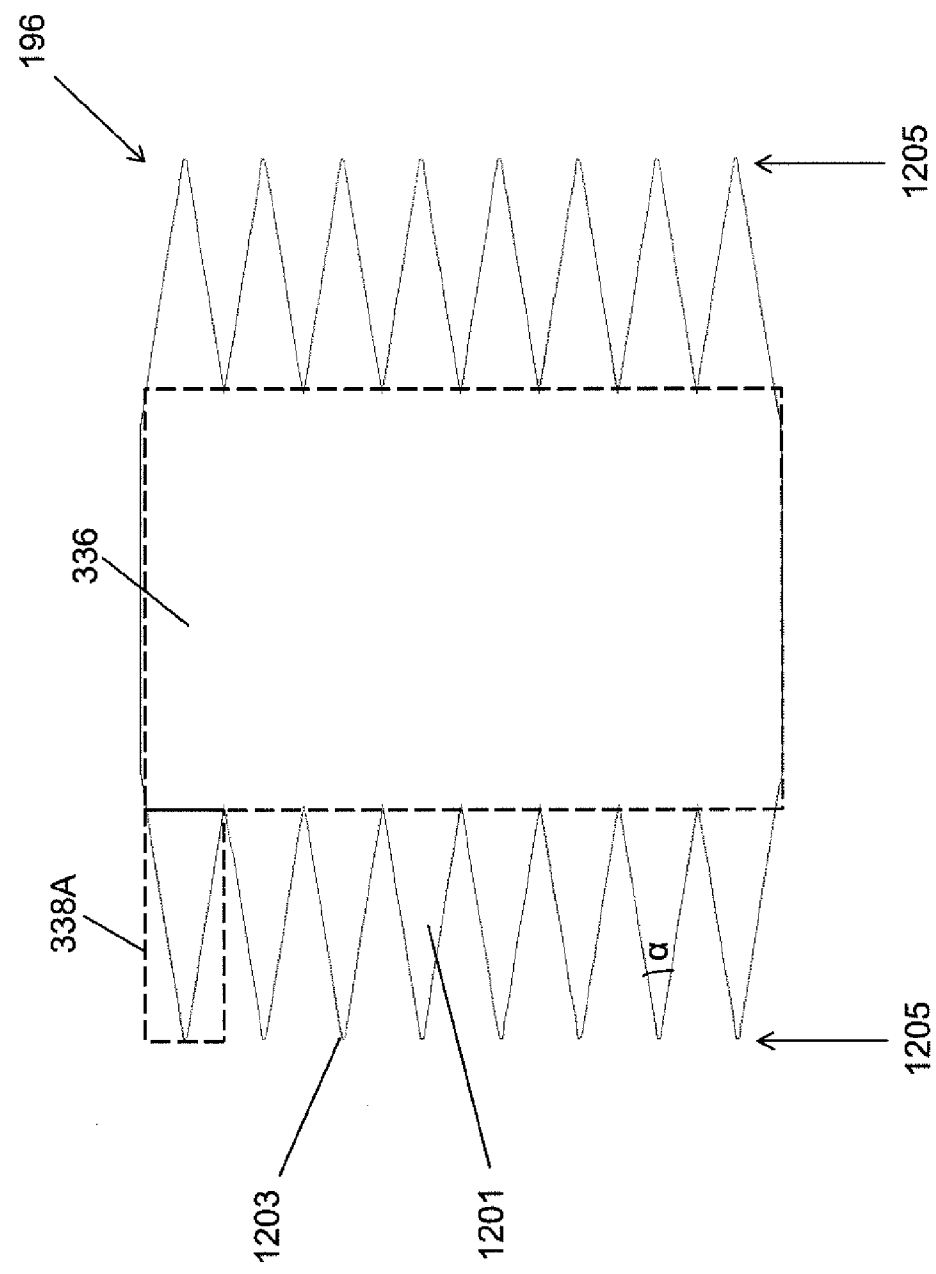


Figure 66A

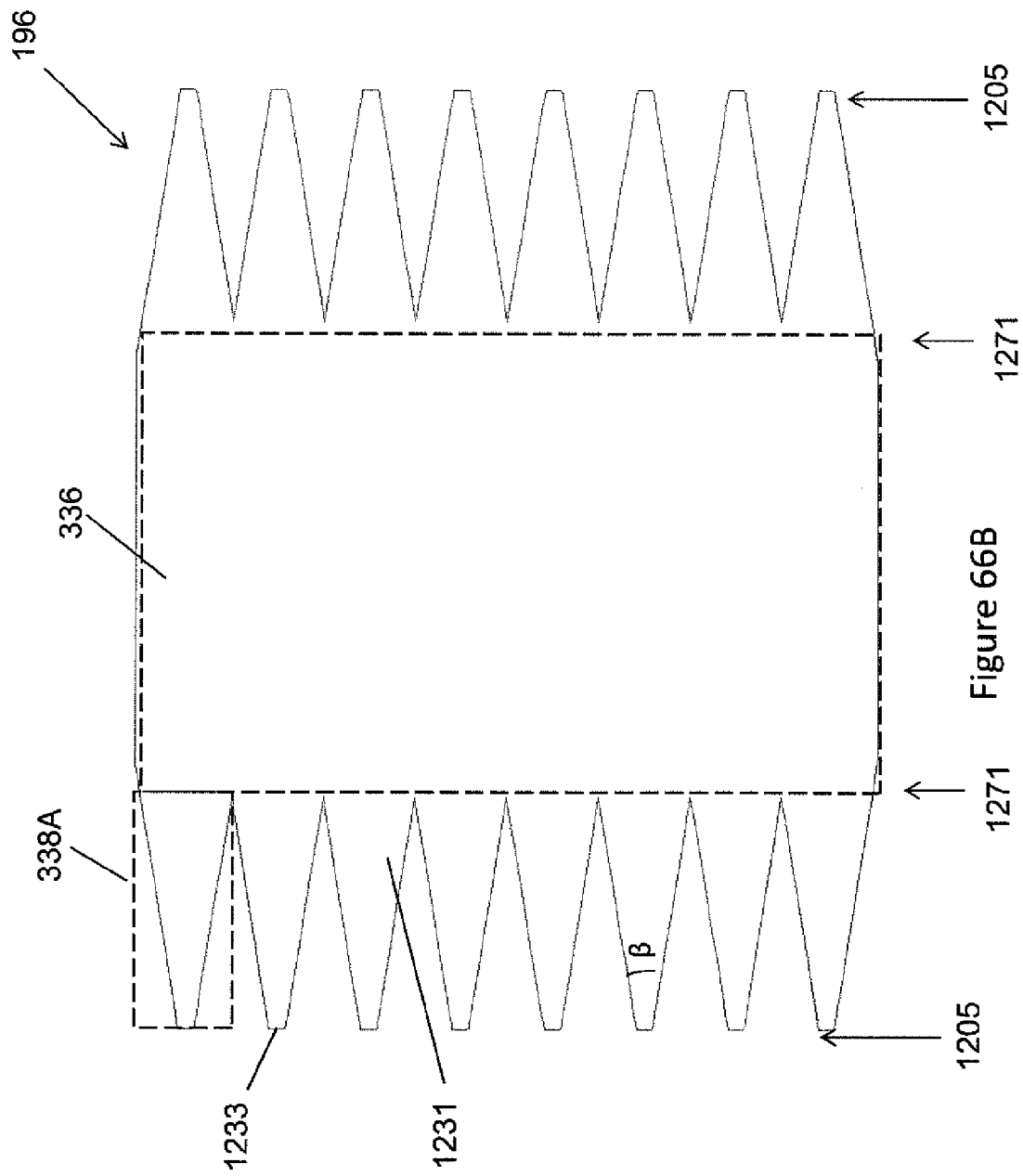


Figure 66B

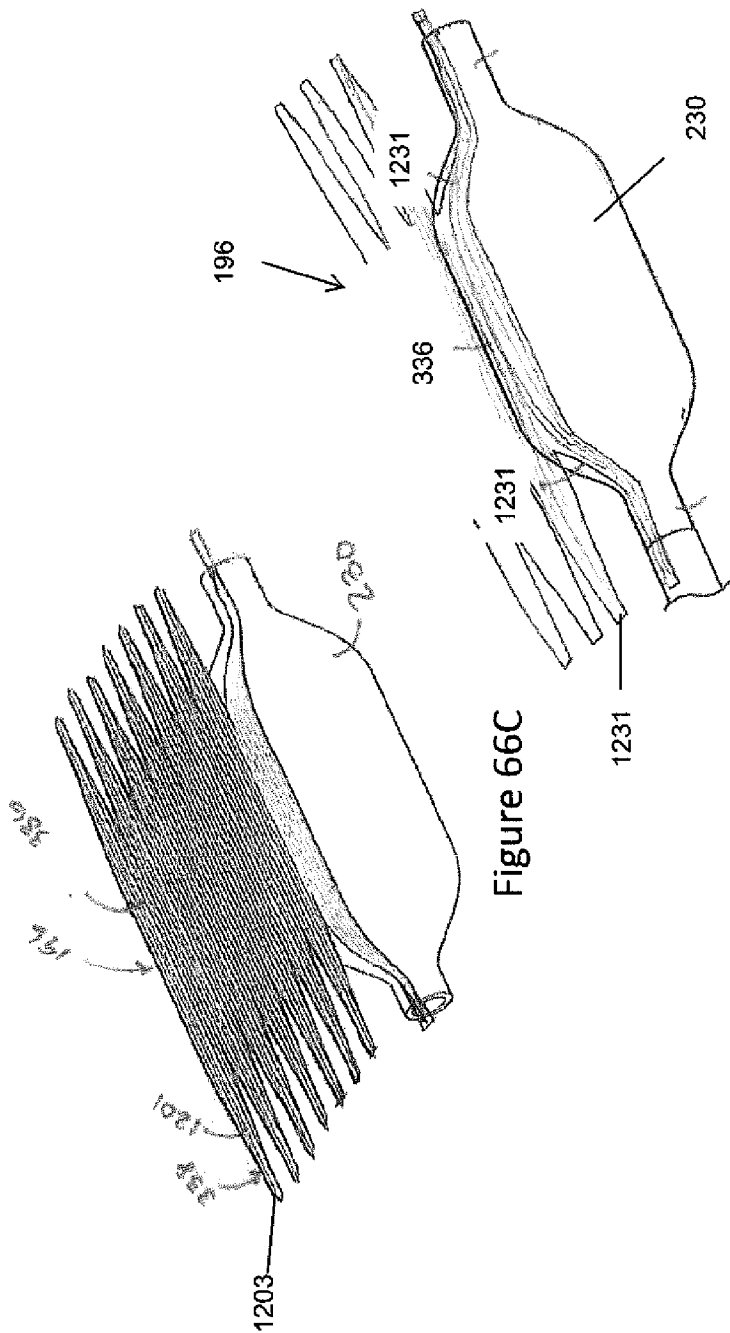


Figure 66C

Figure 66D

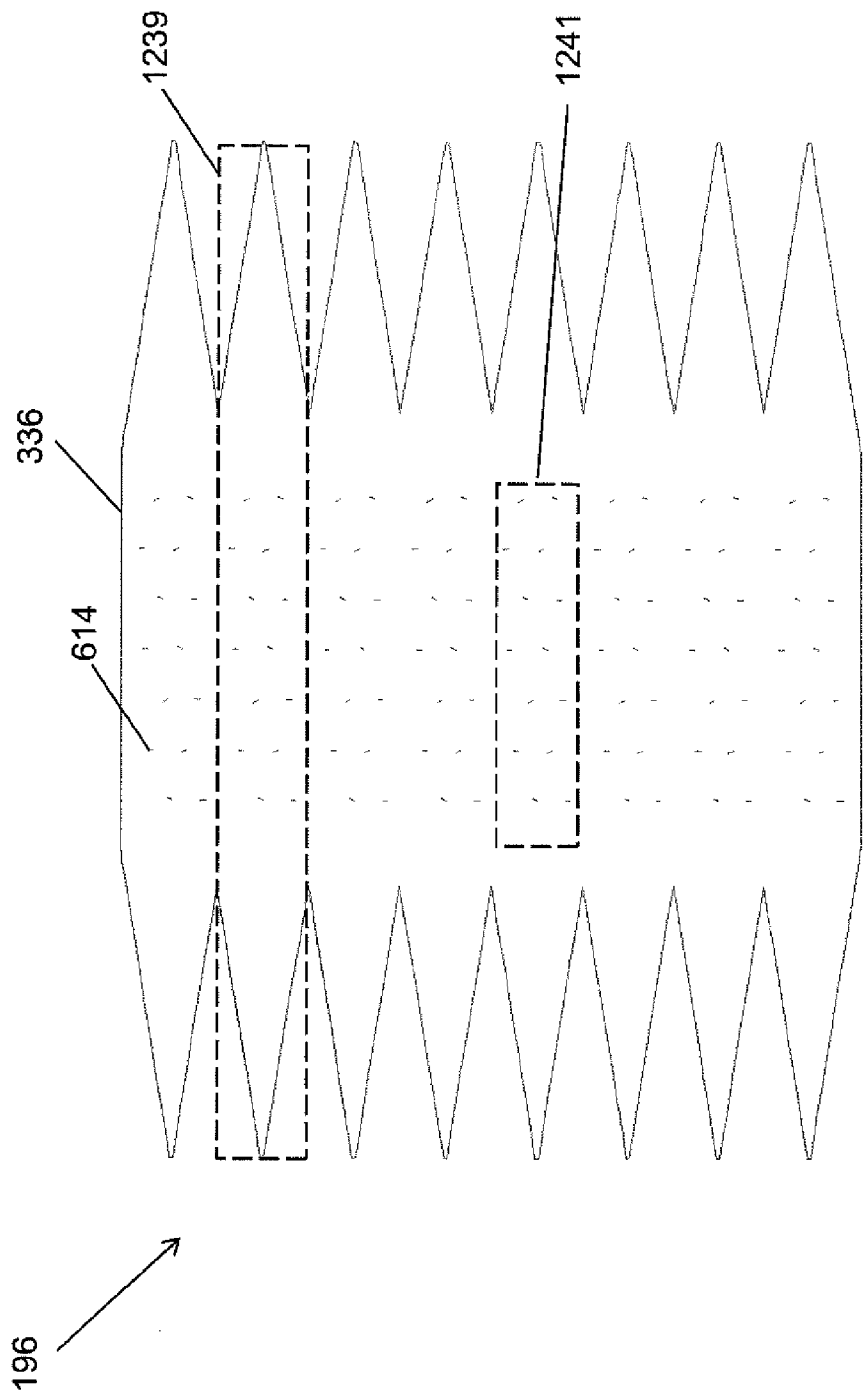


Figure 67A

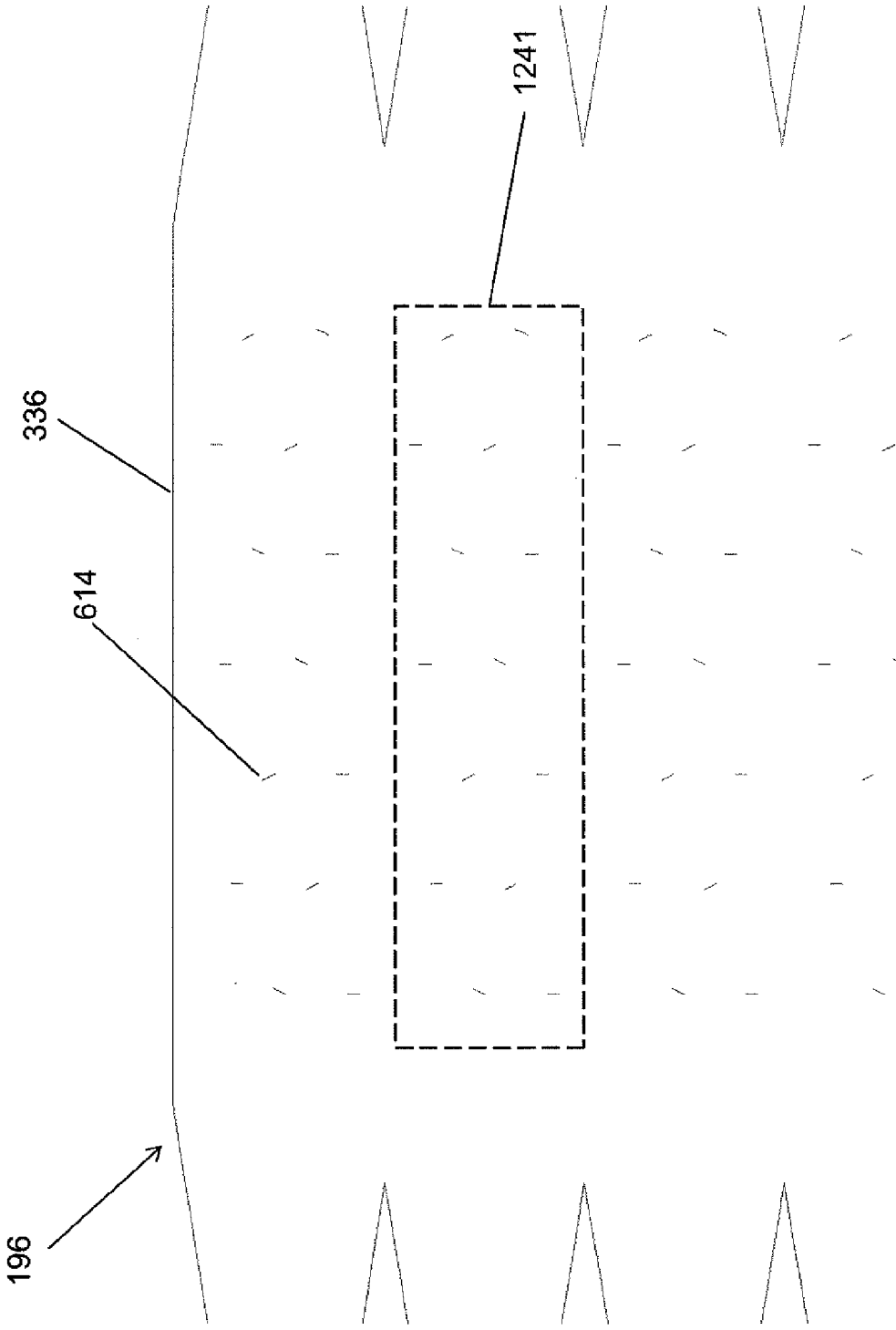


Figure 67B

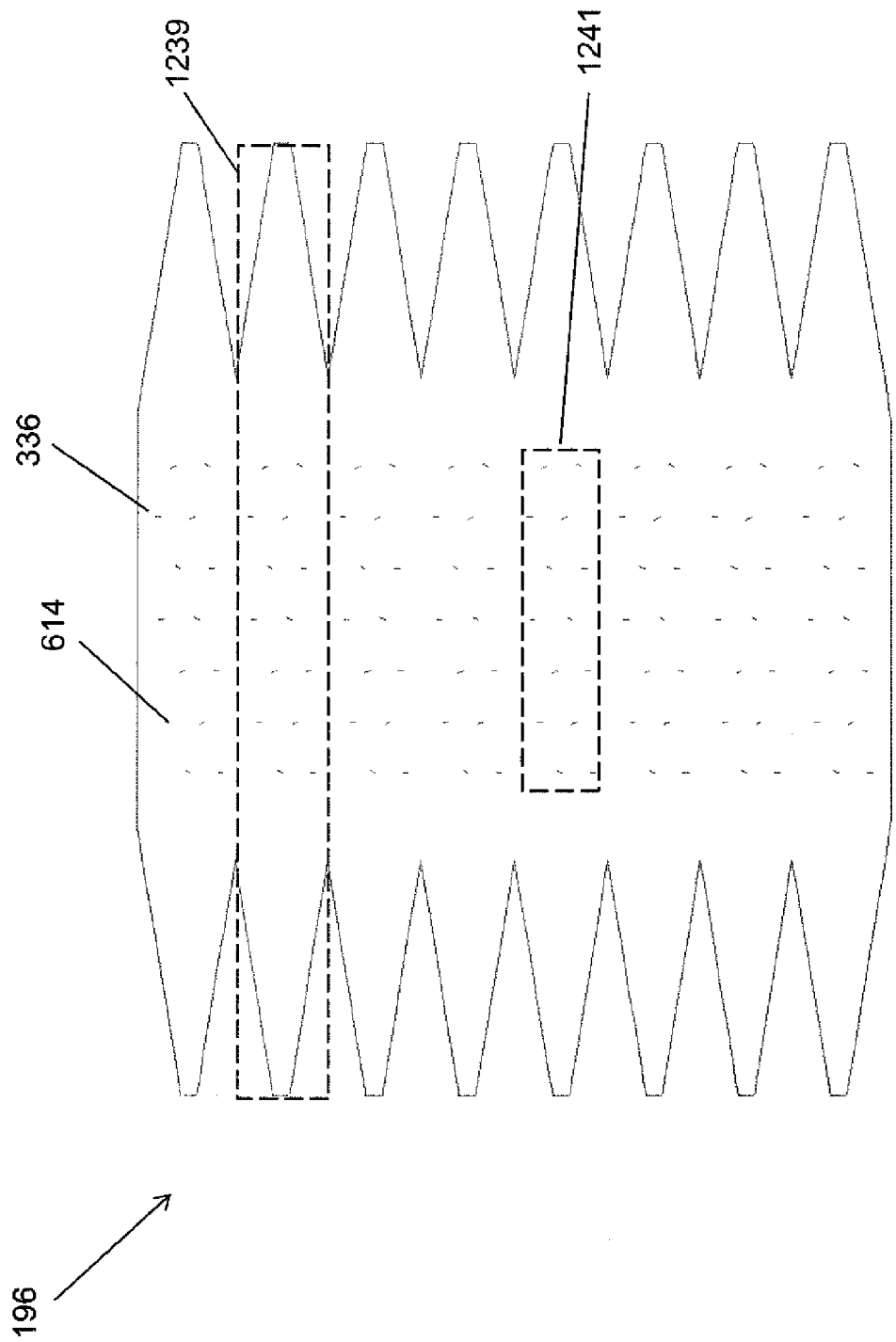
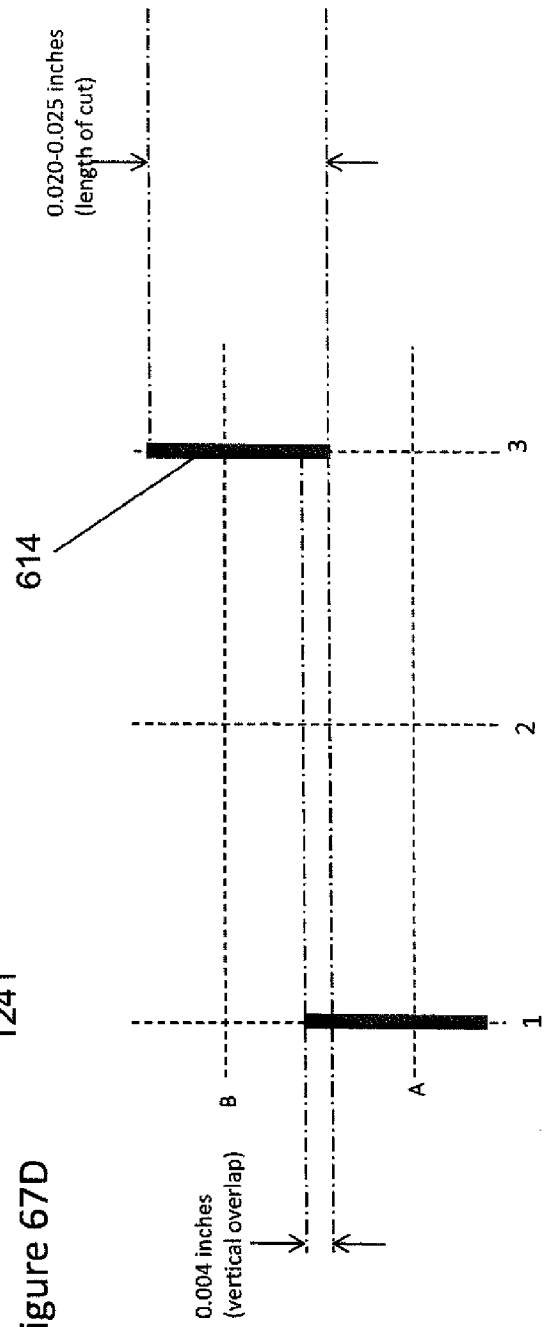
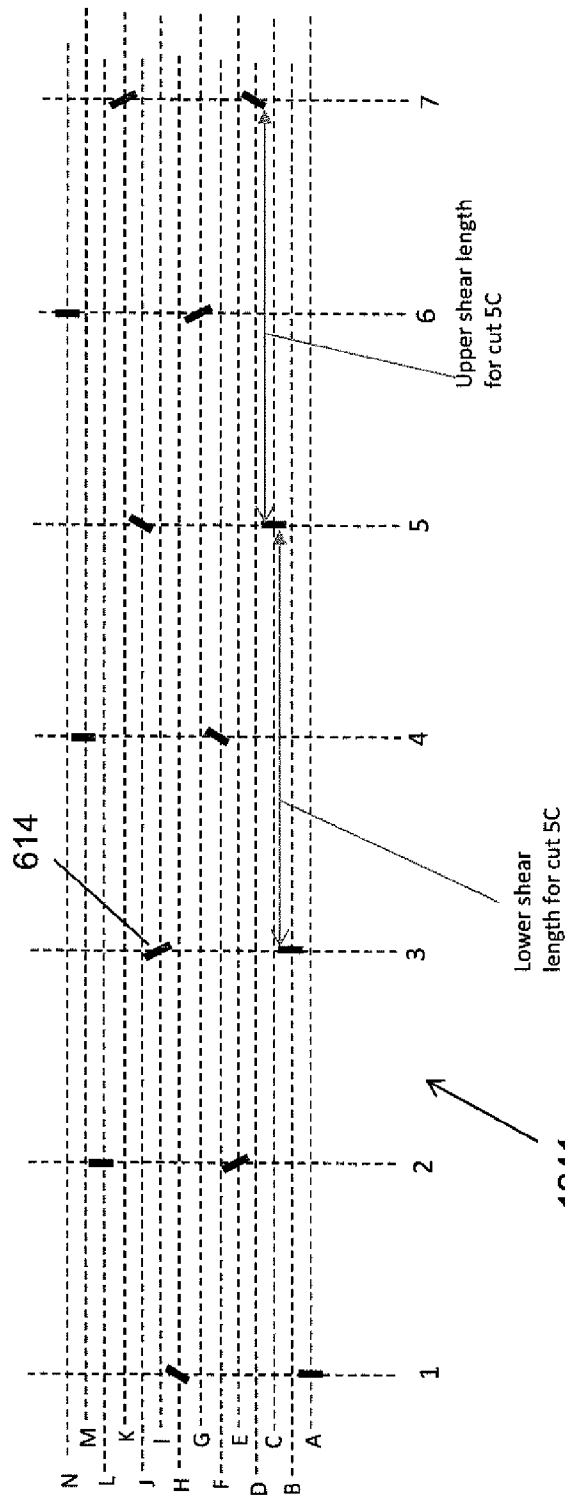


Figure 67C



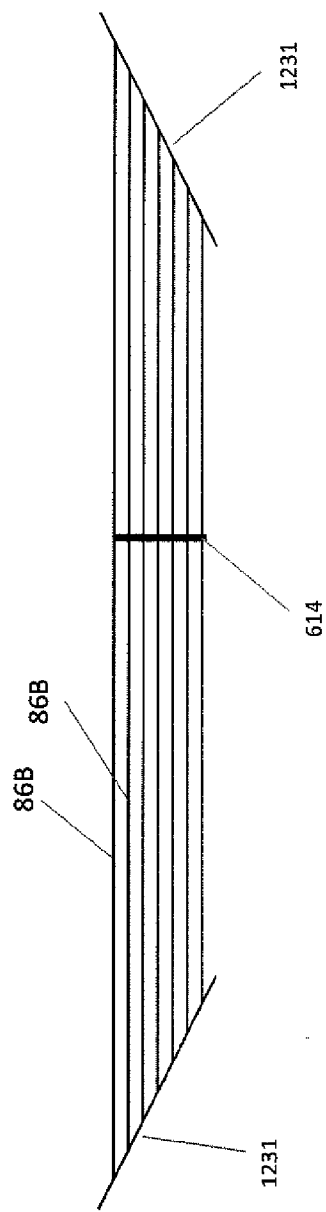


Figure 67F

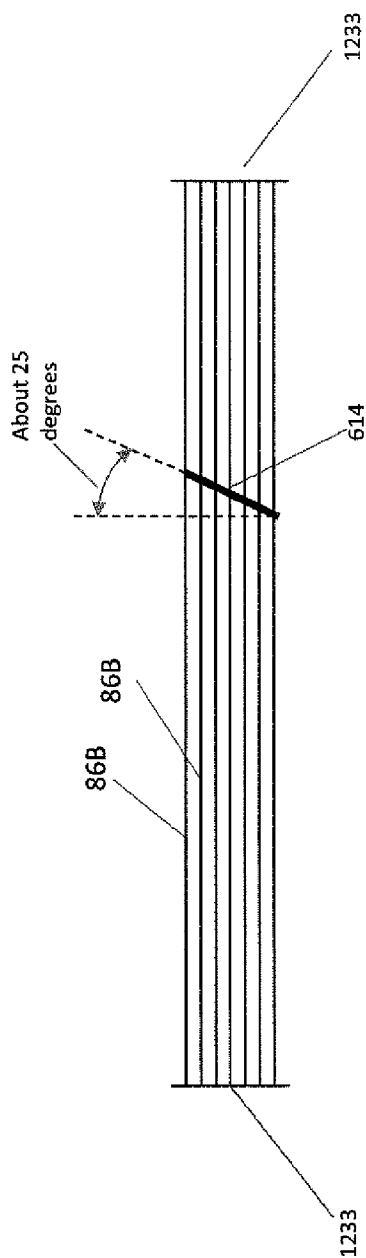


Figure 67G

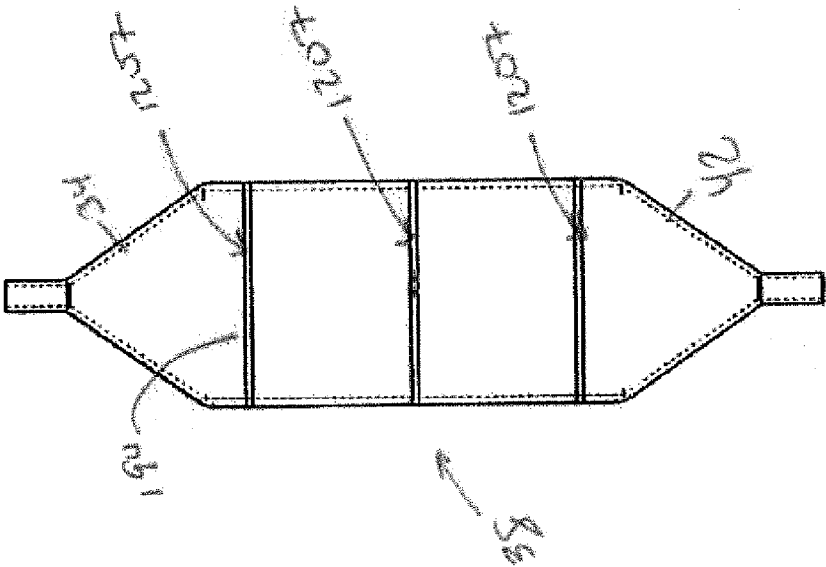


Figure 68A

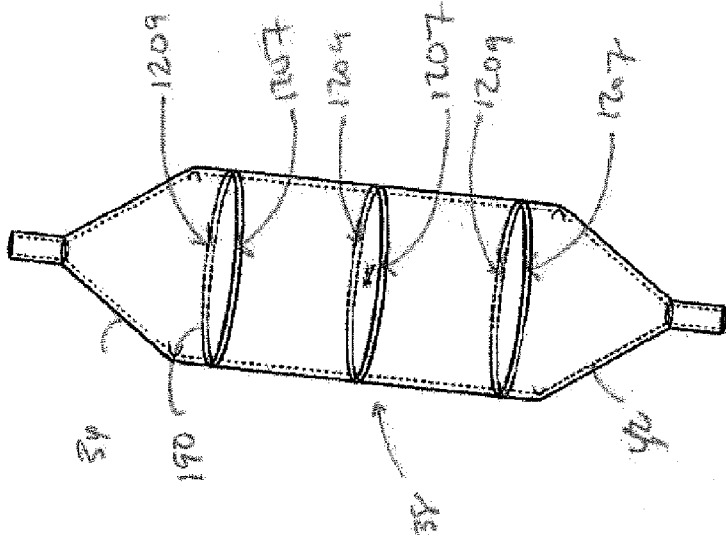


Figure 68B

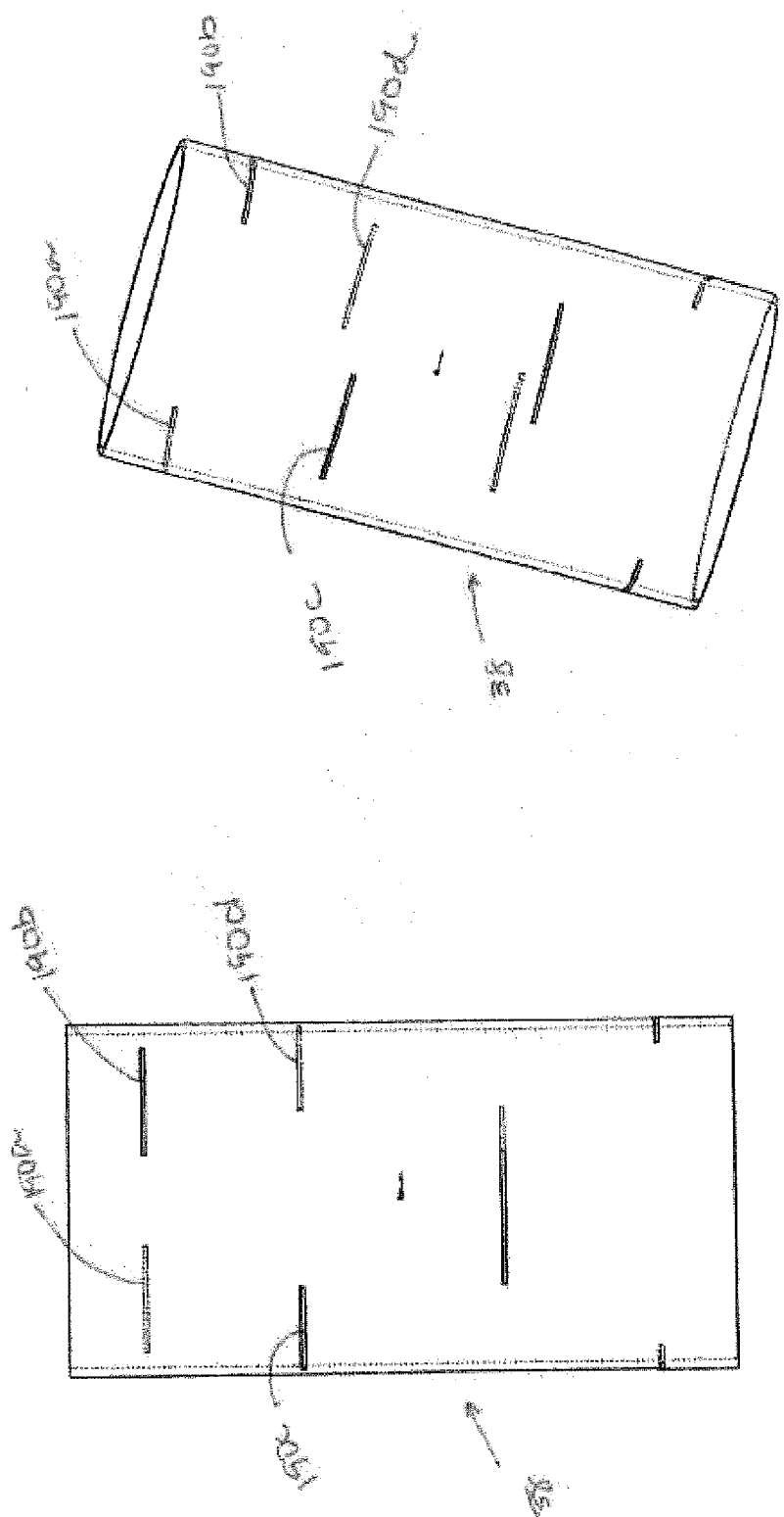


Figure 69B

Figure 69A

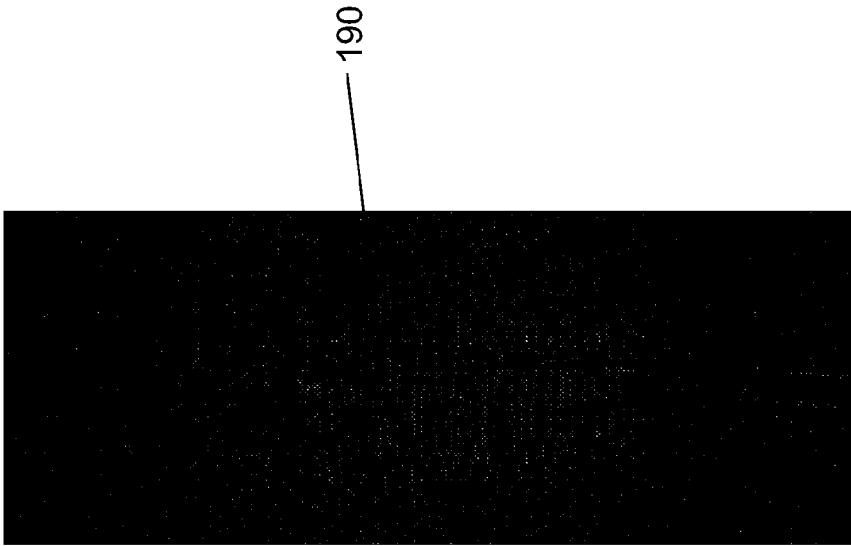


Figure 70B

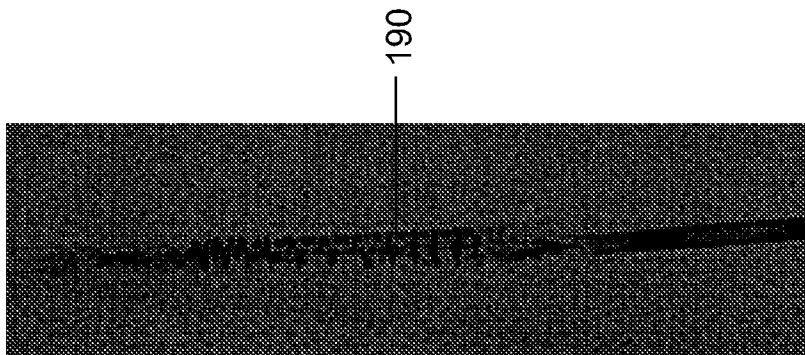


Figure 70A

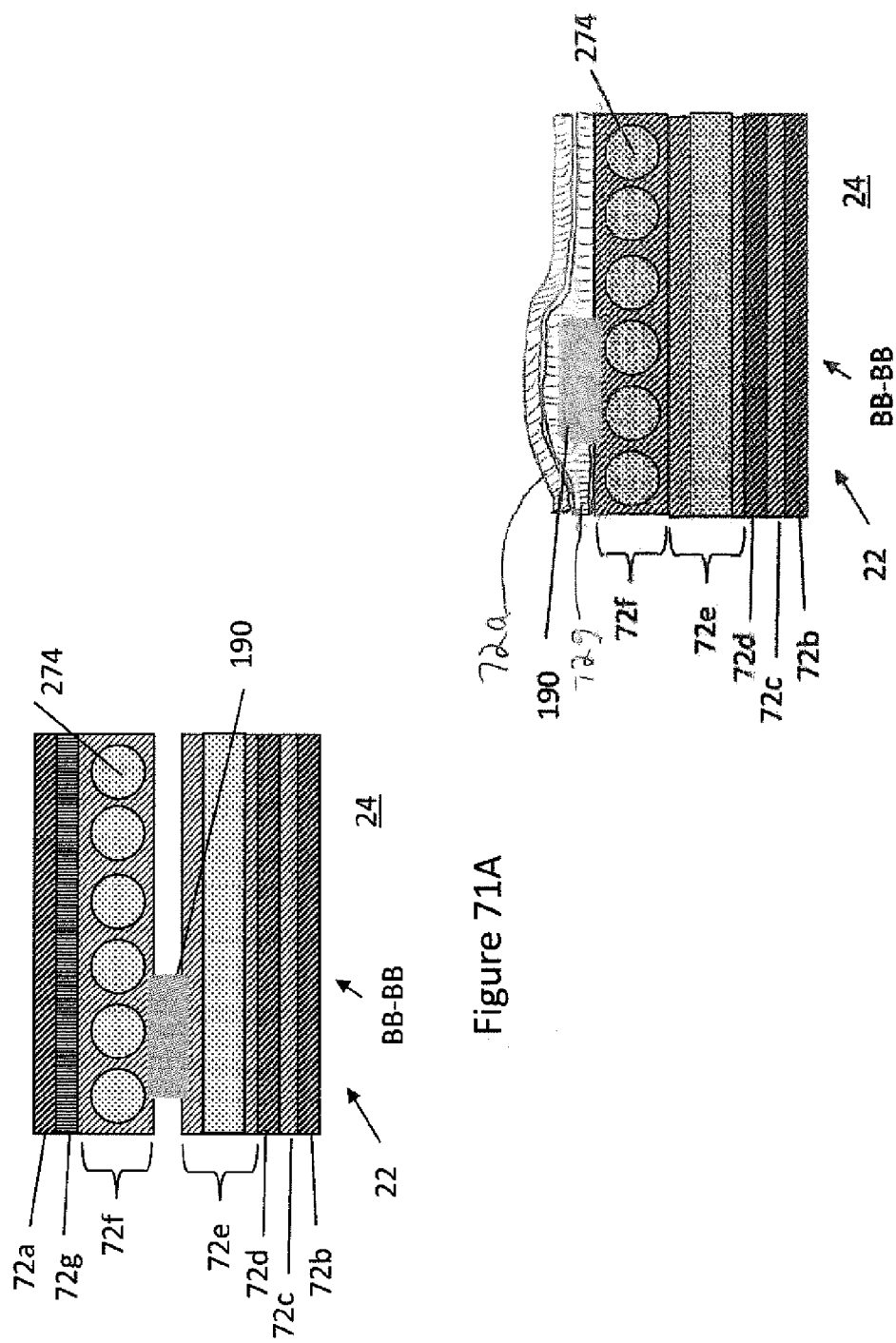


Figure 71A

Figure 71B

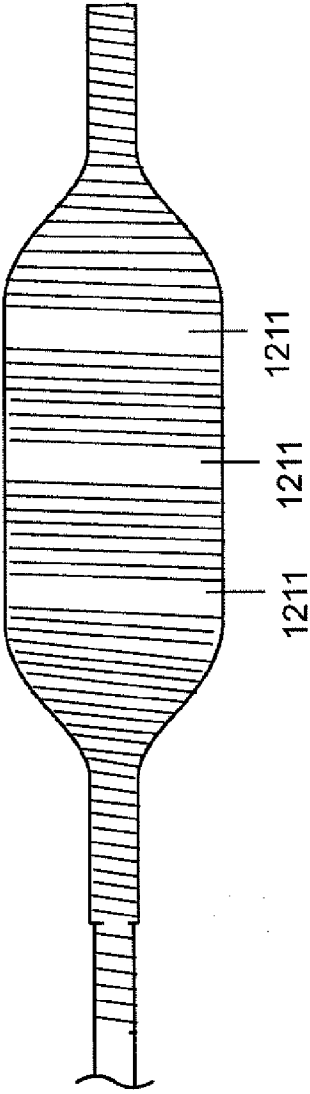


Figure 72

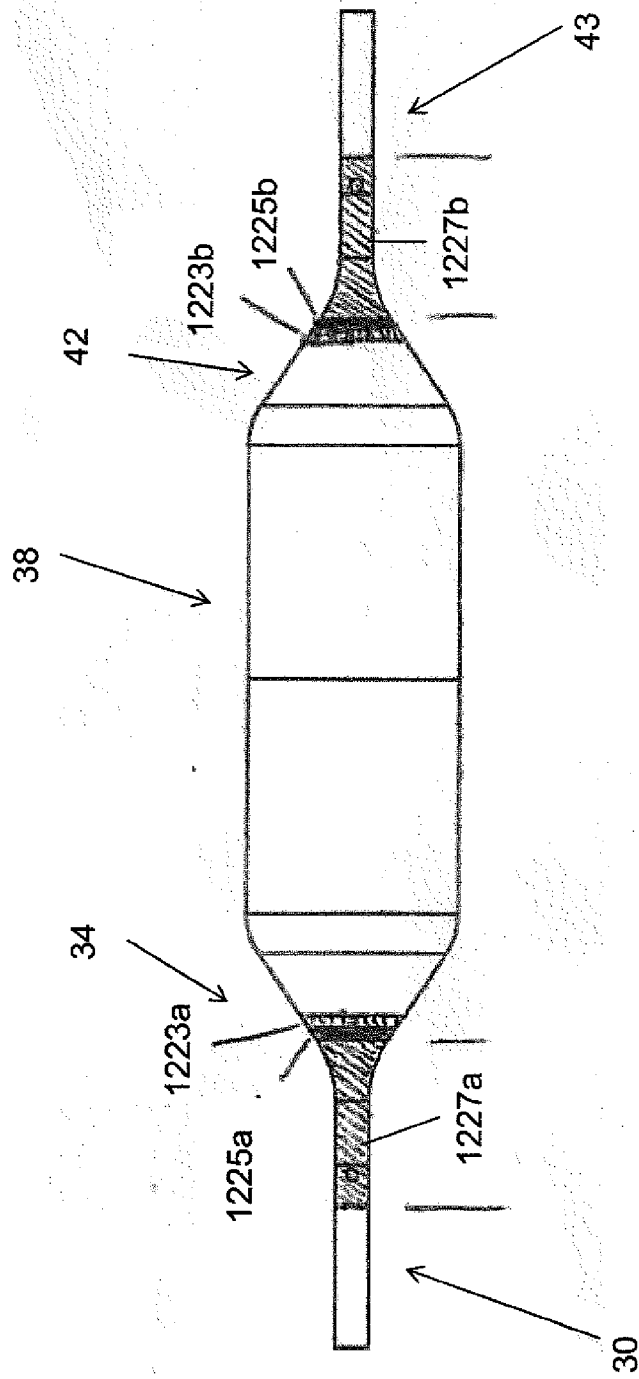


Figure 73

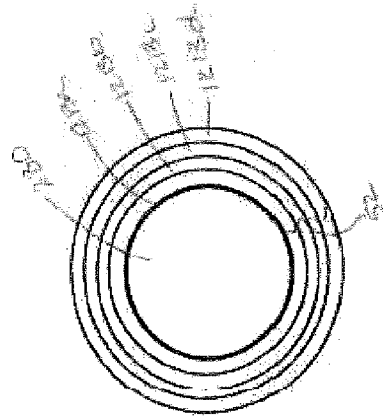


Figure 74

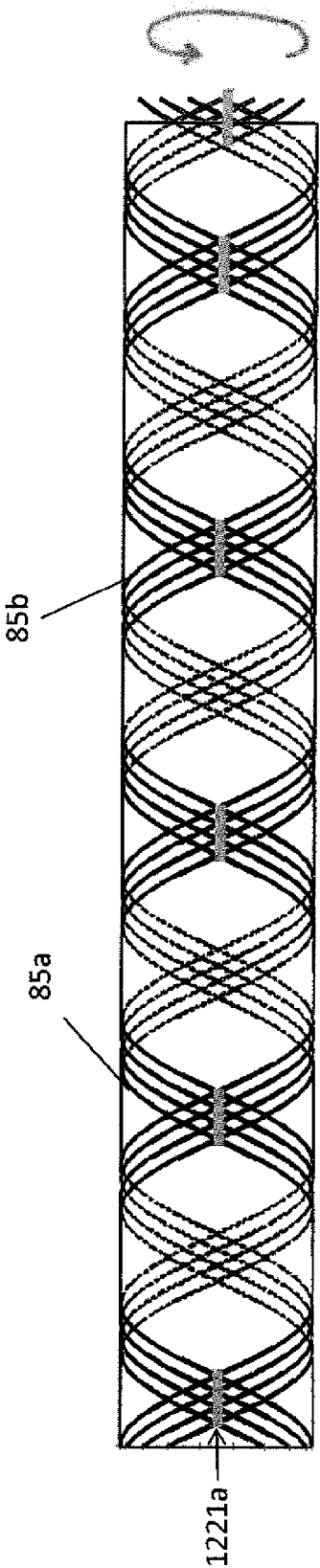


Figure 75A

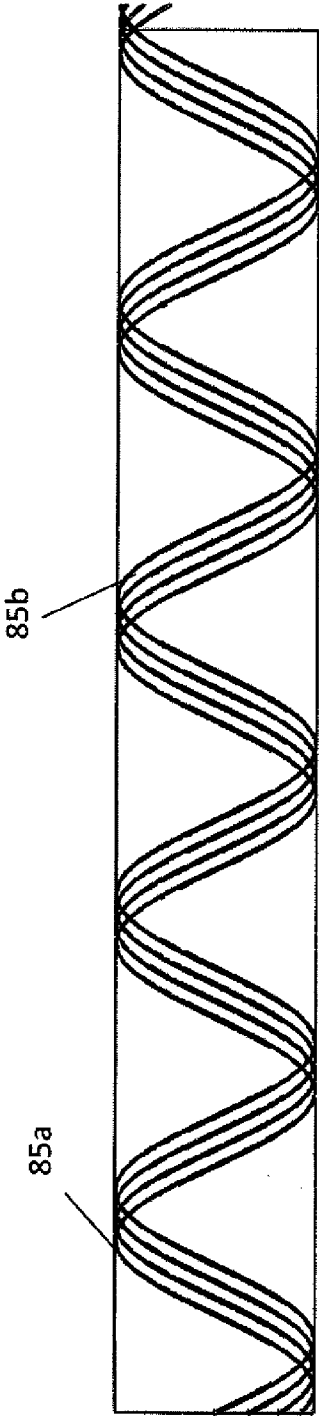


Figure 75B

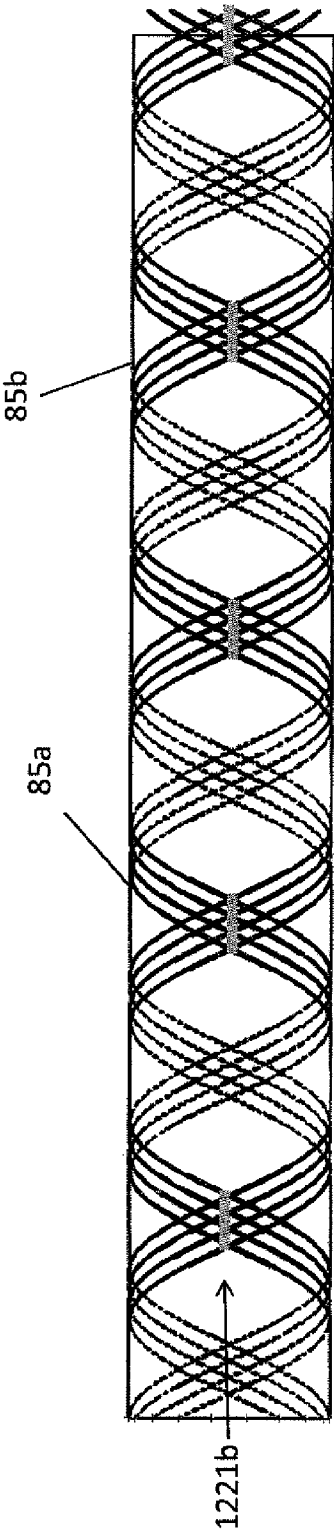


Figure 75C

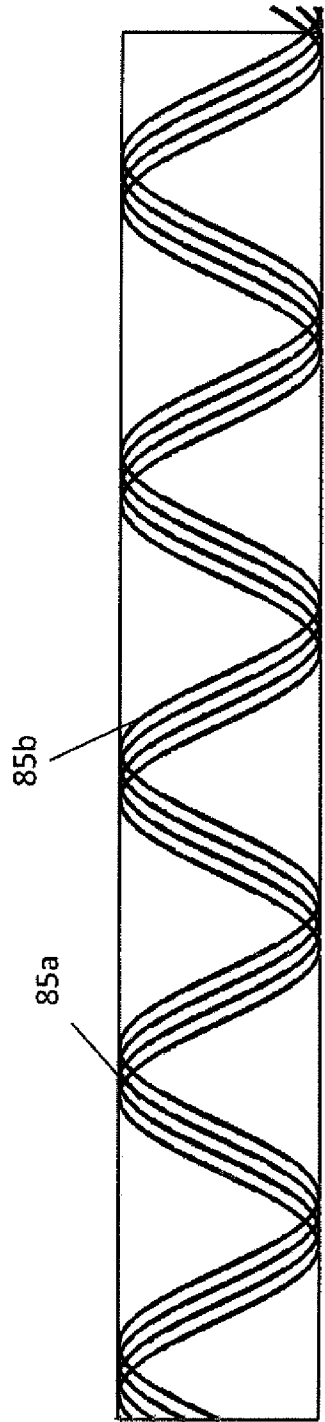


Figure 75D