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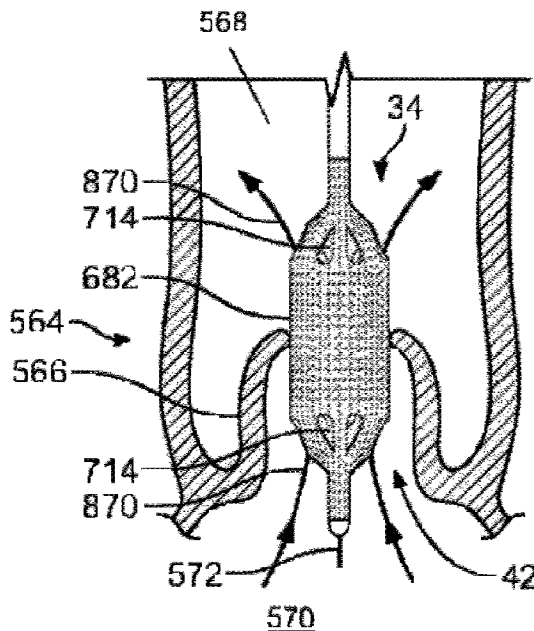
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(54) Titre : DISPOSITIFS MEDICAUX GONFLABLES  
 (54) Title: INFLATABLE MEDICAL DEVICES



(57) Abrégé/Abstract:

An inflatable structure for use in biological lumens and methods of making and using the same are disclosed. The structure can have an inflatable balloon encircled by a shell. The shell can have proximal and distal tapered necks, longitudinally-oriented flutes, and apertures at the proximal and distal ends of the shell. The apertures can be recessed in the flutes in the necks. The shell can also have fiber reinforced walls.

**ABSTRACT**

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An inflatable structure for use in biological lumens and methods of making and using the same are disclosed. The structure can have an inflatable balloon encircled by a shell. The shell can have proximal and distal tapered necks, longitudinally-oriented flutes, and apertures at the proximal and distal ends of the shell. The apertures can be recessed in the flutes in the necks. The shell can also have fiber reinforced walls.

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**TITLE OF THE INVENTION**  
**INFLATABLE MEDICAL DEVICES**

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**CROSS-REFERENCE TO RELATED APPLICATIONS**

**[0001]** The present application claims priority to U.S. Application No. 61/433,896 filed 18 Jan 2011; and 61/486,720 filed 16 May 2011.

**BACKGROUND**

**1. Technical Field**

**[0002]** Inflatable medical devices and methods for making and using the same are disclosed. More narrowly, medical invasive balloons, such as those used for trans-cutaneous heart valve implantation are disclosed. For example, those balloons used for trans-catheter aortic-valve implantation.

**[0003]** Inflatable structures are widely used in medical procedures. A structure is inserted, typically on the end of a catheter, until the structure reaches the area of interest. Adding pressure to the structure causes the structure to inflate. In one variation of use, the structure creates a space inside the body when the structure inflates.

**[0004]** Inflatable structures may be used in the heart valves, including during Balloon Aortic Valvuloplasty (BAV) and Transcatheter Aortic Valve Implantation (TAVI). The structures 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 structure. Additionally, a precise inflated structure diameter may be desired for increased safety and control.

**[0005]** Inflatable structures may be used to move plaque or a constriction away from the center of a vascular or other lumen toward the lumen walls, such as during an angioplasty or a peripheral vasculature or an airway procedure. During this procedure, an inflatable structure on the distal end of

1 the catheter is placed in an obstruction. As the structure is inflated, the constriction is dilated,  
2 resulting in improved flow of the liquid (such as blood) or gas (such as air).  
3 **[0006]** Current or typical inflatable structures can be balloons. When a typical balloon inflates, it may  
4 block a body lumen. For instance, a typical balloon may block the flow of blood in the vasculature or  
5 air in the airway. Blocking this vital supply of liquid or gas may cause short or long term health  
6 problems for the patient. This blockage may minimize the time that the physician can keep a balloon  
7 inflated during medical procedure.  
8 **[0007]** Typical balloons, when used to perform a BAV and/or TAVI procedure will block the entire  
9 output of the heart at the aortic valve. This causes the pressure in the heart to increase to  
10 uncomfortable levels. It may also generate enough force to eject the balloon from the aortic valve.  
11 Finally, typical balloons provide poor dimensional (particularly diametric) control and do not resist  
12 tear and puncture (from, for instance, aortic calcifications) well.  
13 **[0008]** Alternately, a physician may use rapid pacing of the heart (artificially accelerating the natural  
14 heart beat pace) during BAV and/or TAVI to minimize pressure buildup and the forces on the balloon.  
15 However, rapid pacing carries risk for the patient as well. Even with rapid pacing, typical balloons  
16 may only be inflated for a few seconds before being withdrawn and still suffer from poor dimensional  
17 control and toughness.  
18 **[0009]** A balloon or inflatable structure is desired that can maintain flow of liquid or gas while  
19 providing precise shape control and being highly resistant to tear and puncture.

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#### SUMMARY OF THE INVENTION

22 **[0010]** An inflatable medical device such as inflatable structure apparatus is disclosed. The apparatus  
23 can have a shell having a shell longitudinal axis, a central section and a first neck section. The first  
24 neck section can have a first neck first end and a first neck second end. The first neck first end can  
25 have a first neck first end diameter. The first neck second end can have a first neck second end  
26 diameter. The first neck first end diameter can be larger than the first neck second neck diameter. The  
27 first neck first end can be adjacent to the central section.  
28 **[0011]** The apparatus can have a balloon at least partially inside of the shell. The balloon can be  
29 fixed in the shell.  
30 **[0012]** The shell can have a shell longitudinal axis and a central fluid passage. The central fluid  
31 passage can be radially inside of the balloon with respect to the shell longitudinal axis. The first  
32 aperture can be in fluid communication with the central fluid passage. The balloon can have a first  
33 cell and second cell in a single cross-section of the inflatable structure. The balloon can have a

1 balloon surface area in the single cross section. At least 5% of the balloon surface area can be  
2 concentric (i.e., have the same center of radius of curvature) with the shell.

3 **[0013]** A wall of the first cell adjacent to the second cell can be greater than about 5% in contact with  
4 the second cell. The apparatus can have a first flute in the shell. The first flute can have a first flute  
5 first inner pleat, a first flute second inner pleat, and a first flute outer pleat between the first flute first  
6 inner pleat and the first flute second inner pleat. The apparatus can have a first aperture. The first  
7 aperture can be at least partially on the first flute. The first aperture can be arranged as to not cross the  
8 first flute outer pleat.

9 **[0014]** The first neck section can have a first neck section stiffness. The central section can have a  
10 central section stiffness. The first neck section stiffness can be greater than the central section  
11 stiffness.

12 **[0015]** The apparatus can have a tube extending along the shell longitudinal axis. The central fluid  
13 passage can be between the tube and the inside radius of the balloon with respect to the shell  
14 longitudinal axis. The tube can have a lumen extending therethrough.

15 **[0016]** The first neck section can have a first neck section average wall thickness. The central section  
16 can have a central section average wall thickness. The first neck section average wall thickness can be  
17 greater than the central section average wall thickness. The first flute can be in the first neck section.

18 **[0017]** At least 30% of the perimeter of the shell can be concentric with the balloon surface area. The  
19 balloon can have a first cell and second cell in a single cross-section of the inflatable structure. At  
20 least 30% of the perimeter of the shell can be in contact with the cells.

21 **[0018]** The balloon can have a first cell and second cell in a single cross-section of the inflatable  
22 structure. At least 5% of the balloon surface area can be in contact with the shell.

23 **[0019]** The apparatus can have a second flute. The first aperture can be covered by the second flute  
24 when the inflatable structure is in a deflated configuration. The second flute can have a second flute  
25 first inner pleat, a second flute second inner pleat, and a second flute outer pleat between the second  
26 flute first inner pleat and the second flute second inner pleat. The apparatus can have a second  
27 aperture. The second aperture can be at least partially on the second flute. The second aperture can be  
28 arranged to not cross the second flute outer pleat.

29 **[0020]** The shell can have a second neck section. The second neck section can have a second neck  
30 first end and a second neck second end. The second neck first end can have a second neck first end  
31 diameter. The second neck second end can have a second neck second end diameter. The second  
32 neck first end diameter can be greater than the second neck second end diameter. The second neck  
33 first end can be adjacent to the central section.

1 [0021] The apparatus can have a second aperture on the second neck section. The first aperture and  
2 the second aperture can be in fluid communication with the central fluid passage.

3 [0022] The central section can have a central section diameter. The central section diameter can be  
4 constant along the length of the central section. The balloon can be at least partially in the central  
5 section of the shell.

6 [0023] The shell can have a shell wall having a fiber. The shell can be non-compliant. The shell can  
7 have a fiber.

8 [0024] A method for using an inflatable structure in a biological body is disclosed. The method can  
9 include positioning the inflatable structure at an aortic valve in the body. The inflatable structure can  
10 have a balloon that can have first and second flexed flexion sections. The method can include  
11 inflating the balloon. The method can include perfusing the aortic valve. Perfusing can include  
12 perfusing through the inflatable structure. Perfusing can occur while the balloon is inflated.

13 [0025] The aperture can be in fluid communication with the central fluid passage.

14 [0026] The method can also include expanding the expandable implant. The expanding of the  
15 expandable implant can include inflating the inflatable structure. At least some of the flow routes  
16 through the aperture and central fluid passage. The method can include separating the expandable  
17 implant from the inflatable structure.

18 [0027] A method for using an inflatable structure in a biological body is disclosed. The method can  
19 include positioning the inflatable structure at an aortic valve in the body. The inflatable structure can  
20 have a shell. The balloon can be at least partially inside the shell. The shell can have a shell  
21 longitudinal axis and a central fluid passage radially inside of the balloon with respect to the shell  
22 longitudinal axis. The shell can have a flute and an aperture on the flute. The aperture can be in fluid  
23 communication with the central fluid passage. The method can include inflating the balloon. The  
24 method can include perfusing the aortic valve. Perfusing can include perfusing through the inflatable  
25 structure.

26 [0028] A method of manufacturing the inflatable structure is disclosed. The method can include  
27 making a shell. The shell can have a central section, a first neck section, and a second neck section.  
28 The first neck section can be distal to the central section and the second neck section can be proximal  
29 to the central section. The method can include cutting apertures in the first neck section. The method  
30 can include loading the balloon into the shell. The method can include pressing the balloon against the  
31 shell. The method can include fixing that balloon to the inside of the shell.

32 [0029] Making the shell can include applying a first film on the first neck section, and applying a  
33 second film to the first neck section. Making the shell can include adding a first layer and a second  
34 layer to the shell. The first layer can have a first fiber. The second layer can have a second fiber.

1 The method can include compressing the balloon in the shell. Compressing can include forming the  
2 balloon such that at least 5% of balloon circumference can contact the shell in the central section of  
3 the shell. Loading can include inserting the balloon through the aperture.  
4 **[0030]** Another method of manufacturing the inflatable structure is disclosed. The method can  
5 include forming a balloon along a longitudinal axis of the balloon. Forming can include bending the  
6 balloon at a flexion section of the balloon. The method can also include joining the balloon in a  
7 compression fixture. The compression fixture can have the same inner diameter as the shell.

#### BRIEF DESCRIPTION OF THE DRAWINGS

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- 10 **[0031]** Figure 1A illustrates a variation of the device.  
11 **[0032]** Figure 1B illustrates a variation of cross section A-A of Figure 1.  
12 **[0033]** Figure 2A illustrates a variation of the device.  
13 **[0034]** Figure 2B illustrates a variation of the device.  
14 **[0035]** Figure 2C illustrates a variation of the device.  
15 **[0036]** Figures 3A through 3D illustrate variations of the device.  
16 **[0037]** Figures 4 through 6 illustrate variations of the device.  
17 **[0038]** Figure 7A illustrates a variation of the device in a partially deflated condition.  
18 **[0039]** Figure 7B illustrates a variation of cross-section D-D of Figure 7A .  
19 **[0040]** Figure 7C illustrates a variation of cross-section E-E of Figure 7A .  
20 **[0041]** Figure 7D illustrates a variation of the device in a deflated condition.  
21 **[0042]** Figure 8 illustrates a variation of the device.  
22 **[0043]** Figures 9A through 9D illustrate variations of the device.  
23 **[0044]** Figures 10A through 10B illustrate variations of cross-section B-B of Figure 1A .  
24 **[0045]** Figures 11A through 11B illustrate variations of cross-section C-C of Figure 3C .  
25 **[0046]** Figures 12 through 14B illustrate variations of the device.  
26 **[0047]** Figures 15 through 18 illustrate variations of the device.  
27 **[0048]** Figure 19 illustrates a method of manufacturing a variation of the inflatable device.  
28 **[0049]** Figure 20A illustrates a variation of the device.  
29 **[0050]** Figure 20B illustrates a variation of a tool for manufacturing a variation of the inflatable  
30 device.  
31 **[0051]** Figure 20C illustrates a method of manufacturing a variation of the inflatable device.  
32 **[0052]** Figures 21 through 22B illustrate variations of the device.  
33 **[0053]** Figure 23A illustrates a variation of the device.

1 [0054] Figure 23B illustrates a variation of cross-section F-F of Figure 23A .  
2 [0055] Figure 24A illustrates a variation of the device.  
3 [0056] Figure 24B illustrates a variation of cross-section G-G of Figure 24A .  
4 [0057] Figure 25A illustrates a variation of the device.  
5 [0058] Figure 25B illustrates a variation of cross-section H-H of Figure 25A .  
6 [0059] Figure 26A illustrates a variation of the device.  
7 [0060] Figure 26B illustrates a variation of cross-section J-J of Figure 26A .  
8 [0061] Figure 27A illustrates a variation of the device.  
9 [0062] Figure 27B illustrates a variation of cross-section K-K of Figure 27A .  
10 [0063] Figure 27C illustrates a variation of Figure 27B in a deflated state.  
11 [0064] Figure 27D illustrates a variation of a close-up cross sectional view of Figure 27B.  
12 [0065] Figure 27E illustrates a variation of a close-up cross sectional view of Figure 27C.  
13 [0066] Figure 28A illustrates a variation of cross-section K-K of Figure 27A .  
14 [0067] Figure 28B illustrates a variation of Figure 28A in a deflated state.  
15 [0068] Figure 28C illustrates a variation of a close-up cross sectional view of Figure 28A.  
16 [0069] Figure 28D illustrates a variation of a close-up cross sectional view of Figure 28B.  
17 [0070] Figures 29 through 31A illustrate variations of the device.  
18 [0071] Figures 31B through 31C illustrate details of an element shown in Figure 31A.  
19 [0072] Figure 32A illustrates a variation of the device.  
20 [0073] Figure 32B illustrates a variation of a cross section of the device shown in Figure 32A.  
21 [0074] Figure 32C illustrates a variation of the device.  
22 [0075] Figure 32D illustrates a variation of a cross section of the device shown in Figure 32C.  
23 [0076] Figures 33A through 33B illustrate variations of the device.  
24 [0077] Figure 34 illustrates a variation of the device in a deflated state.  
25 [0078] Figures 35A through 35D illustrate variations of a fiber matrix.  
26 [0079] Figure 36 illustrates a variation of a tool for manufacturing a variation of the inflatable device.  
27 [0080] Figures 37A through 37C illustrate a variation of a method for manufacturing the device.  
28 [0081] Figure 37D illustrates a variation of cross-section L-L of Figure 37C .  
29 [0082] Figures 38A through 38B illustrate a method for manufacturing the device.  
30 [0083] Figures 39A through 39C are transverse cross-sections of variations of fiber tows in various  
31 configurations during a method of manufacturing.  
32 [0084] Figures 40A through 40H illustrate a method of making a panel.

- 1 [0085] Figures 41A through 42C illustrate variations of a panel.  
2 [0086] Figures 43A through 43B illustrate a method for manufacturing the device  
3 [0087] Figure 44 illustrates a method for manufacturing the device.  
4 [0088] Figures 45A and 45B illustrate a method for manufacturing the device  
5 [0089] Figures 46A through 46B illustrate variations of a panel.  
6 [0090] Figure 47 illustrates a variation of a method for removing the mandrel.  
7 [0091] Figures 48A through 48C illustrate a method for manufacturing the device  
8 [0092] Figures 49A through 49F illustrate a method for manufacturing the device  
9 [0093] Figure 50 illustrates a variation of a deployment tool for the device.  
10 [0094] Figure 51 illustrates a cross-section of a variation of the device contracted inside of a tube.  
11 [0095] Figure 52 illustrates a cross section of a human heart.  
12 [0096] Figure 53 is a graph showing the flow rate on the y-axis for a vascular lumen during stress and  
13 at rest corresponding with the percent stenosis of the lumen.  
14 [0097] Figures 54A through 54E illustrate a variation of a method for using the device.  
15 [0098] Figures 55A through 55F illustrate a variation of a method for using the device.  
16 [0099] Figures 56A through 56C illustrate a variation of a method for using the device.  
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#### 18 DETAILED DESCRIPTION

- 19 [0100] Figures 1A and 1B illustrate a shell 678. The shell 678 can have a shell longitudinal axis 26.  
20 The shell 678 can have a shell wall 684 with an average shell thickness 686.  
21 [0101] The shell 678 can be a tube or a sheath or combinations thereof.  
22 [0102] Figure 1B illustrates a cross section A-A of shell 678. The shell can have a shell proximal  
23 stem 30 and/or a shell proximal taper 34 and/or a central section 38 and/or a shell distal taper 42  
24 and/or a shell distal stem.  
25 [0103] The shell 678 can have shell length 28. Shell length 28 may be the sum of lengths 32, 36, 40,  
26 44 and 45. The shell 678 can have a shell proximal stem 30 having a shell proximal stem length 32.  
27 The proximal stem length 32 can be from about 3 mm to about 15 mm, more narrowly about 10mm.  
28 The shell 678 can have a shell proximal taper 34 having a shell proximal taper length 36. The shell  
29 proximal taper length 36 can be from about 0 mm to about 25 mm, more narrowly from about 10 mm  
30 to about 22 mm, yet more narrowly from about 16 mm to about 20 mm. The shell 678 can have a  
31 central section 38 having a central section length 40. The central section length 40 can be from about  
32 0 mm to about 55 mm, more narrowly from about 30 mm to about 50 mm. The shell 678 can have a  
33 shell proximal taper 42 having a shell proximal taper length 44. The shell proximal taper length 44 can

1 be from about 0 mm to about 25 mm, more narrowly from about 10 mm to about 22 mm, yet more  
2 narrowly from about 16 mm to about 20 mm. The shell 678 can have a shell distal stem 43 having a  
3 shell proximal stem length 45. The proximal stem length 45 can be from about 3 mm to about 15 mm,  
4 more narrowly about 10mm. The shell length 28 can be from about 10mm to about 250 mm, more  
5 narrowly from about 50mm to about 150mm, still more narrowly about 75mm to about 125mm.

6 **[0104]** The shell 678 can have a shell central section outer diameter 50. The central section 38 may  
7 have a shell inside radius 706 and a shell outside radius 708. Diameter 50 may be twice shell outside  
8 radius 708. The central section 38 may be cylindrically shaped, as shown. The shell central section  
9 outer diameter 50 can be from about 2mm mm to about 40 mm, more narrowly about 8mm to about  
10 30mm, still more narrowly from about 16mm to about 28mm, for example 26, 24, 22 or 20mm.

11 **[0105]** The central section 38 may have a shell outside radius 708. The shell outside radius 708 can  
12 have a maximum dimension at the longitudinal location where the central section 38 meets the tapers  
13 34 or 42. The shell outside radius 708 can have a minimum dimension in the longitudinal center of the  
14 central section 38.

15 **[0106]** The shell 678 can have a shell proximal stem diameter 31. The shell proximal stem diameter  
16 31 can be from about 0.5mm to about 8mm, more narrowly about 1mm to about 5mm, for example  
17 about 3mm. The shell 678 can have a shell distal stem diameter 41. The shell distal stem diameter 41  
18 can be from about 0.5mm to about 8mm, more narrowly about 1mm to about 5mm, for example about  
19 3mm.

20 **[0107]** The shell 678 can have one or more neck sections adjacent to and extending from the central  
21 section 38. For example, a proximal neck section can be a shell proximal taper 34 extending  
22 proximally from the central section 38. A distal neck section can be a shell distal taper 42 extending  
23 distally from the central section 38. Each of the neck sections can have a neck first end 60 and a neck  
24 second end 62. The neck first end 60 can have identical or different dimensions that the neck second  
25 end 62. The neck first end 60 may be adjacent to the central section 38. The neck first end 60 can  
26 have a neck first end diameter 61. The neck second end 62 can have a neck second end diameter 63.  
27 The neck first end diameter 61 can be larger than the neck second end diameter 63. The neck sections  
28 can be tapered, conical, multi-splined (e.g., having a plurality of concave and a plurality of convex  
29 portions on each neck section), or combinations thereof.

30 **[0108]** The shell 678 can have an inner lumen 154A and an outer lumen 154B. Inner lumen 154A  
31 may be formed by second hollow shaft 2000B. Inner lumen 154A may provide a lumen thru the entire  
32 shell. Inner lumen 154A may allow a guidewire to pass thru the interior of the shell. Outer lumen

1 **154B** may connect to balloon inflation/deflation ports **654**. Outer lumen **154B** may be formed  
2 between the inner wall of first hollow shaft **2000A** and the outer wall of second hollow shaft **2000B**.  
3 **[0109]** The distal taper angle **90A** can be from about 0 to about 90°, more narrowly about 50° to  
4 about 20°, yet more narrowly about 45° to about 30°, for example about 35°. The proximal taper  
5 angle **90b** can be from about 0 to about 90°, more narrowly about 50° to about 20°, yet more narrowly  
6 about 45° to about 30°, for example about 35°.

7 **[0110]** The first hollow shaft **2000a** can have a hollow shaft distal port **54**. One of the balloon  
8 inflation/deflation ports **654** can attach to the hollow shaft distal port **54**.

9 **[0111]** The shell **678** can be resilient (i.e., elastic) or non-compliant (i.e., inelastic).

10 **[0112]** If shell **678** is configured to be patent and used as a balloon, the shell **678** may have a burst  
11 pressure of greater than 3atm, more narrowly, greater than 10atm, still more narrowly greater than  
12 15atm. If shell **678** is configured to be patent and used as a balloon, the shell **678** may have a  
13 diametric elasticity of less than 0.35mm/atm, more narrowly less than 0.2mm/atm, still more narrowly  
14 less than 0.03mm/atm, still more narrowly less than 0.02mm/atm.

15 **[0113]** The shell wall **684** can have high puncture strength. For example, when a shell **678** is  
16 pressurized to about 4atm and a 1mm gauge pin is driven into the balloon at about 1mm/sec, the pin  
17 may need to exert more than 13 newtons of force to puncture the balloon wall, more narrowly more  
18 than 18 newtons. The shell wall **684** can be non-compliant. The shell wall **684** can have a polymer.  
19 The shell wall **684** can be fluid-tight (e.g., non-porous enough to prevent water, and/or saline solution,  
20 and/or air transfer or osmosis through the shell wall **684**). The shell wall **684** can have a wall  
21 thickness of about 0.04mm to about 0.8mm.

22 **[0114]** Figure 2A shows a shell **678** with first, second and third shell taper reinforcements **862a**, **862b**  
23 and **862c** respectively in the proximal taper **34** and fourth, fifth and sixth shell taper reinforcements  
24 **862d**, **862e** and **862f** respectively in the distal taper. Each of the shell taper reinforcements **862** may  
25 have different sizes, for instance different lengths. In Figure 2A, shell taper reinforcements **862** can be  
26 arranged such that a portion of each reinforcement **862** is visible. Shell taper reinforcements **862** may  
27 cover part or all of the shell tapers **34** and **42**, stems **30** and **43** and central section **38**. Shell taper  
28 reinforcements **862** may have shell taper reinforcement lobes **866**. Shell taper reinforcement lobes **866**  
29 may have a semi-circular shape and extend in the shell longitudinal direction, as shown in Figure  
30 2A. Shell taper reinforcements **862** may increase the stiffness of the shell wall **684** in areas covered by  
31 shell taper reinforcements **862**. For example, either or both the neck sections **34** and/or **42** can have a  
32 greater stiffness than the central section **38**. Shell taper reinforcements **862** may be panels **196**. Shell

1 wall 684 may comprise a polymer such as PET, Mylar, Nylon, Pebax, polyurethane or combinations  
2 thereof.

3 [0115] Figure 2B shows a shell 678 with shell apertures 714. Shell apertures 714 may penetrate the  
4 entire wall of the shell 678. Shell apertures 714 may release internal pressure from the shell 678 and  
5 may allow materials such as blood or air to cross the plane of the shell wall 684. The shell apertures  
6 714 can be in fluid communication with the inside and outside of the shell 678. Shell apertures 714  
7 may be circular, elliptical, rectangular, teardrop shaped, hexagonal or other shapes or combinations  
8 thereof. Shell apertures 714 may be located in the shell proximal stem 30, the proximal taper 34, the  
9 central section 38, the distal taper 42 or the shell distal stem 43 or combinations thereof. There may be  
10 less than 500 apertures 714 in shell 678, more narrowly less than 100, still more narrowly less than 25.  
11 For instance, there may be 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 or  
12 24 apertures 714 in shell 678.

13 [0116] Figure 2C illustrates that shell 678 may have teardrop shaped shell apertures 714. Shell  
14 apertures 714 may be cut through shell taper reinforcements 862. The portion of the edge of the shell  
15 aperture 714 that extends furthest towards the longitudinal center of the shell 678 may align with the  
16 part of the shell taper reinforcement lobe 866 that extends furthest towards the longitudinal center of  
17 shell 678 as shown in Figure 2C. Thus the aperture 714 can be angularly aligned with lobe 866.

18 [0117] Figures 3A, 3B, 3C and 3D illustrate that the shell 678 can have reinforcement fibers 86.  
19 Second or latitudinal reinforcement fibers 86a can be perpendicular to the shell longitudinal axis 26.  
20 Fibers 86a may be one continuous fiber wound around the part (a “hoop wind”). Fibers may be  
21 applied with a certain density. For example, fibers may be applied at 100 winds per 1 inch (25.4mm).  
22 The number of winds per inch is often referred to as the “pitch” of the wind. The pitch can vary across  
23 the length of the shell. Fibers 86a may be omitted entirely from portions of the shell 678.

24 [0118] First or longitudinal reinforcement fibers 86b can be parallel with the shell longitudinal axis  
25 26. Fibers can be applied with a certain density. For instance, there may be 50 fibers 86b per 1 inch  
26 (25.4mm) around the circumference of the shell 678. Fiber 86b density can vary around the  
27 circumference of the shell. Fibers 86b may be omitted entirely from portions of the shell 678.

28 [0119] The angle between fibers 86a and 86b may be approximately perpendicular and may not  
29 change between inflation and deflation.

30 [0120] Figures 3A, 3B, 3C and 3D show that the shell can have a longitudinal proximal zone 618a, a  
31 longitudinal central zone 618b and a longitudinal distal zone 618c. Proximal zone 618a may cover the  
32 proximal taper 34 and proximal stem 30. Distal zone 618c may cover the distal taper 42 and distal  
33 stem 43. Central zone 618b may cover the central section 38. Fibers 86a and/or 86b may be present or

1 absent in zones **618a** and/or **618b** and/or **618c**. The fiber **86a** pitch may be different in each of zones  
2 **618a**, **618b** and **618c**. The fiber **86a** pitch may vary within each of zones **618a**, **618b** and **618c**. The  
3 fiber **86b** density may be different in each of zones **618a**, **618b** and **618c**. The fiber **86b** density may  
4 vary within each of zones **618a**, **618b** and **618c**.

5 **[0121]** Figure 3A shows that fibers **86a** and **86b** can be present in zone **618b**. Fibers **86a** and **86b**  
6 may not present in zones **618a** and **618c**. Figure 3B shows that fibers **86b** can be present in zones  
7 **618a**, **618b** and **618c**. Fibers **86a** may be present only in zone **618b**. Figure 3C shows that fibers **86b**  
8 and **86a** can present in zones **618a**, **618b** and **618c**. Figure 3D shows that the pitch of fibers **86a** in  
9 zone **618b** may be less than the pitches in zones **618a** and **618c**. The pitches in zones **618a** and **618c**  
10 may be substantially equivalent. For example, the pitch in zones **618a** and **618c** may be 128 winds per  
11 inch, while the pitch in zone **618b** may be 100 winds per inch. Lower pitch fibers **86** in one zone **618**  
12 may cause the shell wall to structurally fail in the lower pitch zone **86** before the pitch zones **86** with a  
13 higher fiber pitch. In the example above, zone **618b** can burst before zones **618a** and **618c** when the  
14 shell wall **684** experiences structural failure. Zones **618** with lower pitch may be more compliant and  
15 foldable than zones **618** with higher pitch. A zone **618** may have a 10% lower pitch than the remainder  
16 of the part, more narrowly a 20% lower pitch than the remainder of the shell wall **684**.

17 **[0122]** The boundaries between zones **618a** and **618b** and between **618b** and **618c** may move. For  
18 instance, the boundaries may be located in the shell tapers **34** or **42** or the central section **38**. Second or  
19 latitudinal reinforcement fibers **86a** may or may not be a continuously wound single fiber.

20 **[0123]** Figure 4 illustrates that first reinforcement fiber **85a** can be at a first reinforcement fiber angle  
21 with respect to the shell longitudinal axis **26**. For instance, the first reinforcement fiber angle can be  
22 10, 15, 20, 25, 50, 55 or 60 degrees to the shell longitudinal axis. Second reinforcement fiber **85b** can  
23 be at a second reinforcement fiber angle with respect to the shell longitudinal axis **26**. For instance,  
24 the second reinforcement fiber angle can be 10, 15, 20, 25, 50, 55 or 60 degrees to the shell  
25 longitudinal axis. Second reinforcement fiber **85b** can have an equal but opposite angle to first  
26 reinforcement fiber **85a**. For example, first reinforcement fiber **85a** can be at +20 degrees and second  
27 reinforcement fiber **85b** can be at -20 degrees to the shell longitudinal axis. Third reinforcement fiber  
28 **85c** can be substantially perpendicular to the shell longitudinal axis. Third reinforcement fiber **85c**  
29 may be omitted from the shell wall **684**.

30 **[0124]** Figure 5 illustrates longitudinal reinforcement fiber **86b** can be parallel with the shell  
31 longitudinal axis **26**. Second longitudinal reinforcement fiber **87b** can be parallel with the shell  
32 longitudinal axis **26**. Fibers **86b** and **87b** can be separated by areas of missing longitudinal fiber **614**.  
33 Areas **614** may separate fibers **86b** and **87b** by 2mm, more narrowly less than 1mm, still more  
34 narrowly less than 0.25mm. Areas **614** may be distributed on the shell surface such that no area

1 longitudinally substantially overlaps any other area on the shell. Areas 614 may be distributed such  
2 that latitudinally adjacent areas do not have any longitudinal overlap. Areas 614 may be distributed in  
3 a regular, repeating pattern around the diameter of the shell sufficient to prevent any fiber from  
4 reaching from one end of the shell to the other while still maximizing the longitudinal strength of the  
5 shell. Fibers 86B and 87B may be less than 80% as long as the shell, more narrowly less than 75%,  
6 still more narrowly less than 70%, still more narrowly less than 65%, still more narrowly less than  
7 60%. Second or latitudinal reinforcement fibers 86a can be substantially perpendicular to the shell  
8 longitudinal axis  
9 26.

10 [0125] Figure 6 illustrates that the longitudinal reinforcement fiber 86b can be parallel with the shell  
11 longitudinal axis 26. Second longitudinal reinforcement fiber 87b can be parallel with the shell  
12 longitudinal axis 26. Fibers 86b and 87b can overlap in reinforcement fiber overlap area 612.  
13 Reinforcement fiber overlap area 612 may form a hoop shaped area that can completely encircle the  
14 central section 38.

15 [0126] Figure 7A illustrates that a shell 678 can be pleated to form flutes 84, for example four, five,  
16 six, seven or eight flutes 84, such as first flute 84a, second flute 84b. The flutes 84 can be made from  
17 accordion pleats, box pleats, cartridge pleats, fluted pleats, honeycomb pleats, knife pleats, rolled  
18 pleats, or combinations thereof. The pleating can be heat and/or pressure formed and/or the  
19 reinforcement fibers and/or panels can be oriented to form the flutes 84. Pleating the shell 678 may  
20 create first inner pleat line 822a and second inner pleat line 822b and outer pleat lines 826a between  
21 inner pleat lines 822a and 822b. Pleat lines 822 and 826 may be areas where the shell wall 684 can be  
22 creased. Inner pleat lines 822 may be positioned radially inward from outer pleat lines 826 when the  
23 shell is collapsed as shown in Figure 7A. Each flute 84 can be the portion of the shell wall 684  
24 between two inner pleat lines 822. The shell apertures 714 can be between adjacent outer pleat lines  
25 826 and interrupt an inner pleat line 822 as shown. The apertures 714 may or may not cross an inner  
26 pleat line 822. The apertures 714 may or may not cross an outer pleat line 826.

27 [0127] Figure 7B illustrates a section view at D-D of Figure 7A. The portion of the section view that  
28 shows aperture 714 is highlighted with a dotted line. The width of aperture 714 at section D-D can be  
29 divided into aperture first partial width 830 and aperture second partial width 834. Aperture first  
30 partial width 830 may be about the same as aperture second partial width 834. For example, the  
31 aperture 714 can be centered on the inner pleat line 822. The aperture first partial width 830 may be  
32 different than width 834, for instance equal to one to three times width 834, thus placing aperture 714  
33 off center from inner pleat line 822. Aperture 714 can be wholly between two adjacent outer pleat  
34 lines 826, for instance between outer pleat lines 826a and 826b.

1 [0128] Figure 7C illustrates a section view at E-E of Figure 7A. The central zone of the shell can have  
2 apertures or no apertures (as shown) interrupting the shell wall 684, as shown at section E-E.

3 [0129] Figure 7D illustrates that the pleated shell 678 or annular balloon structure 682 can be  
4 collapsed into a compact form with a reduced diameter. Pleating may allow the shell 678 or structure  
5 682 to collapse and expand in a repeatable and regular way. In this collapsed state, apertures 714 may  
6 be wholly (as shown) or partially covered or concealed by collapsed flutes 84, for instance second  
7 flute 84b may cover or conceal aperture 714. Covering the apertures 714 may give the collapsed shell  
8 678 or annular balloon 682 an outer surface free of interruptions from the apertures 714. The diameter  
9 of the structure can be minimized and the apertures can be covered by the structure surface before and  
10 during insertion of the structure into the body during a medical procedure.

11 [0130] Annular balloon structure 682 may be subjected to a first cycle and a second cycle of inflation  
12 and deflation. Annular balloon structure 682 may have the same number of pleats after first and  
13 second cycles of inflation and deflation. For example, the fold position angle of the pleats, and the  
14 number and location of the pleats can remain about constant after an inflation and deflation cycle.

15 [0131] A material, such as a gas or a liquid, may flow from the shell exterior 49 through shell  
16 apertures 714 on one taper of the shell (for instance, the distal taper 42), pass through the shell interior  
17 47 and flow out of shell apertures 714 on the other taper of the shell (for instance, the proximal taper  
18 34) to the shell exterior 49. Figure 8 shows that apertures 714 may be fitted with shell aperture  
19 unidirectional flow valves or flaps 718, for instance apertures 714 may be fitted with shell aperture  
20 flaps 718 on proximal taper 34. Shell aperture flaps 718 may be configured so that they will partially  
21 or completely cover apertures 714 when there is no material flowing through the shell interior 47 to  
22 the proximal end, for example, of the shell exterior 49. When material is urged to flow with sufficient  
23 pressure from the shell interior 47 to the shell exterior 49, flaps 718 may open to allow flow through  
24 apertures 714. When pressure is reduced or removed, flaps 718 may partially or completely cover  
25 apertures 714. Flaps 718 may act as one-way or two-way valves. For example, flow and flow pressure  
26 (e.g., of a body fluid such as blood) through the apertures 714 may be generated by a beating heart  
27 during a medical procedure. Flaps 718 may be a temporary or permanent replacement for a heart valve  
28 (such as the aortic valve) during a medical procedure. Flaps may be made of a polymer film or be  
29 made similar to the shell wall 684 described herein or be made of a compliant material such as, for  
30 instance, an elastomer. The flap may be made integral to the shell by cutting the aperture 714 but  
31 omitting the circumferential cut, for example leaving a hinge 719.

32 [0132] Figure 9A shows a pattern for a marker wire 190. Marker wire 190 may be wound around the  
33 shell 678. The marker wire 190 can partially cover the distal and proximal ends of the central section  
34 38 of the shell 678.

1 [0133] Figure 9B shows that marker wire 190 may be wound around the shell on both the distal 42  
2 and proximal tapers 34 of the shell 678. The marker wire 190 may be wound up to the distal and  
3 proximal borders of the central section 38 without any substantial amount of the wire being placed in  
4 the central section 38. The marker wire may be wound in a helical pattern in both directions on the  
5 shell or be wound in a single direction. The marker wire crossing angle 191 between two layers of  
6 marker wire may be less than 20 degrees, more narrowly less than 10 degrees, still more narrowly less  
7 than 6 degrees.

8 [0134] Figure 9C illustrates that the shell 678 can have a marker wire 190 wrapped over  
9 approximately the entire length of central section 38. The marker wire 190 may be centered on the  
10 central section 38. The marker wire 190 may cover only a portion of the central section 38. For  
11 instance, the marker wire 190 may cover more than 70% of the central section 38, more narrowly more  
12 than 80%, still more narrowly more than 90%. The marker wire 190 may cover a portion of the distal  
13 tapers 42 and proximal tapers 34. For example, the marker wire 190 may cover 100% of the distal  
14 tapers 42 and proximal tapers 34, more narrowly more than 50%, still more narrowly more than 25%.  
15 The marker wire 190 may be a latitudinal reinforcement fiber 86a.

16 [0135] Figure 9D illustrates that the shell 678 can have a marker wire 190 wrapped over substantially  
17 the whole length of the shell 678.

18 [0136] The pitch of the marker wire 190 may be less than about 150 winds per 1 inch (25.4mm),  
19 more narrowly less than about 75 winds per 1 inch (25.4mm), still more narrowly less than about 25  
20 winds per 1 inch (25.4mm), still more narrowly less than about 10 winds per 1 inch (25.4mm). The  
21 pitch of the marker wire 190 may be about 6, 5, 4, 3 or 2 winds per 1 inch (25.4mm).

22 [0137] Figure 10A illustrates that the shell wall 684 at section B-B or at other sections taken through  
23 a single wall of the shell can have a layer 72 that can have a fiber matrix. The fiber matrix can have  
24 one or more monofilaments 274 and one or more adhesives 208. The adhesive can remain flexible  
25 when cured or melted to form an annular balloon structure 682. A fiber matrix may comprise a layer  
26 72 or a panel 196.

27 [0138] The reinforcement fiber 85, 86 and 87 can be a monofilament 274 and/or a tow 270. A tow  
28 270 may contain one or more monofilaments 274. Reinforcement fiber 86 can be a marker wire 190. A  
29 fiber matrix may have one, two or more reinforcement fibers 86 running substantially parallel to each  
30 other and embedded in an adhesive 208. The substantially parallel reinforcement fibers 86 may be  
31 positioned within the adhesive such that they are touching each other along their length. The  
32 substantially parallel reinforcement fibers 86 may be positioned such that there is adhesive separating  
33 each fiber along its length.

1 [0139] Figure 10A illustrates a layer 72 with a fiber matrix having a layer width 210 in cross-section.  
2 The layer width 210 can include a number of monofilaments 274. The layer 72 can have a linear  
3 quantity fiber density measured, for example, as the number of fibers 86 per unit of layer width 210.  
4 The linear quantity fiber density can be equal to or greater than about 500 monofilaments 274 per inch,  
5 more narrowly equal to or greater than about 1000 monofilaments 274 per inch, more narrowly equal  
6 to or greater than about 2000 monofilaments 274 per inch, yet more narrowly equal to or greater than  
7 about 4000 monofilaments 274 per inch. For example, the liner quantity monofilaments 274 density  
8 can be from about 1,000 monofilaments 274 per inch to about 2,000 monofilaments 274 per inch.

9 [0140] The layer 72 with a fiber matrix can have a layer thickness 216 from about 1  $\mu\text{m}$  (0.00004 in.)  
10 to about 50 $\mu\text{m}$  (0.002 in.), more narrowly from about 8 $\mu\text{m}$  (0.0003 in.) to about 25 $\mu\text{m}$  (0.001 in.), yet  
11 more narrowly from about 10 $\mu\text{m}$  (0.0004 in.) to about 20 $\mu\text{m}$  (0.0008 in.). Monofilaments 274 or fibers  
12 86 may have a non-circular cross section, for instance an oval cross-section.

13 [0141] Part or all of the shell wall 684 can have a volumetric quantitative density of monofilaments  
14 274 measured, for example, as the number of monofilaments 274 per unit of area. The area quantity  
15 monofilaments 274 density can be equal to or greater than about 100,000 monofilaments 274 per  
16 square inch, more narrowly equal to or greater than about 250,000 monofilaments 274 per square inch,  
17 more narrowly equal to or greater than about 1,000,000 monofilaments 274 per square inch, yet more  
18 narrowly equal to or greater than about 4,000,000 monofilaments 274 per square inch. The area  
19 quantity of fiber can be about 25% of the area of a wall cross section, more narrowly about 50%, more  
20 narrowly about 75%.

21 [0142] The ratio of the volume of a fiber matrix to the volume of the monofilaments 274 can be about  
22 equal to or greater than about 15%, more narrowly equal to or greater than about 30%, more narrowly  
23 equal to or greater than about 50%, yet more narrowly equal to or greater than about 75%.

24 [0143] Figure 10B illustrates that the outer layer 72a and the inner layer 72b can be polymer films,  
25 for example as described infra. In any variation, the polymer films can be the same or different  
26 polymers, or any combination thereof. The first middle layer 72c can have a fiber matrix, for example  
27 with the fibers oriented as longitudinal fibers 86b. The second middle layer 72d can have a fiber  
28 matrix, for example with the fibers oriented as latitudinal or hoop fibers 86a. The third middle layer  
29 72e can be an adhesive. The fourth middle layer 72f can be a radiopaque layer, such as a metal foil or  
30 wire.

31 [0144] Figure 11A is a cross section taken at C-C in Figure 3C. Figure 11A illustrates that the outer  
32 layer 72a and the inner layer 72b can be polymer films, for example as described infra. The first  
33 middle layer 72c can have a fiber matrix, for example with the fibers oriented as longitudinal fibers  
34 86b. The second middle layer 72d can have a fiber matrix, for example with the fibers oriented as

1 latitudinal or hoop fibers 86a. The third middle layer 72e, the fourth middle layer 72f and the fifth  
2 middle layer 72g can be shell taper reinforcements 862. Shell taper reinforcements may be of unequal  
3 longitudinal lengths as shown in Figure 11A. An adhesive may be placed between any of the layers 72  
4 shown. Any of the layers 72 shown in Figure 11A may be omitted.

5 [0145] As shown in figure 11A, proximal taper 34 or distal taper 42 may have a first wall average  
6 shell thickness 686a. Central section 38 may a second wall average shell thickness 686b. First wall  
7 average thickness 686a may be greater than second wall average thickness 686b.

8 [0146] The shell wall 684 of the proximal taper 34 and/or distal taper 42 can be the same or more stiff  
9 per unit of area than the shell wall 684 of the central section 36. For example, the shell wall 684 of the  
10 proximal taper 34 and/or distal taper 42 can have a measured bending stiffness of about two, about  
11 three, or about five times greater per unit of area than the shell wall 684 of the central section 36.

12 [0147] Figure 11B is a cross section taken at C-C in Figure 3C. Figure 11A illustrates that shell taper  
13 reinforcements 862 may be placed nearer to inner layer 72b than outer layer 72a.

14 [0148] A layer 72 can be a panel 196. Layers 72 and/or panels 196 may comprise a polymer. The  
15 polymer may be a film. The thickness of the polymer films can be from about 2  $\mu\text{m}$  to about 50  $\mu\text{m}$ ,  
16 more narrowly from about 2  $\mu\text{m}$  to about 18  $\mu\text{m}$ , yet more narrowly from about 4  $\mu\text{m}$  to about 12  $\mu\text{m}$ .  
17 Films may be metalized or coated to change their surface properties. Metallization or coating may take  
18 place before or after a film is formed. Films may be treated chemically or via plasma or via corona  
19 treating or by combinations thereof in order to modify their bondability. A layer 72 and/or a panel 196  
20 and/or a film may comprise polyamide, co-polyamide, polyester, co-polyester, ECTFE, Solef®, EPTFE,  
21 FEP, Kapton®, Pebax, HDPE, LDPE, PET, Mylar®, micrton, nylon, PEEK, PEN (polyethylene  
22 Napthalate), Tedlar®, PVF, Polyurethane, Thermoplastic Polyurethane (TPU), Parylene or  
23 combinations thereof.

24 [0149] The reinforcement fibers 86 can be high strength and inelastic. Inelastic fibers may have a  
25 strain to failure of less than 10%, more narrowly less than 5%. High strength fibers may have an  
26 ultimate tensile strength greater than 1.8 GPa (260 ksi), more narrowly greater than 2.4 GPa (350 ksi),  
27 still more narrowly greater than 2.9 GPa (420 ksi).

28 [0150] The reinforcement fibers 86 can have a fiber or monofilament diameter 212, for example,  
29 from about 1  $\mu\text{m}$  to about 50  $\mu\text{m}$ , for example less than about 25  $\mu\text{m}$ , more narrowly less than about  
30 20  $\mu\text{m}$ .

31 [0151] The reinforcement fibers 86 may be a wire or wires. The reinforcement fibers 86 may be a  
32 metal. Wire may have a strain to failure of less than 10%, more narrowly less than 5%, still more  
33 narrowly less than 2%. The wire may be annealed or tempered to adjust its mechanical properties. The

1 wire may have a breaking strength of greater than 150KSI, more narrowly greater than 250KSI, more  
2 narrowly greater than 400KSI

3 **[0152]** Wire may be ductile and have a strain to failure of greater than 20%, more narrowly greater  
4 than 40%, still more narrowly greater than 80%. Ductile wire may allow the shell 678 the fold without  
5 fracturing the wire.

6 **[0153]** The wire may be less than 25um in diameter. The wire may be substantially rectangular and  
7 less than 25um in thickness 1068, more narrowly less than 15um in thickness 1068 when integrated  
8 into the wall of the balloon. The ratio of the width 1072 of the wire to the thickness 1069 of the wire  
9 may be greater than or equal to about 3, more narrowly greater than or equal to about 5, more narrowly  
10 greater than or equal to about 10. The wire may be a foil wherein the ratio of the width 1072 of the  
11 wire to the thickness 1069 of the wire may be greater than or equal to about 100, more narrowly  
12 greater than or equal to about 300, more narrowly greater than or equal to about 500. The density of  
13 the wire may be greater than about 2.4 g/cm<sup>3</sup>, more narrowly greater than about 6.9 g/cm<sup>3</sup>, more  
14 narrowly greater than about 15 g/cm<sup>3</sup>.

15 **[0154]** The reinforcement fiber 86 or wire may be substantially radiopaque when used under a  
16 flourosocpe as part of a medical procedure in the human body. The use of radiopaque material, such as  
17 radiopaque fibers 86, may allow the physician to use an inflation medium, such as saline, which is not  
18 radiopaque when inflating a balloon 650 or annular balloon structure 682. The use of radiopaque  
19 material, such as radiopaque fibers 86 may allow the physician to visualize how well pleated or folded  
20 the balloon structure 682 is when placed in the human body. The fibers 86 may be substantially  
21 radiolucent. A fiber matrix can have the same or different sizes and materials of fibers 86 within the  
22 same fiber matrix.

23 **[0155]** The reinforcement fibers 86 or wires may be coated. The coating may enhance adhesion. The  
24 coating may be an adhesive 208. The adhesive 208 may be melted as part of the process of applying  
25 reinforcement fibers 86 to a shell 678.

26 **[0156]** A reinforcement fiber 86 may comprise Vectran®, PBO (p-phenylene-2,6-benzobisoxazole),  
27 Zylon®, Spectra®, Dyneema®, UHMWPE, Conex®, Technora®, Twaron®, Dacron®, Polyester, Compet®,  
28 Nylon, PEEK, PPS®, Boron, Cermic, Kevlar®, aramid, Carbon, Carbon Fiber, Inorganic Silicon, glass,  
29 fiberglass, Tungsten and its alloys, Tantalum and its alloys, Molybdenum and its alloys, bismuth and  
30 its alloys, gold and its alloys, silver and its alloys, platinum and its alloys, iridium® and its alloys,  
31 stainless steel (for instance, alloys 302, 304, 316, 440), Nickel and its alloys, cobalt and its alloys,  
32 Titanium and its alloys, copper and its alloys, Barium and its alloys, bismuth and its alloys, Iodine and  
33 its alloys, Nitinol alloys or combinations thereof

1 **[0157]** Adhesive **208** can be an thermoset material, a thermoplastic material, or a combination  
2 thereof. Adhesive **208** can be elastomeric. Adhesive **208** can be a polymer or a monomer or  
3 combinations thereof. The adhesive **208** can be a urethane, a polyurethane, a thermoplastic  
4 polyurethane (TPU), a thermoplastic, a cyanoacrylate, a UV curing adhesive, a polyester, a nylon, a  
5 polyamide, a silicone, a polypropylene, a polyolefin, ULDPE, VLPDE, LOPE, an epoxy, a pebax®,  
6 Tefzel, an EVA®, Solef®, a parylene or combinations thereof. The adhesive **208** can be a resin or a glue.

7 **[0158]** Any of layers **72** or panels **196** can be leak proof, water tight, air tight, MMA (Methyl  
8 methacrylate)-resistant, MMA-releasing, or combinations thereof.

9 **[0159]** Magnetic resonance visualization enhancement materials, such as magnetic contrast agents,  
10 can be added to the adhesive **208** or any layer **72** or panel **196**. The magnetic resonance visualization  
11 enhancement materials can enhance the visualization of the balloon during an magnetic resonance  
12 imaging (MRI) procedure. For example, the magnetic resonance visualization enhancement material  
13 can be gadolium, Omniscan, Optimark, ProHance, Magnevist, Multihance, or combinations thereof.

14 **[0160]** Any of the layers **72**, for example the outer layer **72a**, can be tinted or dyed a visible spectrum  
15 color. For example, a pigment, coloring additive, dispersions or other coloring agents, such as a  
16 coloring additive from Plasticolors® (Ashtabula, Ohio) can be added. A paint or coating can be added to the  
17 outer surface of the shell **678**.

18 **[0161]** The color can be selected for branding , market differentiating, as an indication of the type of  
19 device, the size of the device, or combinations thereof. For example, devices having a selected  
20 diameter, length, pressure rating, clinical indication or efficacy, other common performance metric, or  
21 combinations thereof, can be dyed a specific color (e.g., green for a first type of device, red for a  
22 second type of device).

23 **[0162]** The layers **72** can have one or more optical fibers. The fiber optic can be a strain sensor. The  
24 strain sensor can monitor mechanical status in real time. The fiber optic can guide light delivery into  
25 the body. The fiber optic can visualize a target site (e.g., gather light from the body to produce a  
26 visual image).

27 **[0163]** Figure 12 shows that a balloon **650** can have a balloon main diameter **662**, a balloon length  
28 **666** and a balloon wall thickness **658**. The balloon may have a balloon taper section **652** at either end.  
29 The taper sections may connect the balloon diameter to the balloon inflation/deflation ports **654**. The  
30 balloon **650** may be inflated by putting a pressurized fluid, such as saline, contrast, water or a gas, into  
31 both inflation/deflation ports or by putting fluid into one of the inflation/deflation ports **654** while  
32 closing the other inflation/deflation ports **654**.

1 [0164] Balloon 650 may have a main diameter 662 of about 1mm to about 15.3mm, more narrowly  
2 about 4mm to about 12mm, still more narrowly about 6mm to about 10mm. The balloon wall  
3 thickness 658 may be about 5 $\mu$ m to about 50 $\mu$ m, more narrowly about 8 $\mu$ m to about 25 $\mu$ m, still more  
4 narrowly about 8 $\mu$ m to about 15 $\mu$ m. The balloon length 666 may be about 125mm to about 635mm,  
5 more narrowly about 200mm to about 500mm, still more narrowly about 250mm to about 380mm.

6 [0165] Figure 13 shows that balloon 650 can have balloon segments 656a-656f. Balloon segments  
7 656a-656f may form a continuous internal inflation/deflation lumen. Each balloon segment 656 may  
8 be joined by a balloon flexion section 670a-670e to the adjacent balloon segment 656. The balloon  
9 flexion sections 670 may have a smaller balloon flexion section diameter 664 than the balloon main  
10 diameter 662 (i.e., of the balloon segments 656). Balloon 650 may have a balloon flexion section  
11 diameter 664 of about 1mm to about 10mm, more narrowly about 2mm to about 6mm, still more  
12 narrowly about 2.5mm to about 5mm. Balloon 650 may have a balloon flexion section diameter 664 of  
13 about 3.3mm. Multi-segment balloon taper section 653 can connect the balloon flexion sections 670 to  
14 the balloon segments 656. The balloon 650 can bend or flex at the balloon flexion sections 670 before  
15 bending at the balloon segments 656, for example, when the balloon 650 is inflated. The balloon 650  
16 could have 4, 5, 6, 7, 8, 9, 10 or more balloon segments 656.

17 [0166] The balloon 650 may be made of one polymer, or use several layers or a mix of different polymers.  
18 Polymers such as Nylon, PEBA<sup>X</sup>, PET, parylene and /or polyurethane may be used to make the balloon  
19 650. The balloon 650 may be fabricated by blow molding. The balloon may comprise a layer 72, a panel 196  
20 or a film as described supra.

21 [0167] Heat shrink tubing may be used to form the balloon 650. For instance, the balloon 650 could  
22 be formed by placing heat shrink tubing over a removable mandrel, heating the tubing and then  
23 removing the mandrel. The mandrel may be removed mechanically, with a solvent such as water, by  
24 the application of heat, or combinations thereof.

25 [0168] The balloon 650 may be formed by depositing a material either onto a mandrel or into a cavity  
26 mold. The mandrel may be removed as described above or a mold may be opened to remove the  
27 balloon 650. Deposition could be by various techniques of physical vapor deposition, dipping, coating  
28 or spraying. Parylene may be deposited using a physical vapor deposition process. The balloon 650  
29 may be deposited directly onto a mandrel with the shape shown in Figures 15, 16, 17 and 18. The  
30 mandrel could then be removed.

31 [0169] The balloon may comprise a fiber and be designed and fabricated as described in U.S.  
32 Provisional Application No. 61/363,793, filed 13 July 2010, and in PCT Application No.

1 PCT/US2011/43925, filed July 13, 2011.

2

3 [0170] Figure 14A shows a balloon with balloon restraints 674 wrapped around the length of balloon  
4 650. Figure 14B shows a balloon with balloon restraints 674 wrapped around the portions of the length  
5 of the balloon. The balloon restraints 674 may be bonded to the outside of the balloon. The restraints  
6 674 may be knotted or tied around the balloon. The balloon restraints 674 may serve to narrow and  
7 bunch the balloon at the point they are applied, thus creating a balloon flexion section 670. A balloon  
8 flexion section 670 could also be created by locally twisting the balloon.

9 [0171] Figures 15 and 16 show a balloon 650 after balloon segments 656 have been formed into an  
10 annular balloon structure 682 and inflated. The balloon segments can form a ring with a clear or  
11 hollow passageway or channel in the center. The annular balloon structure working length 680 can be  
12 the about equal to the longitudinal length of the largest diameter constant diameter section of each  
13 balloon segment 656. Working length 680 may be about 12mm to about 100mm, more narrowly about  
14 25mm to about 75mm, still more narrowly 32mm to 65mm. Working length 680 may be about 45mm.  
15 The balloon segments 656 may be attached to each other with adhesive, solvent, the application of  
16 heat or combinations thereof. Figure 15 shows that the local balloon diameter of the flexed or relaxed  
17 (i.e., unflexed) flexion section 670 can be less than the main balloon diameter of the balloon segments  
18 656. Figure 16 shows a flexion section 670 where the balloon has been bent or folded with no previous  
19 narrowing of the balloon diameter. The balloon may be inflated by putting pressure into balloon  
20 inflation/deflation ports 654a and 654b. The inflation/deflation ports 654a and 654b may be joined  
21 into a single inflation/deflation port.

22 [0172] First balloon segment 656a may have a first balloon segment longitudinal axis 657a. Second  
23 balloon segment 656b may have a second balloon segment longitudinal axis 657b. Balloon segment  
24 longitudinal axis angle 659 may be the angle between first balloon segment longitudinal axis 657a and  
25 second balloon segment longitudinal axis 657b. Balloon segment longitudinal axis angle 659 may be  
26 zero degrees to 200 degrees, more narrowly, 160 degrees to 200 degrees, for example 180 degrees.  
27 The longitudinal axis angle 659 can be the angle formed by the opposite terminal ends of the balloon  
28 flexion section 670 adjacent to the respective balloon segments 656.

29 [0173] Figure 17 shows a group of inflated balloons 650 arranged into an annular balloon structure  
30 682. Rather than sharing an inflation/deflation lumen, each balloon has two inflation/deflation ports  
31 654. Figure 18 shows a balloon design with one inflation/deflation port and the other end closed. The  
32 balloon in 8B could be arranged into an annular balloon structure 682 similar to that shown in Figures  
33 15, 16 and 17. Balloons 650 may have their interior volumes connected together by piercing or

1 punching holes in the wall of each balloon and then aligning the holes in each balloon before bonding  
2 the balloons 650 together.

3 [0174] Figure 19 shows one method of forming the balloon 650 into an annulus. Adhesive 208 or a  
4 solvent may be applied to the outside of the balloon. The balloon 650 may be threaded around pins  
5 676. The balloon flexion section 670 may be twisted about the balloon longitudinal axis, for instance  
6 45 or 90 degrees. A compression fixture, for instance a balloon assembly fixture compression sleeve  
7 898 (e.g., a non-stick tube such as one made out of fluorinated ethylene propylene (FEP), such as  
8 Teflon) may be slid over the balloon 650 in order to hold and radially compress the balloon segments  
9 656 together. The balloon assembly fixture compression sleeve 898 may have an inside diameter  
10 smaller than the outside diameter of the annular balloon structure 682 shown in, for instance, Figures  
11 15, 16 or 17. A cross section of balloon 650 in balloon assembly fixture compression sleeve 898 may  
12 look similar to figure 24B with shell 678 being replaced by balloon assembly fixture compression  
13 sleeve 898. Heat may be applied to cure the adhesive 208 or to melt and fuse the segments 656  
14 together.

15 [0175] Figure 20A shows a balloon 650 after having been formed into a spiral to make an inflated  
16 annular balloon structure 682. That is, the balloon 650 forms a spiral ring with a central fluid passage  
17 692 in the center. The coils of the spiral may be attached to each other with adhesive, solvent, the  
18 application of heat or combinations thereof. The balloon may be inflated by putting pressure into  
19 balloon inflation/deflations port 654. Multiple spiral coils may be interleaved to form one annular  
20 balloon structure.

21 [0176] Figures 20B and 20C shows a spiral forming tool 742. The spiral forming tool has a spiral  
22 groove 746. A nominally straight balloon 650 may be wrapped around the spiral groove and  
23 pressurized. The pressurized assembly may be placed in the oven. The balloon dimensions may  
24 gradually creep until the balloon has been formed into the spiral shown in 11a.

25 [0177] Figure 21 shows that the balloons 650 can have torroidal configurations. The balloons 650  
26 can be stacked to make an annular balloon structure 682. The balloons 650 can form a ring with a clear  
27 passageway in the center. The balloons 650 may be attached to each other with adhesive, solvent, the  
28 application of heat or combinations thereof. The balloons 650 may be inflated by putting pressure into  
29 the balloon inflation/deflations port 654 (not shown). The lumens of each balloon 650 may be in fluid  
30 communication with one or more (e.g., all) of the other lumens and connected to one or more (e.g., all)  
31 of the other lumens internally.

32 [0178] Figures 22A and 22B show the balloon 650 can be attached to a balloon strap 672. The  
33 balloon 650 can be in a spiral configuration. The balloon strap 672 may be removed during a medical

1 procedure such that the balloon 650 may unwind along the first hollow shaft 2000a. This may make it  
2 easier to extract the balloon 650 thru an introducer after a procedure.

3 [0179] An annular balloon structure may comprise a balloon 650 and a shell 678.

4 [0180] Figure 23A shows that the inflated annular balloon structure can have a shell 678. The shell  
5 678 may wrap, encircle or enclose the balloon segments 656. The shell 678 may entirely or partially  
6 (as shown) cover the balloon segments 656.

7 [0181] Figure 23B shows a cross section F-F thru the center of the inflated annular balloon structure  
8 682 in figure 23A. The annular balloon structure 682 can have a central fluid passage 692 that may  
9 allow the annular balloon structure 682 to perfuse when used in a lumen in the body. The annular  
10 balloon structure 682 can have an inside radius 690. This inside radius 690 can be  $\frac{1}{2}$  the maximum  
11 circular diameter that can pass through central fluid passage 692 of the annular balloon structure 682.  
12 For example, the inside radius might be from about 2.5mm to about 10mm, more narrowly from about  
13 5mm to about 7.5mm. The inside radius may be about 6.4mm.

14 [0182] Figures 23B and 24B illustrate that the annular balloon structure 682 may have a first balloon  
15 cell 691a and a second balloon cell 691b. Figures 23B and 24B show a total of 8 balloon cells 691.  
16 Balloon cells 691a and 691b may be joined by balloon contact line 710. Similar balloon contact lines  
17 may exist between adjacent balloon cells 691 in figures 23B and 24B. The annular balloon structure  
18 682 may have a balloon contact inner radius 694 and a balloon contact outer radius 698. These radii  
19 are aligned with the innermost and outermost extent of the contact between balloon cells 691a and  
20 691b. The difference between the inner and outer contact radii can be about zero. For example the  
21 balloon cells 691a and 691b can be touching only at a point of tangency. The balloon contact inner  
22 radius and outer radius may be about 3.8mm to about 15mm, more narrowly about 7.5mm to about  
23 11.5mm. The balloon contact inner radius and outer radius may be about 9.5.

24 [0183] The balloon radius 704 can be the radius of the circle intersecting all of the center axes of each  
25 balloon cell 691. The balloon radius 704 may be about 5mm to about 15mm more narrowly about  
26 5mm to about 13mm. The balloon radius 704 may be about 10mm. The shell wall 684 may have a  
27 shell average thickness 686 of about  $7\mu\text{m}$  to about  $65\mu\text{m}$ , more narrowly about  $13\mu\text{m}$  to about  $38\mu\text{m}$ ,  
28 still more narrowly about  $20\mu\text{m}$  to about  $30\mu\text{m}$ . The shell outside radius 708 may be the shell inside  
29 radius 706 plus the shell thickness. The shell outside radius 708 may be equal to one half of the shell  
30 central section outer diameter 50.

31 [0184] The balloon radius 702 may be about 0.5mm to about 7.6mm, more narrowly about 2mm to  
32 about 5.8mm, still more narrowly about 3mm to about 5mm. The balloon radius 702 may be about  
33 3.8mm.

1 **[0185]** The balloon cells **691** may have about zero contact with each other and with the inside of the  
2 shell **678** (as shown in figure 23B at shell contact line **712**). The leakage area **700** between the inner  
3 wall of the shell and the balloon contacts **710** may be 12-22% of the total area enclosed by the shell  
4 cross section, more narrowly about 17%. The leakage area may be greater than 10%, more narrowly  
5 greater than 15%.

6 **[0186]** Figure 24A shows an inflated annular balloon structure **682** with a shell **678**. The shell **678**  
7 may entirely or partially (as shown) cover the balloon segments **656**. The balloon **650** shown in figure  
8 24A may have similar or identical dimensions to the balloon **650** shown in figure 23A. The shell **678**  
9 shown in figure 24A may have a smaller shell outside radius **708** than the shell **678** shown in figure  
10 23A. The shell **678** in figure 24A may be placed over the balloon segments **656**. The shell may  
11 compress or squeeze balloon segments **656** such that the balloon segments **656** may be deformed and  
12 driven closer to the shell longitudinal axis **26**. The shell **678** may be in tension when the balloon  
13 segments **656** are inflated

14 **[0187]** Figure 24B shows a cross section G-G thru the center of the inflated annular balloon structure  
15 **682** in figure 24A. The annular balloon structure can have a central fluid passage **692**. The central  
16 fluid passage **692** can be an open channel along the entire length of the inflated annular balloon  
17 structure **682**. The central fluid passage **692** may fluidly connect to apertures **714** in proximal taper **34**  
18 and distal taper **42**. When the annular balloon structure **682** is placed in a body lumen, for example in  
19 the vasculature, fluid (such as blood) or gas (such as air) in the lumen can flow through the central  
20 fluid passage **692**. For example, the balloon can perfuse when in the vasculature or in an airway.

21 **[0188]** The annular balloon structure may have a second hollow shaft **2000b** in the central fluid  
22 passage **692**. There may be a flow area gap **693** between the second hollow shaft **2000b** and the  
23 balloon **650**. The flow area gap **693** might be from about 2 mm to about 10mm, more narrowly from  
24 about 4mm to about 7mm., for example 5.5mm. Second hollow shaft **2000b** is not shown in Figures  
25 23A, 23B and 24A.

26 **[0189]** The inside radius **690** of annular balloon structure **682** shown in Figure 24B may be, for  
27 example, about 2.5mm to about 10mm, more narrowly about 3mm to about 5.6mm, for example about  
28 4.3mm. The area of the circle defined by the inside radius **690** may be about 0.091 inches squared or  
29 about 0.59 centimeters squared.

30 **[0190]** The balloon cells **691a** and **691b** may be joined by balloon contact line **710**, for example with  
31 a bond. The annular balloon structure **682** may have a balloon contact inner radius **694** and a balloon  
32 contact outer radius **698**. These radii are aligned with the innermost and outermost extent of the  
33 balloon contact **710** between balloon cells **691a** and **691b**. The balloon contact inner radius **694** may

1 about 1mm to about 20mm, more narrowly 2.5mm to about 13mm, more narrowly about 5mm to  
2 about 7.5mm. The balloon contact inner radius may be about 6.4mm. The balloon contact outer radius  
3 698 may be about 2mm to about 20mm, more narrowly 5mm to about 15mm, more narrowly about  
4 7.6mm to about 12.7mm. The balloon contact outer radius may be about 10mm. Balloon contact line  
5 710 can have a contact length about equal to the inner radius subtracted from the outer radius  
6 [0191] The balloon cell perimeter 696 is about equal to the total length of the dotted line 696 shown  
7 in Figures 23B and 24B (the dotted line matches the wall of the balloon cell 691). Balloon cells 691  
8 may have a balloon cell perimeter 696 of about 3mm to about 48mm, more narrowly about 12.7mm to  
9 about 37mm, still more narrowly about 19mm to about 32mm, for example about 24mm.

10 [0192] The length of the balloon contact line 710 may be greater than about 5% of the balloon cell  
11 perimeter 696, more narrowly greater than about 10%, still more narrowly greater than about 12%, for  
12 example about 16%.

13 [0193] The balloon outer radius 702a may be about 0mm to about 5mm, more narrowly about 0.5mm  
14 to about 3mm, still more narrowly about 1mm to about 2.5mm, for example about 1.5mm. The balloon  
15 inner radius 702b may be about 0.5mm to about 7.5mm, more narrowly about 1mm to about 5mm,  
16 still more narrowly about 1.5mm to about 3.8mm, for example about 2.5mm.

17 [0194] The leakage area 700 between the inner wall of the shell 678 and the balloon contact line 710  
18 may be less than about 15% of the total area enclosed by the shell cross section, more narrowly less  
19 than about 10%, still more narrowly less than about 5%, for example 2%.

20 [0195] The leakage area 700 can be sealed (no fluid communication) from central fluid passage 692.  
21 The leakage area 700 can be connected to a pressure source accessible by the physician. Leakage area  
22 700 may contain a fluid, for instance, a drug. Shell wall 684 may have pores, for instance holes less  
23 than 0.005mm in diameter. Shell wall 684 may perfuse from shell interior 47 to shell exterior 49.  
24 Pressurizing the fluid in leakage area 700 may cause the fluid in area 700 to travel from shell interior  
25 47 to shell exterior 49.

26 [0196] The arc length of the shell contact line 712 may be about 1.3mm to about 10mm, more  
27 narrowly about 3.3mm to about 8.4mm, still more narrowly about 4mm to about 7.5mm, for example  
28 about 5.8mm.

29 [0197] Figure 24b illustrates that the balloon cells 691 at the shell contact line 712 can be concentric  
30 with the shell 678, for example with the shell inner perimeter. The length of the wall of the balloon  
31 cells 691 at the shell contact line 712 can be equal to or greater than about 5%, more narrowly equal  
32 to or greater than about 10%, yet more narrowly equal to or greater than about 20%, of the balloon cell

1 perimeter 696 (i.e., the total length of the wall of the balloon cells in lateral section, i.e., the section  
2 shown in Figure 24b).

3 [0198] The shell inner perimeter in a plane can be about equal to the shell inside radius 706  
4 multiplied by 2 multiplied by pi. The sum of the arc lengths of all the shell contact lines 712 in a plane  
5 in the annular balloon structure 682 may be greater than 30% of the shell inner perimeter, more  
6 narrowly greater than 45%, still more narrowly greater than 55%, for example 61%.

7 [0199] A bond may be formed between the balloon segment 656 and the shell 678 at the shell contact  
8 line 712 with adhesive, solvent, heat or combinations thereof. The shell 678 may have adhesive 208  
9 on the shell inside surface, for instance a thermoplastic or a thermoset.

10 [0200] The arc length of the shell contact line 712 may be greater than 10% of the balloon cell  
11 perimeter 696, more narrowly greater than 15%, still more narrowly greater than 20%, for example  
12 24%.

13 [0201] Figure 25a shows an inflated spiral balloon 650 (such as shown in figure 20a) with a shell 678.  
14 The shell 678 may wrap, encircle or enclose the balloon 650. The shell 678 may entirely or partially  
15 (as shown) cover the balloon 650. Figure 25b shows a longitudinal cross-section H-H of the annular  
16 balloon structure 682 shown in Figure 25A.

17 [0202] Figure 26a shows an inflated spiral balloon with a shell 678. The balloon 650 shown in figure  
18 26A may have similar or identical dimensions to the balloon 650 shown in figure 25A. The shell 678  
19 shown in figure 26A may have a smaller shell outside radius 708 than the shell 678 shown in figure  
20 25A. The shell 678 in figure 26A may be placed over the balloon 650. The shell may compress or  
21 squeeze balloon 650 such that the balloon 650 may be deformed and driven closer to the shell  
22 longitudinal axis 26. The shell 678 may be in tension when the balloon 650 is inflated. Figure 17b  
23 shows a longitudinal cross-section of a spiral balloon with a shell 678. Shell contact line 712 may be  
24 oriented in the longitudinal direction. Shell leakage area may be shaped like a spiral.

25 [0203] Figures 27A and 27B illustrate that the shell 678 can have a balloon 650 in the shell interior  
26 47. Shell strut 716 may contain additional elements not included in the shell central section 38. For  
27 example, shell strut 716 may comprise additional longitudinally aligned fiber and/or additional fiber at  
28 other angles to the longitudinal axis and/or an additional polymer film and or shell taper  
29 reinforcements 862. The polymer film may have a low coefficient of friction on the outermost surface,  
30 for example it may have a coefficient of friction of less than 0.25, more narrowly less than 0.15, still  
31 more narrowly less than 0.1. Proximal taper 34 and distal taper 42 may help to introduce and withdraw  
32 the annular balloon structure 682 through a standard vascular introducer. For instance, the tapers 34  
33 and 42 may protect the balloon 650 from being damaged by rubbing on the vascular introducer or

1 features, such as calcifications, in the body. The tapers 34 and 42 may guide the annular balloon  
2 structure 682 thru the introducer.

3 [0204] Figure 27B shows cross section K-K of an inflated annular balloon structure 682. Figure 27D  
4 shows a closeup of a portion of Figure 27B. Balloon segments 656 can be compressed by shell 678.  
5 The annular balloon structure 682 can have a second hollow shaft 2000b, a third hollow shaft 2000c  
6 and a fourth hollow shaft 2000d. As shown in Figures 27B and 27D, fourth hollow shaft 2000d can fit  
7 over the outsides of shafts 2000b and 2000c to make shafts 2000b and 2000c approximately coaxial.  
8 Shafts 2000b and 2000c may slide within in the inside diameter of shaft 2000d. Shafts 2000b and  
9 2000c may be in fluid communication. A hollow shaft gap 2002 is formed between the distal end of  
10 shaft 2000b and the proximal end of shaft 2000c.

11 [0205] Figure 27C shows figure 27B with the annular balloon structure 682 in a deflated state. Figure  
12 27E shows a closeup of a portion of Figure 27C. Figure 27E shows that shafts 2000b and 2000c move  
13 within the inside diameter of shaft 2000d when the annular balloon structure 682 is deflated. Hollow  
14 shaft gap 2002 increases when the annular balloon structure 682 moves from an inflated to a deflated  
15 state. The second hollow shaft 2000b, third hollow shaft 2000c and fourth hollow shaft 2000d can  
16 form an inner lumen 154a. The inner lumen 154a can extend thru the center of the annular balloon  
17 structure 682. A guidewire may be inserted into inner lumen 154a to locate the balloon during a  
18 medical procedure. Third hollow shaft 2000c and fourth hollow shaft 2000d may be omitted and  
19 second hollow shaft 2000b may be extended to catheter tip 838.

20 [0206] First hollow shaft 2000a may be in fluid communication with hollow shaft distal port 54 and  
21 balloon inflation/deflation ports 654. The addition of fluid or gas into ports 654 may cause balloon  
22 segments 656 to inflate and for the annular balloon structure 682 to expand. Removal of fluid or gas  
23 from ports 654 may cause balloon segments 656 to deflate and for the annular balloon structure 682 to  
24 return to a pleated state, for example as shown in figure 7C.

25 [0207] Figure 28A shows cross section K-K of an inflated annular balloon structure 682. Figure 28C  
26 shows a closeup of a portion of Figure 28A. The annular balloon structure can have a second hollow  
27 shaft 2000b that slidably fits into catheter tip 838. A hollow shaft gap 2002 is formed between the  
28 distal end of shaft 2000b and the catheter tip pocket bottom 840. The catheter tip 838 may have a  
29 catheter tip exit 841. Fluid flow 870 (shown with a dashed line in Figure 28A) may pass through shell  
30 apertures 714 on the distal taper 42 or proximal taper 34, into central fluid passage 692 and through  
31 shell apertures 714 on the proximal taper 34 or distal taper 42.

32 [0208] Figure 28B shows figure 27A with the annular balloon structure 682 in a deflated state. Figure  
33 28D shows a closeup of a portion of Figure 28B. Figure 28D shows that shaft 2000b moves within the

1 catheter tip 838 when the annular balloon structure 682 is deflated. Hollow shaft gap 2002 increases  
2 when the annular balloon structure 682 moves from an inflated to a deflated state. The second hollow  
3 shaft 2000b can form an inner lumen 154a. Inner lumen 154a may be in fluid communication with the  
4 catheter tip exit 841.

5 [0209] Figure 28A shows that balloon flexion sections 670 may stay within the volume enclosed by  
6 shell central section 38 with central length 40. Figure 27B shows that balloon flexion sections 670  
7 may touch the shell wall 684 in taper sections 42 and 34.

8 [0210] Figures 29 and 30 show that the annular balloon structure 682 can have 2,3,4,5,6,7,8 or more  
9 support members 722 and/or support sheets 726. The support members 722 and/or support sheets 726  
10 may cross the central fluid passage 692. Support members 722 and/or sheets 726 may be anchored to  
11 balloon segments 656 and/or second hollow shaft 2000b. Sheets 726 may be notched or forked so that  
12 they may pass by each other. Support members 722 and/or sheets 726 may be constructed similarly  
13 similar to the shell wall 684 and be substantially non-compliant. Support members 722 and/or sheets  
14 726 may be semi-compliant, compliant or highly compliant. Support members 722 and/or sheets 726  
15 may made of an elastomer such as urethane. Support members 722 and/or sheets 726 may comprise a  
16 fiber. Support members 722 and/or sheets 726 may have a strain to failure of less than about 10%.  
17 Support members 722 and/or sheets 726 may be in tension when the annular balloon structure 682 is  
18 inflated and serve to control the maximum diameter of the annular balloon structure 682 when  
19 inflated. When pressure is withdrawn from the annular balloon structure 682, support members 722  
20 and/or sheets 726 may help to collapse the structure 682 in a way that helps pleats or flutes to re-form.  
21 The re-forming of pleats or flutes may make the collapsed balloon easier to withdraw through body  
22 lumens, for example through the vasculature and through an introducer.

23 [0211] Figures 31A show that a valve 730 may be placed in central fluid passage 692. Figures 31A  
24 and 31B show the valve 730 in a closed position. Figure 31C shows the valve 730 in an open position.  
25 The valve leaflets 734 may be anchored to the balloon segments 656 or the inside of the shell wall  
26 684. The valve leaflets can be thin and flexible. The valve leaflets may contact the outside of second  
27 hollow shaft 2000b when in a relaxed state.

28 [0212] Referring to Figure 31A, central fluid passage 692 may be filled with a liquid or a gas. When  
29 the pressure in the liquid or gas is higher in the distal taper 42 than the proximal taper 34, valve  
30 leaflets 734 may open (as shown in Figures 31A and 31C) to allow fluid flow 870 through the central  
31 fluid passage. When the pressure difference in the liquid or gas between the distal taper 42 and the  
32 proximal taper 34 is reduced or removed the valve leaflets 734 may shut and reduce or eliminate fluid  
33 flow in central fluid passage 692. Valve leaflets 734 may act as a one way valve. A pressure difference  
34 in the liquid or gas between the distal taper 42 and the proximal taper 34 pressure may be generated by

1 a beating heart during a medical procedure. Valve leaflets 734 may serve as a temporary replacement  
2 for a heart valve (such as the aortic valve) during a medical procedure. Valve leaflets 734 may be  
3 made of a polymer film or be made similar to the shell wall 684 or be made of a highly compliant  
4 material such as, for instance, an elastomer.

5 [0213] The exterior of shell wall 684 may be coated with a drug, such as paclitaxil. The drug may be  
6 delivered to the body when the annular balloon structure 682 is inflated during a medical procedure.  
7 Layer 72 or panel 196 may comprise a drug. For instance, Layer 72 or panel 196 could be a film  
8 soaked in a drug, a film with pores to hold drugs, a fiber matrix holding drugs or combinations thereof.  
9 Layer 72 may be an outer layer 72a, an inner layer 72b or a middle layer, such as 72c.

10 [0214] Figure 32A shows a capsule 874. Capsule 874 may be an annular balloon structure 682.  
11 Figure 32B shows a cross section of the capsule 874 in Figure 32A. Capsule 874 may have a capsule  
12 length 878, a capsule diameter 882 and capsule inside diameter 890.

13 [0215] Figure 32C shows a capsule 874 with hourglass shape on the outer diameter. Figure 32D  
14 shows a cross section of the capsule 874 in Figure 32C. Capsule 874 may have a capsule waist  
15 diameter 886.

16 [0216] The capsule length 878 divided by the capsule diameter 882 may form a capsule length to  
17 width ratio. The capsule length to width ratio may be from about 10:1 to about 1:1, more narrowly  
18 from about 5:1 to about 1:1, more narrowly still from about 3:1 to 1:1. The capsule waist diameter 886  
19 may less than about 90% of capsule diameter 882, more narrowly less than about 80% of capsule  
20 diameter 882, still more narrowly less than about 70% of capsule diameter 882.

21 [0217] Figure 33A shows a capsule 874 with capsule taper section 894 and capsule inflation port 896.  
22 Providing material, such as a liquid or a gas, at capsule inflation port 896 may cause capsule 874 to  
23 inflate. Withdrawing material at capsule inflation port 896 may cause capsule 874 to deflate.

24 [0218] Figure 33B shows that a first capsule 874a and a second capsule 874b may be aligned  
25 concentrically and in contact to form an annular balloon structure 682 with an hourglass shape. First  
26 capsule 874a may be inflated or deflated at first inflation port 896a. Second capsule 874b may be  
27 inflated or deflated at second inflation port 896b. The internal lumens of capsules 874a and 874b may  
28 be connected over a portion of the area where the capsules touch. Three, Four, Five or more capsules  
29 874 may be joined to form an annular balloon structure 874.

30 [0219] Figure 34 shows a capsule 874 in a pleated condition. Capsule 874 may have a distal taper 42  
31 with a distal taper length 44 of about 0mm.

32 [0220] Capsule wall 876 may comprise a fiber matrix, a layer 72 a panel 196 or combinations thereof.  
33 Figure 35a shows a fiber matrix with fiber 86 and adhesive 208. The fiber matrix in Figure 35a may be

1 referred to as a unidirectional fiber matrix. Figure 35b shows a fiber matrix with reinforcement fiber  
2 **86a** and reinforcement fiber **86b** at an angle of about 90 degrees to each other. Figure 35C shows a  
3 fiber matrix with reinforcement fiber **86a** and reinforcement fiber **86b** placed at layer angle **738** to one  
4 another. Layer angle **738** may be from 45 to 70 degrees, more specifically 45, 50, 55, 60, 65, or 70  
5 degrees. Figure 35D shows that the fiber matrix shown in Figure 35D may be combined with another  
6 unidirectional fiber matrix. Capsule **874** may have a non-compliant capsule diameter **882** when  
7 inflated.

8 **[0221]** Figure 36 illustrates that the shell **678** can be partially or completely manufactured in a  
9 pressure chamber **219**. The pressure chamber **219** can be in a pressure chamber case **218**. The  
10 pressure chamber case **218** can have a case top **220a** separable from a case bottom **220b**. The case top  
11 **220a** can have a case top port **222**. The case bottom **220b** can have a case bottom port **224**. The case  
12 top port **222** can be in fluid communication with the top of the pressure chamber **219**. The case  
13 bottom port **224** can be in fluid communication with the bottom of the pressure chamber **219**.

14 **[0222]** The case top can screw or otherwise tightly join to the case bottom. The pressure chamber  
15 case can have one or more o-rings (not shown) in o-ring seats **226**.

16 **[0223]** The pressure chamber can have a mandrel seat **228**. The mandrel seat **228** can be configured  
17 to receive a mandrel **230**. The mandrel seat **228** can have holes or pores. The holes or pores in the  
18 mandrel seat **228** can allow pressure from the case bottom port and the bottom of the pressure chamber  
19 to reach the top surface of the mandrel seat around the mandrel and/or directly under the mandrel.

20 **[0224]** The mandrel **230** can have the inner dimensions of the shell **678**.

21 **[0225]** The mandrel **230** may be made from a low melting point wax or metal, a foam, some  
22 collapsing structure or an inflatable bladder. The mandrel **230** can be made from a eutectic or non-  
23 eutectic bismuth alloy and removed by raising the temperature to the melt point of the metal. The  
24 mandrel **230** can be a water soluble mandrel. The mandrel **230** can be made from aluminum, glass,  
25 sugar, salt, corn syrup, hydroxypropylcellulose, ambergum, polyvinyl alcohol (PVA, PVAL or  
26 PVOH), hydroxypropyl methyl cellulose, polyglycolic acid, a ceramic powder, wax, ballistic gelatin,  
27 polylactic acid, polycaprolactone or combinations thereof.

28 **[0226]** A panel **196a** may be positioned over the mandrel **230**. The panel **196a** may be a single layer  
29 or multiple layers. For instance, the panel **196a** could be a layer of film and meltable adhesive  
30 **208**. The panel **196a** can be positioned with film on the side that touches the mandrel and adhesive on  
31 the radially outer side.

32 **[0227]** Figure 37A illustrates that a positive pressure can be applied to the top **220a** of the pressure  
33 chamber (e.g., through the case top port **222**) and/or a negative pressure or differential pressure or

1 suction or vacuum applied to the bottom **220b** of the pressure chamber (e.g., through the case bottom  
2 port **224**). The panel **196A** can get sucked and/or pressed down and/or formed onto the mandrel **230**.  
3 The first panel **196A** can be smoothly fitted to the mandrel **230** and adhered to the mandrel at the first  
4 adhesive **208A**. The first panel **196A** can stretch and/or yield and or/deform. The first panel **196A** can  
5 be have thinner after being stretched, yielded or formed. The first adhesive **208a** can be water soluble.  
6 The first adhesive **208a** can be sugar syrup. Heat may be applied to panel **196a** before forming onto  
7 mandrel **230**. Forming of one panel **196a** may be done more than once on different sized mandrels  
8 before the panel **196a** reaches the form shown in Figure 37A.

9 **[0228]** Forming of panel **196a** may also be accomplished with a mechanical die. The mechanical die  
10 may be heated and conform closely to the shape of the mandrel **230**. The mechanical die may have a  
11 shape similar to the mandrel seat **228**.

12 **[0229]** The mandrel **230** and panel **196a** can be mounted into a trimming jig. Any excess portion of  
13 the first panel **196a** extending from the mandrel **230** can be trimmed with a blade, with a laser, with a  
14 water jet cutter, with a die cut tool or combinations thereof. The trimming jig can cover the mandrel  
15 **230** and the first panel **196a** attached to the mandrel. Several panels **196a** and/or layers **72** can be  
16 formed over the mandrel **230** and cut. The panels **196a** and/or layers **72** may be trimmed at the same  
17 time or one at time.

18 **[0230]** Figure 37B illustrates that the mandrel can have the excess area of the first panel **196A**  
19 removed in preparation for attachment of the second panel **196b**.

20 **[0231]** A second adhesive **208b** can be applied to the first panel **196a** around the perimeter of the  
21 second panel's **196b** contact area with the first panel **196a**. The mandrel **230** can be seated in the  
22 mandrel seat **228** with the first panel **196a** in the mandrel seat.

23 **[0232]** Figure 37C illustrates that after the case top **220a** is secured to the case bottom **220b**, the  
24 positive and/or negative pressures can be applied to the pressure chamber as described infra. The  
25 second panel **196b** can be smoothly fitted or pressure formed to or against the mandrel **230** and  
26 adhered to the first panel **196a** at the second adhesive **208b**. Adhesion can be accomplished by the  
27 application of heat. The first and second panels (**196A** and **196B**) can form the inner layer **72b** or  
28 bladder **52** of the shell wall **684**. The inner layer may be leaktight. The inner layer may be capable of  
29 sustaining pressure. Multiple layers can be made by repeating the method described infra. The  
30 pressure chamber can be heated, for example, to decrease the viscosity of and decrease the modulus of  
31 the panels **196**.

1 [0233] Figure 37D shows cross section L-L with the mandrel 230 omitted. Bladder 52 may have first  
2 internal seam 69a, second internal seam 69b inner layer first panel 74a, inner layer second panel 74b  
3 and inner layer 72b. The bladder 52 may be leaktight.

4 [0234] Figure 38A shows the bladder 52 after being fit over a mandrel 230 (mandrel 230 is inside  
5 bladder 52 and not directly shown in Figure 38A). The bladder 52 may be made slightly larger in  
6 diameter and/or longer in length than the mandrel 230 onto which the bladder 52 is fit. This may allow  
7 the bladder 52 to be re-assembled on the mandrel 230 with an internal seam 66 that may be sealed.  
8 Figure 38A shows a longitudinal seam 66 running the length of the bladder 52. The seam 66 may be  
9 sealed with adhesive, by fusing, by heating, with a solvent or combinations thereof. The sealed bladder  
10 52 may form the inner layer 72b of a shell 678 and be leak-tight. Seam 66 may be an external seam  
11 66a or internal seam 66b.

12 [0235] Figure 38B illustrates that the first bladder portion 52a can overlap at a lap joint or overlap (as  
13 shown), abut at an abutment, or flange with the second bladder portion 52b at the seam 66. Seam 66  
14 may be angled, vertical or a spiral or combinations thereof.

15 [0236] Figure 39A shows a cross section of a tow 270. The tow 270 may contain about 6, 25, 100,  
16 500 or 1500 monofilaments. The tow 270 may have a tow height 271 and a tow width 272. The tow  
17 270 may be approximately circular. For example, the tow height 271 and tow width 272 may be about  
18 0.025 mm (0.001 in) to about 0.150 mm (0.006 in), more narrowly about 0.050 mm (0.020 in) to about  
19 0.100 mm (0.040 in), still more narrowly about 0.075 mm (0.003 in). The tow 270 may be loosely held  
20 together by a polymer finish (not shown).

21 [0237] Figure 39B shows that tow 270 may contain a marker wire 190. Marker wire 190 may be  
22 circular, as shown, and radiopaque.

23 [0238] Figure 39C shows the tow 270 after the tow 270 has been spread. The tow 270 may be  
24 flattened or spread by passing the tow 270 through a closely spaced set of rollers that form a narrow  
25 pinch gap. The tow 270 may be spread by pulling the tow 270 under tension over a set of rollers or  
26 pins. After spreading, the tow 270 may have a tow height 271 less than about twice the fiber height  
27 1068, for example about the same as fiber height 1068. The fiber height 1068 and fiber width 1072  
28 may be substantially unchanged after spreading. For example, the fiber width 1072 and fiber height  
29 1068 may be about 15  $\mu\text{m}$  (0.0006 in), tow width 272 may be about 210  $\mu\text{m}$  (0.008 in) and tow height  
30 271 may be about 15  $\mu\text{m}$  (0.0006 in). The marker wire 190 is not shown in figure 39C but may be  
31 present after the tow 270 has been spread.

32 [0239] Figure 40A illustrates that a layer of fiber matrix can be made on a roller 232. The roller 232  
33 can be configured to rotate about a roller axle 234. The roller 232 may have a diameter from about

1 100 mm to about 1,000 mm. The roller 232 may be made or coated with an anti-stick material such as  
2 a fluoropolymer.

3 [0240] Figure 40B illustrates that a releaser 236, such as a release layer, can be placed around the  
4 circumference of the roller 232. The release layer can be a low friction film or coating. The release  
5 layer may be a thin and/or flexible fluoropolymer sheet.

6 [0241] Figure 40C shows that an adhesive 208 can be placed on the releaser or directly onto the roller  
7 232 (e.g., if no releaser 236 is used). The adhesive 208 may be a thermoplastic film. The adhesive 208  
8 may be a thermoset adhesive. The adhesive 208 may be a solvated thermoplastic or thermoset. The  
9 adhesive 208 may have a backing film, such as paper.

10 [0242] Figure 40D shows the application of the reinforcement fiber 86 to the roller 232. The fiber 86  
11 may be unwound from a spool (not shown) and rolled onto the top surface of the adhesive 208. Before  
12 winding, the fiber 86 may be infused or coated with an adhesive 208, a solvent, or both. The coating  
13 may be a thermoplastic. The fiber 86 may have been previously flattened as detailed supra. The fiber  
14 86 may have a non-circular cross section, such as a rectangle or an ellipse. Any coating or sizing on  
15 the fiber may have been removed using a solvent. The fiber 86 may be placed with a gap between each  
16 successive fiber wrap. The gap may be less than about 200  $\mu\text{m}$  (0.008 in), more narrowly less than  
17 about 5  $\mu\text{m}$  (0.0002 in). A heat source or a solvent may be used to fix the fiber 86 to the adhesive 208  
18 (i.e., tack the fiber 86 in place on the adhesive 208), to melt or solvate a material onto the release layer  
19 236, to melt or solvate a material on the fiber 86 or combinations thereof. For example, a separate  
20 resistive heater, a laser, a source of hot air, or an RF welder may be used. A solvent such as methyl  
21 ethyl ketone or tetrahydrofuran may be used. The fiber 86 can be wound with a pitch of 3000 to 30  
22 turns per 1 inch (25.4 mm). The pitch can be chosen based on the total size of the fiber 86 or tow 270  
23 being applied and the chosen gap between each subsequent fiber 86 or tow 270 on the roller 232.  
24 Applications of a single monofilament 274, which may be a wire, can have pitches from about 2000 to  
25 about 100 turns per 1 inch (25.4 mm).

26 [0243] Figure 40E shows reinforcement fiber 86 on top of adhesive 208 on top of release layer 236.  
27 Figure 40E may show a cross section after the operation shown in Figure 40D is performed.

28 [0244] Figure 40F illustrates that the roller can be placed between a vacuum top sheet 238a and a  
29 vacuum bottom sheet 238b, for example in a vacuum bag. A vacuum seal tape 240 can surround the  
30 roller 232 between the vacuum bottom and top sheets 238b and 238a, respectively. Air can be  
31 removed from between the vacuum top and bottom sheets 238a and 238b and within the vacuum seal  
32 tape, for example by suction from a suction tube 242. Inside and/or outside of the vacuum bag, the  
33 roller 232 can be heated, for example to melt or cure the adhesive 208. Roller 234 can be removed  
34 from the vacuum bag, for example after melting or curing of the adhesive is complete.

1 [0245] Figure 40G shows the removal of the panel 196. For instance, a cut may be made substantially  
2 perpendicular to the fiber. The panel 196 may be peeled away from the release layer. The panel 196  
3 may be substantially foldable and/or flexible.

4 [0246] Figure 40H illustrates that the panel 196 of fiber matrix can be removed from the roller 232.  
5 For example, the panel 196 can be peeled off the releaser 236. The panel 196 can be repositioned on  
6 the roller 232 at about 90 degrees to the layer's previous angle and additional reinforcement fibers 86  
7 can be applied as shown in figure 39D. This may result in a panel 196 with fibers 86 running  
8 perpendicular to each other (e.g., a "0-90" layer, so called for the angle the two layers of fiber make  
9 with respect to each other). The panel 196 can be cut into a smaller panel. For instance, the panel 196  
10 can be cut with a trimming jig, a laser, a water jet cutter, a die cut tool, or a combination thereof.

11 [0247] Figure 41A shows that a panel 196 may have reinforcement fibers 86b oriented substantially  
12 parallel to panel longitudinal edge 332. The panel 196 can have a panel width 334. The panel width  
13 334 can be about equal to the circumference of the shell 678 in the central section 38. The panel 196  
14 can have a panel length 335. The panel length 335 can be greater than the shell length 28. The panel  
15 196 can have a panel rectangular section 336 and one or more panel serrations 338a, 338b and 338c.  
16 Each panel serration 338a, 338b and 338c can have a portion of the panel 186 that forms a portion of  
17 the stem 30 or 43 and taper 34 or 44. Each serration 338a, 338b and 338c can have a serration edge  
18 339a, 339b and 339c, respectively. The angle between the serration edges 339 and a line parallel to  
19 the reinforcement fibers 86b can be a panel serration angle 340. The panel serration angle 340 can be  
20 about 30°, about 20°, about 10°, or about 0°. A first panel serration 338a can be substantially in line  
21 with a second panel serration 338b. One or more fibers 86b may run from the terminal end of the first  
22 serration 338a to the terminal end of the second serration 338b.

23 [0248] Figure 41B illustrates that longitudinal reinforcement fiber 86b can be parallel with  
24 longitudinal edge 332. Second longitudinal reinforcement fiber 87b can be parallel with the fiber 86b.  
25 Fibers 86b and 87b can be separated by fiber separation areas 614. The fiber separation areas 614 may  
26 separate fibers 86b and 87b by about 2 mm, more narrowly less than about 1 mm, still more narrowly  
27 less than about 0.25 mm. The fiber separation areas 614 may be distributed on the panel such that no  
28 area 614 substantially overlaps any other area in the X and/or Y direction. The fiber separation areas  
29 614 may be positioned in the X and Y directions on the panel 196 in a pattern sufficient to prevent any  
30 fiber from reaching all the way across the panel rectangular section in the X direction. The shell 678 in  
31 figure 5 may be built in part with the panel 196 shown in figure 41B. Fibers 86b and 87b may have  
32 fiber lengths 88 less than about 80% of the shell length 28 more narrowly less than about 75% as long,  
33 more narrowly less than about 70% as long, still more narrowly less than about 65% as long, still more  
34 narrowly less than about 60% as long.

1 [0249] Figure 41C shows that a panel 196 can have a panel rectangular section 336 and one or more  
2 panel serrations 338a, 338b and 338c. Panel serration 338b can be oriented in the Y direction  
3 substantially midway between panel serrations 338a and 338c. Panel serration 338b can be oriented in  
4 the Y direction substantially closer to either panel serrations 338a or 338c. The longest reinforcement  
5 fiber length 88 in panel 196 may be less than about 75% of the length 28 of the shell, more narrowly  
6 less than about 70%.

7 [0250] Figure 42A shows that panel 196 may contain reinforcement fibers 85a and 85b arranged in a  
8 woven pattern. A woven pattern can have fibers 85a and 85b that alternately pass over and under each  
9 other.

10 [0251] Figure 42B shows that the panel 196 may contain reinforcement fibers 85 in a braided  
11 configuration.

12 [0252] Figure 42C shows that the panel 196 may contain reinforcement fibers 85 of various lengths in  
13 random orientations, sometimes referred to as chopped or chopper fiber.

14 [0253] Figures 43A and 43B illustrate that a panel 196 may be applied to a mandrel 230 with none,  
15 one or more layers 72 on the mandrel 230. The panel 196 may be joined to layers 72 by the  
16 application of adhesive or by heat or by combinations thereof. The panel 196, when folded onto the  
17 shape of the mandrel 230 may give a substantially complete coverage of the mandrel 230 with  
18 minimal or no overlap of the panel 196. Panel rectangular section 336 may cover the shell central  
19 section 38. Panel serrations 338 may cover proximal taper 34, distal taper 42, proximal stem 30 and  
20 distal stem 43.

21 [0254] A die may be used to press the panel 196 onto the shell 678. The die may be heated and the  
22 panel 196 may contain a thermoplastic. The die may melt the thermoplastic and adhere the panel 196  
23 to the shell 678. The die may be shaped to match the mandrel 230 shape. After attaching two  
24 serrations 338 (one serration at each end of the mandrel 230. See figure 43A), the mandrel 230 may be  
25 rotated about its longitudinal axis to advance the next set of serrations 338 into place under the die.  
26 The die may again press two serrations 338 into place on the shell 678. Subsequent use of the die in  
27 this manner may attach substantially the entire panel 196 to shell 678 as shown in Figure 43B.

28 [0255] Figure 44 illustrates that fiber 86 can be wound over the mandrel 230 or over shell 678. The  
29 fiber 86 may be continuous or discontinuous. The mandrel can be rotated, as shown by arrow 252,  
30 about the mandrel longitudinal axis 250 or shell longitudinal axis. The first spool 244a can be  
31 passively (e.g., freely) or actively rotated, as shown by arrow 254, deploying fiber 86 (shown) or tow  
32 270. Before or during winding, the fiber 86 may be infused or coated with an adhesive, a solvent, or  
33 both. The coating may be a thermoplastic. A fiber distal end can fix to the shell 678 or directly to the  
34 mandrel 230.

1 [0256] The fiber 86a may be wound with a gap between each successive fiber wind. The gap can be  
2 less than about 200  $\mu\text{m}$  (0.008in), more narrowly less than about 5  $\mu\text{m}$  (0.0002in).

3 [0257] The fiber 86 can be wound with a pitch of about 3000 to about 30 winds per 1 inch (25.4mm).  
4 The pitch can be chosen based on the total size of the fiber 86 or tow 270 being applied to the part  
5 from first spool 244a and the chosen gap between each subsequent fiber 86 or tow 270 on the part.  
6 Applications of a single monofilament 274, which may be a wire, can have pitches from about 2000 to  
7 about 100 turns per 1 inch (25.4mm).

8 [0258] A tool arm 246 can be attached to a rotating tool wheel 248. The tool arm 246 can rotate and  
9 translate, as shown by arrows 256 and 258, to position the tool wheel 248 normal to and in contact  
10 with the shell 678. A second tool wheel 248' (attached to tool arm 246') can have a range of motion  
11 sufficient to apply pressure normal to the surface of a shell taper section.

12 [0259] The tool wheel 248 can press the fiber 86 or tow 270 against the shell 678 and spread the  
13 monofilaments 274. The tool wheel 248 may help to adhere the tow 270 to the shell, for example by  
14 applying pressure and following closely the surface of the shell. The tool wheel 248 can be heated to  
15 soften or melt the material on the surface of the shell 678. Another heat source or a solvent may be  
16 used to tack the fiber in place, to melt or solvate a material on the shell, to melt or solvate a material  
17 on the fiber or combinations thereof. A separate resistive heater, a laser, a UV light source, an infrared  
18 light source, a source of hot air, or an RF welder may be used with or without the tool wheel 248 to  
19 attach the fiber. A solvent such as methyl ethyl ketone or tetrahydrofuran or alcohol or combinations  
20 thereof may promote adhesion of the fiber 86 and may be used with or without the tool wheel 248.  
21 The tool wheel 248 can be made of or coated with a non-stick material. The tool wheel 248 may not  
22 rotate. The tool wheel 248 may comprise a hard surface, for example carbide.

23 [0260] A second spool 244b may deploy marker wire 190 during a winding operation. Second spool  
24 244b may also deploy a reinforcement fiber 85 (not shown). Marker wire 190 (or reinforcement fiber  
25 85) may be applied simultaneously with fiber 86 and/or tow 270 to the shell. Marker wire 190 may  
26 interleave with reinforcement fiber 86 to form a single fiber layer on shell 678. Marker wire 190 may  
27 be deposited on top bellow another existing fiber layer.

28 [0261] The resulting layer deposited in Figure 44 can have a layer thickness 216 of from about 1  $\mu\text{m}$   
29 (0.00004 in) to about 50  $\mu\text{m}$  (0.002 in), more narrowly from about 8  $\mu\text{m}$  (0.0003 in) to about 25  $\mu\text{m}$   
30 (0.001 in).

31 [0262] The techniques described in Figures 36, 37A, 37B and 37C may be used to apply additional  
32 panels 196 or layers 72 to shell 678. For example, two panels 196 may be applied to form an outer  
33 layer 72a on the shell 678 as shown in Figure 45A.

1 [0263] Figure 45B shows that a panel 196e can applied to the proximal end of the balloon. Similarly,  
2 a panel 196f can be applied to the distal end of the balloon. The panels 196e and 196f could be like  
3 those shown in figures 46A and 46B.

4 [0264] Figure 46A shows a panel 196 with panel cutout 842 and panel lobe 846. Panel cutout 842 can  
5 be aligned on a shell 678 to form an aperture 714. Panel lobe 846 can be placed on a shell 678 to form  
6 a shell reinforcement lobe 866.

7 [0265] Figure 46B shows a panel 196 with a panel cut 850. Panel cut 850 may allow the panel to  
8 form over shell 678.

9 [0266] Figure 47 illustrates that a wash tube 264 can be inserted into a mandrel washout port 262. A  
10 dissolving or solvating fluid can be delivered through the wash tube and into the washout port 262.  
11 The mandrel can be removed by delivery of a fluid solvent such as water, alcohol or a ketone. The  
12 solvent may be applied during the consolidation process such that the solvent melts or partially softens  
13 the mandrel and concurrently pressurizes the bladder. The mandrel 230 can be removed by raising the  
14 mandrel to a melting temperature for the mandrel. The mandrel 230 can be removed by deflating the  
15 mandrel or by collapsing an internal structure.

16 [0267] Figure 48A illustrates that the shell 678 may be placed in a shell mold 622 containing a shell  
17 pocket 624. The shell mold 622 may be porous such that substantial amounts of gas may be drawn  
18 from shell pocket 624 thru the wall of shell mold 622 and out into the surrounding atmosphere. The  
19 shell 678 may have a tube (not shown) placed in its inner volume that may extend out either end of the  
20 shell 622. The tube may be thin and very flexible. The tube may be a silicon rubber.

21 [0268] A coating may be sprayed into mold 622 that bonds to the shell 678 during cure and forms an  
22 outer layer 72a on the shell 678.

23 [0269] Figure 48B illustrates that the shell mold 622 may be closed around the shell 678. Pressure  
24 may be applied thru shell second fluid port such that the shell expands to contact the inside of shell  
25 pocket 624. Alternately, the tube (not shown) extending out either end of the shell may be pressurized  
26 to force the shell into contact with pocket 624.

27 [0270] Figure 48C shows Pressure P inside the shell volume pressing the shell wall 684 outwards.  
28 Mold 622 may be placed in an oven and heated. Mold 622 may have built in heaters. The shell mold  
29 622 may be placed under vacuum or placed in a vacuum chamber during heating. The shell mold 622  
30 may have a texture, such as a texture created by abrading or sand blasting or bead blasting the shell  
31 mold 622. The texture may impart a texture to the outer layer 72b of the shell.

32 [0271] Heating the shell under pressure may cause one or more layers 72 to melt and/or fuse and/or  
33 bond with adjoining layers 72. Melting under pressure may remove voids in the shell wall. The inner  
34 and outer films may not melt. Heating the shell under pressure may cause the walls of the shell 678 to

1 fuse or laminate into one continuous structure. The shell outer layer 72a may be substantially  
2 smoothed by this process. The shell outer layer 72a may be permeable or perforated such that gas or  
3 other material trapped in the shell wall 684 during manufacture may escape when the shell is heated  
4 under pressure.

5 [0272] The shell outside radius 708 may be very accurate and repeatable. For instance, at a given  
6 pressure, the outside radius 708 of a group of shells 678 may all be within about 2% (+/- 1%) of each  
7 other. For instance, if the nominal dimension of the outside radius 708 of the shell is about 12 mm at  
8 about 60 psi (414 kPa), all shells may have an outside radius 708 of about 11.88 mm to about 12.12  
9 mm.

10 [0273] A shell 678 can be clamped in a pleating tool with two, three, four, five or more removable  
11 pleating blocks. Heating the pleating blocks to about 80C and then pressing them against the shell 678  
12 for about 1 minute causes the shell to become pleated or fluted. Commercial pleating machines such  
13 as folding machinery from Interface Associates (Laguna Niguel, CA) can also be used. A small  
14 amount of wax may be used to hold the pleated and folded shell into its desired shape.

15 [0274] As shown in Figures 49A and 49B, a balloon 650 may be placed in an insertion tool 854.  
16 Before being placed in the insertion tool 854, the balloon 650 may be coated in an adhesive 208 or a  
17 solvent. The insertion tool 854 may comprise a tube that will not adhere to most adhesives, for  
18 example the tube may comprise a fluoropolymer.

19 [0275] Figure 49C shows that apertures 714 may be cut in the shell 678, for example with a laser 858.  
20 A shell 678 may be fabricated with apertures 714 already in place. Figure 49D shows that insertion  
21 tool 854 may be inserted through aperture 714 into shell interior 47. Insertion tool 854 may be  
22 inserted through the interior volume of shell proximal stem 30 or shell distal stem 43 or any other  
23 orifice in the shell 678. A cut in the shell 678 may be made to allow the insertion tool 854 into shell  
24 interior 47. Figure 49E shows that the insertion tool 854 can be removed leaving balloon 650 in the  
25 shell interior 47. Figure 49F shows that balloon 650 can be inflated inside shell 678. Adhesive 208 or a  
26 solvent or the application of heat may bond balloon 650 to the inner wall of shell 678 forming annular  
27 balloon structure 682.

28 [0276] Figure 50 illustrates a balloon catheter. Inflation fluid may be provided by detachable syringe  
29 472 thru catheter Y-fitting 634. Inflation fluid may flow between the inside wall of first hollow shaft  
30 2000a and the outside wall of second hollow shaft 2000b. Inflation fluid may flow into the balloon  
31 650 to inflate the annular balloon structure 682. A guide wire may be inserted at guidewire port 632  
32 and pass thru the interior of the second hollow shaft 2000b.

33 [0277] Figure 51 illustrates a cross section of an annular balloon structure 682 in a substantially  
34 deflated and pleated or folded configuration. The annular balloon structure 682 is shown in a tube 428

1 with a tube inside diameter 436 and a tube inside diameter cross sectional area 434. The annular  
2 balloon structure 682 may be inserted into the tube 428 without damaging the annular balloon  
3 structure 682. The tube 428 may be, for instance, an introducer or a balloon protection sleeve used to  
4 store the balloon.

5 [0278] The compression ratio of the annular balloon structure 682 can be from about 3:1 to about  
6 10:1, more narrowly from about 5:1 to about 7:1. The compression ratio can be the ratio between  
7 twice the shell outside radius 708 of the substantially inflated annular balloon structure 682 and tube  
8 inside diameter 436. For instance, an annular balloon structure 682 with shell outside radius 708 equal  
9 to about 12.2mm can be inserted into a tube 428 with a tube inside diameter 436 of about 4.8mm,  
10 more narrowly about 4mm, still more narrowly about 3.6mm.

11 [0279] The annular balloon structure 682 can have a packing density equal to or greater than about  
12 40%, more narrowly greater than or equal to about 55 %, yet more narrowly equal to or greater than  
13 about 70%. The packing density can be the percentage ratio between the cross sectional area of the  
14 walls of the annular balloon structure 682 and the tube inside diameter cross sectional area 434.

15 [0280] The packing density and compression ratios for the annular balloon structure 682 can remain  
16 substantially constant and the wall strength of the annular balloon structure 682 can remain  
17 substantially constant with repeated insertions or withdrawals from tube 428 and/or inflations and  
18 deflations of the annular balloon structure 682, for example 10 or 20 or 40 insertions and withdrawals  
19 or inflations and deflations.

20 [0281] The annular balloon structure 682 can have an unsupported burst pressure. The unsupported  
21 burst pressure is the pressure at which the annular balloon structure 682 ruptures when inflated in free  
22 air without any external constraint on the walls at about 1 atm external pressure and about 20 °C  
23 temperature. The unsupported burst pressure can be from about 2atm to about 20atm, more narrowly  
24 from about 3atm to about 12atm, still more narrowly about 4atm to about 8atm, for example 5atm,  
25 6atm or 7atm.

26 [0282] The annular balloon structure 682 can be non-compliant or inelastic. For example, the annular  
27 balloon structure 682 can have a failure strain of less than about 0.30, more narrowly less than about  
28 0.20, still more narrowly less than about 0.10, yet more narrowly less than about 0.05.

29 [0283] The failure strain of the annular balloon structure 682 is the difference between the shell  
30 outside radius 708 when the balloon is inflated to 100% of the burst pressure and the shell outside  
31 radius 708 when the balloon is inflated to 5% of the burst pressure (i.e., to expand from a deflated state  
32 without stretching the wall material) divided by the shell outside radius 708 when the balloon is  
33 inflated to 100% of the burst pressure.

1 [0284] The annular balloon structure 682 can have a compliance of less than about 2% per  
2 atmosphere, more narrowly less than about 1% per atmosphere, still more narrowly less than about  
3 0.7% per atmosphere, yet more narrowly less than about 0.4% per atmosphere.

4 [0285] The annular balloon structure 682 can be inflated to a pressure A and a pressure B. Pressure B  
5 may be a higher pressure than pressure A. Pressures B and A may be positive pressures. Pressures B  
6 and A may be greater than 1atm. Delta pressure may be pressure B minus pressure A. Delta radius  
7 may be the shell outside radius 708 when annular balloon structure 682 is inflated to pressure B minus  
8 the shell outside radius 708 when annular balloon structure 682 is inflated to pressure A. Compliance  
9 may be Delta radius divided by the shell outside radius 708 when annular balloon structure 682 is  
10 inflated to pressure B divided by Delta pressure.

11 [0286] A shell 678 can be constructed with fiber 85 patterns similar to those shown in Figure 4. For  
12 example, fiber reinforcement member 85c can be omitted and fiber 85a can be placed at +20 degrees  
13 and fiber 85b can be placed at -20 degrees to the shell longitudinal axis. First reinforcement fibers 85A  
14 may form a layer angle 738 with respect to and second reinforcement fibers 85b. The layer angle 738  
15 can be about 40 degrees. As shell 678 is placed under tension by balloon 650, the angle between the  
16 fibers will gradually increase until the layer angle 738 is about 70 degrees. This is the angle 738 where  
17 the fibers balance the longitudinal and hoop loads in the shell. The fibers may change their angle with  
18 respect to each other by straining the adhesive. Shell 678 may rapidly expand to a first diameter where  
19 the a layer angle 738 is, for example, about 40 degrees and then slowly expand in diameter 50 as  
20 internal pressure on the shell 678 from balloon 650 is increased. By choosing the initial diameter 50  
21 and layer angle 738, a shell 678 can be designed that allows for a variety diameters 50 to be achieved.

22 [0287] Figure 52 shows a cross section of the heart 562. The heart 562 has an aorta 568, a left  
23 ventricle 570 and an aortic valve 564

24 [0288] Figure 53 is a graph that shows how the percent stenosis creates acceptable, difficult and  
25 critical flow conditions in both the rest and stress conditions in a patient. The acceptability of a  
26 stenotic condition would further vary as a function of the time spent in each condition.

27 [0289] Figures 54A and 54B illustrate that a guidewire 572 can be inserted through the aorta 568 and  
28 positioned in the left ventricle 570 of the heart 562. The annular balloon structure 682 can be slidably  
29 inserted over the guidewire through the aorta 568. The annular balloon structure 682 may be in a  
30 deflated or pleated state when first placed in the aortic valve 564. The annular balloon structure 682  
31 can be positioned to align along the balloon longitudinal axis with the aortic valve leaflets 566. The  
32 annular balloon structure 682 can also be rotated about the balloon longitudinal axis to align with the  
33 aortic valve 564, for example when cutting apart attached leaflets 566 in a bicuspid aortic valve with a

1 flange, a vane, a blade, other cutting element described herein, or combinations thereof. Fluid flow  
2 **870** may pass out of the left ventricle **570** through aortic valve leaflets **566** and into the aorta **568**.  
3 Fluid flow **870** may comprise blood flow.

4 **[0290]** Figure 54C shows the annular balloon structure **682** in an inflated configuration. The annular  
5 balloon structure **682** can be non-compliant and open the aortic valve **564** to a precise dimension (for  
6 example, about 20 mm or about 24 mm). The annular balloon structure **682** can fixedly reconfigure  
7 and press the aortic valve leaflets **566** against the outer wall or annulus **582** of the aortic valve **564**.  
8 The annular balloon structure **682** can radially expand the aortic valve annulus **582**.

9 **[0291]** Fluid flow **870** may pass through shell apertures **714** on the distal taper **42**, into central fluid  
10 passage **692** and through shell apertures **714** on the proximal taper **34** thus allowing for perfusion of  
11 blood while the balloon structure **692** is inflated. The central fluid passage **692** could have a cross  
12 sectional area of 0.3 to 1.2 centimeters squared, more narrowly 0.5 to 0.8 centimeters squared.

13 **[0292]** When annular balloon structure **682** is inflated, there may be a pressure differential between  
14 left ventricle **570** and aorta **568**. For instance, the pressure differential may be from about 5 mm Hg to  
15 about 50 mm Hg, more narrowly from about 10 mm Hg to about 40 mm Hg, still more narrowly, from  
16 about 10 mm Hg to about 25 mm Hg.

17 **[0293]** Perfusion may allow the physician to leave the balloon structure inflated in the aortic valve  
18 **564** for longer than would be allowed with a balloon that did not perfuse while still avoiding  
19 significant harm to the patient or the patient's hemodynamics. Increasing inflation time may allow for  
20 a more careful and accurate remodeling of the vasculature, such as that done during a valvuloplasty or  
21 a PCTA procedure.

22 **[0294]** One or more segments **656** of balloon **650** may employ a compliant material. Raising and  
23 lowering the pressure in these compliant segments **656** may cause the segment volume to change. A  
24 change in the segment **656** volume may cause the area of the central fluid passage **692** to change. A  
25 physician may initially place the annular balloon structure **682** and then adjust pressure in the balloon  
26 **650** or balloon segments **656** to adjust the flow area gap **693**. The compliant balloon segment **656** may  
27 be an additional balloon enclosed by shell **678** with an inflation lumen separate from the one used to  
28 inflate balloon **650**

29 **[0295]** The physician may inflate the annular balloon structure **682** until the structure **682** makes  
30 contact with the aortic valve **564** or the valve leaflets **566** or other vascular structures. This contact  
31 with the vasculature may be confirmed by the use of small bursts of radiopaque contrast. Once the  
32 annular balloon structure **682** is in contact with the vasculature, increases in the pressure delivered to  
33 annular balloon structure **682** can be used to make changes in central section outside diameter **50** of

1 the annular balloon structure and thus change the shape of the patient's vasculature. The change in  
2 shape of the vasculature can be monitored by ultrasound, fluoroscope or other methods known in the  
3 art. Changing the shape of the patient's vasculature via this method may take more than 10 seconds,  
4 more narrowly more than 30 seconds, still more narrowly more than 60 seconds while not adversely  
5 affecting patient health.

6 **[0296]** The heart 562 may be allowed to beat at its normal rhythm during the procedure. The heart  
7 562 may be forced to beat at an elevated rhythm during the procedure.

8 **[0297]** Figure 54D illustrates that the annular balloon structure 682 can be deflated, contracted and  
9 withdrawn from the aortic valve leaflets 566.

10 **[0298]** Figure 54FE shows the aortic valve leaflets 566 with a larger opening than before the  
11 procedure.

12 **[0299]** Instead of using a guidewire, an IVUS or OCT system can be inserted in the inner lumen  
13 154a. These systems may allow visualization of the aortic valve 564, for instance the positioning of  
14 the valve leaflets 566 at any point during the procedure detailed in figures 54A-54F.

15 **[0300]** The method described in Figures 54 above can be performed on an aortic, mitral, pulmonary,  
16 tricuspid or vascular valve. This method may be described as balloon valvuloplasty or balloon aortic  
17 valvuloplasty. This procedure may be described as pre-dilation when it used to prepare the aortic valve  
18 for the implantation of a prosthetic valve. This procedure may also be employed after a prosthetic  
19 valve is in place in order to better seat the valve into the patient's anatomy. In this case, it is often  
20 referred to as "post-dilation".

21 **[0301]** Referring now to figures 55A-55F, the annular balloon structure 682 can be used to deploy a  
22 prosthetic valve in, for instance, the aortic valve 564 near the coronary ostia 583. A guidewire 572  
23 may first be introduced thru the aorta 568 into the left ventricle 570 as shown in figure 55A. Next, as  
24 shown in Figure 55B, a balloon catheter carrying prosthetic heart valve 626 and deflated annular  
25 balloon structure 682 may be introduced over guidewire 572 into aortic valve 564. In figure 55C,  
26 annular balloon structure 682 is inflated to expand the prosthetic heart valve 626 into the aortic valve  
27 564. While the annular balloon structure 682 is inflated, fluid (for example, blood) flow 870 may pass  
28 through shell apertures 714 on the distal taper 42, into central fluid passage 692 and through shell  
29 apertures 714 on the proximal taper 34. In figure 55D, the annular balloon structure 682 is deflated  
30 and separated from valve prosthesis 626, leaving the valve prosthesis 626 implanted in the aortic valve  
31 564. Figures 55E and 55F show the prosthetic valve closing (55E) and opening (55F) immediately  
32 after the annular balloon structure 682 is withdrawn.

1 [0302] Figure 56A illustrates that the annular balloon structure 682 can be positioned over a  
2 guidewire 572 or stylet in a body lumen 574 having a constriction 576 on the interior of the lumen  
3 wall 578. A stylet may be stiffer than a guidewire.

4 [0303] Figure 56B illustrates that the annular balloon structure 682 can be inflated and expanded.  
5 The annular balloon structure 682 can remodel the body lumen 574, pushing the constriction 576  
6 radially away from the shell longitudinal axis 26. The annular balloon structure 682 can deploy a stent  
7 to the constriction 576. While the annular balloon structure 682 is inflated, fluid (for example, blood)  
8 flow 870 may pass through shell apertures 714 on the proximal taper 34, into central fluid passage 692  
9 and through shell apertures 714 on the distal taper 42.

10 [0304] Figure 56C illustrates that the annular balloon structure 682 can be deflated, contracted and  
11 removed from the body lumen 574. The body lumen 574 can remain patent after the annular balloon  
12 structure 682 is removed, for example restoring blood flow past a treated atherosclerotic length.

13 [0305] Body lumen 574 may be a vessel or an airway. Constriction 576 may be a atherosclerotic  
14 plaque or a local narrowing of the body lumen 574

15 [0306] The annular balloon structure 682 can be implanted in the body semi-permanently or  
16 permanently.

17 [0307] The annular balloon structure 682, can be used for Kyphoplasty, angioplasty including CTO  
18 dilation, stent delivery, sinuplasty, airway dilation, valvuloplasty, drug or other fluid delivery through  
19 the balloon, radiopaque marking, incising the inside of a vessel (e.g., to open or expand a vessel),  
20 brachytherapy, intentionally obstruct a vessel, or combinations thereof. The annular balloon structure  
21 682 can be used to deliver one or more stents and/valves and/or emboli filters to the coronary blood  
22 vessels (e.g., arteries or veins), carotid artery, peripheral blood vessels, the GI tract, the biliary ducts,  
23 the urinary tract, the gynecologic tract, and combinations thereof.

24 [0308] The reinforcement fibers 85, 86 and 87 can be identical to or different from each other.

25 [0309] Any elements described herein as singular can be pluralized (i.e., anything described as “one”  
26 can be more than one), and plural elements can be used individually. Any species element of a genus  
27 element can have the characteristics or elements of any other species element of that genus. The term  
28 “comprising” is not meant to be limiting. The above-described configurations, elements or complete  
29 assemblies and methods and their elements for carrying out the invention, and variations of aspects of  
30 the invention can be combined and modified with each other in any combination.

31

CLAIMS:

1. An apparatus for performing a medical procedure in a vessel for transmitting a fluid flow, comprising:
  - a shaft;
  - an inflatable perfusion balloon supported by the shaft and comprising a plurality of inflatable cells in a single cross-section bounding an internal passage for permitting the fluid flow in the vessel while the perfusion balloon is in an inflated condition; and
  - a valve for controlling the fluid flow within the internal passage.
2. The apparatus of claim 1, wherein the valve is positioned within the internal passage.
3. The apparatus of claim 1, wherein the perfusion balloon includes an opening in fluid communication with the internal passage, and the valve is positioned for controlling flow through the opening.
4. The apparatus of claim 3, wherein the valve comprises a flap.
5. The apparatus of claim 1, wherein the valve comprises a plurality of flaps.
6. The apparatus of claim 1, wherein the valve comprises a flap anchored to at least one of the inflatable cells.
7. The apparatus of claim 6, wherein the flap extends between an inner surface of the at least one of the inflatable cells and a tube extending within an internal passage of the perfusion balloon.
8. The apparatus of claim 1, wherein the valve comprises a plurality of flaps adapted for blocking flow in the internal passage by spanning between an interior surface of the inflatable cells and a tube extending within an internal passage of the perfusion balloon.
9. The apparatus of claim 1, further including a shell having a shell aperture, the valve adapted for selectively blocking the shell aperture for selectively communicating fluid from external to the perfusion balloon to the internal passage.

10. The apparatus of claim 9, wherein the valve comprises a flap connected to the shell by a hinge.

11. An apparatus for performing a medical procedure in a vessel for transmitting a fluid flow, comprising:

a shaft;

an inflatable perfusion balloon supported by the shaft and comprising an internal passage for permitting the fluid flow in the vessel while the perfusion balloon is in an inflated condition; and

a valve external to the internal passage and connected to the perfusion balloon for controlling the fluid flow to the internal passage.

12. The apparatus of claim 11, wherein the perfusion balloon comprises an aperture, the valve adapted for selectively communicating fluid from external to the perfusion balloon to the internal passage.

13. The apparatus of claim 12, wherein the perfusion balloon comprises a shell including the aperture.

14. The apparatus of claim 11, wherein the valve comprises a flap connected to the perfusion balloon by a hinge.

15. The apparatus of claim 11, wherein the valve is located at a proximal end of the perfusion balloon.

16. The apparatus of claim 11, further including a plurality of circumferentially spaced valves.

17. The apparatus of claim 11, wherein the valve is associated with a tapered portion of the perfusion balloon.

18. The apparatus of claim 11, wherein the perfusion balloon comprises a plurality of inflatable cells surrounding the internal passage in a single transverse cross-section.

19. An apparatus for performing a medical procedure in a vessel for transmitting a fluid flow, comprising:

a shaft;

an inflatable perfusion balloon supported by the shaft and an internal passage for permitting the fluid flow in the vessel while the perfusion balloon is in an inflated condition;

a shell for covering the perfusion balloon, the shell including a shell aperture for communicating with the internal passage;

a valve for controlling the fluid flow to the internal passage.

20. The apparatus of claim 19, wherein the valve is located within the internal passage.

21. The apparatus of claim 19, wherein the valve is located external to the perfusion balloon.

22. The apparatus of claim 19, wherein the perfusion balloon comprises a plurality of inflatable cells surrounding the internal passage in a single transverse cross-section.

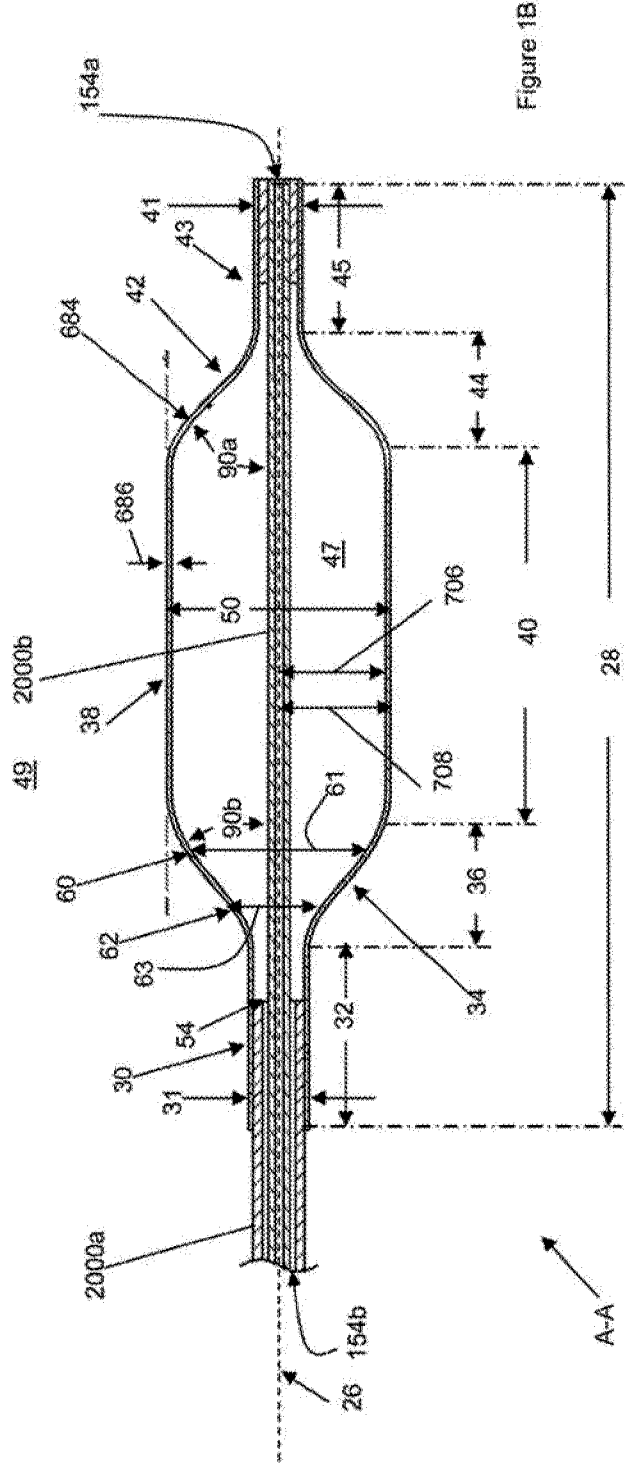
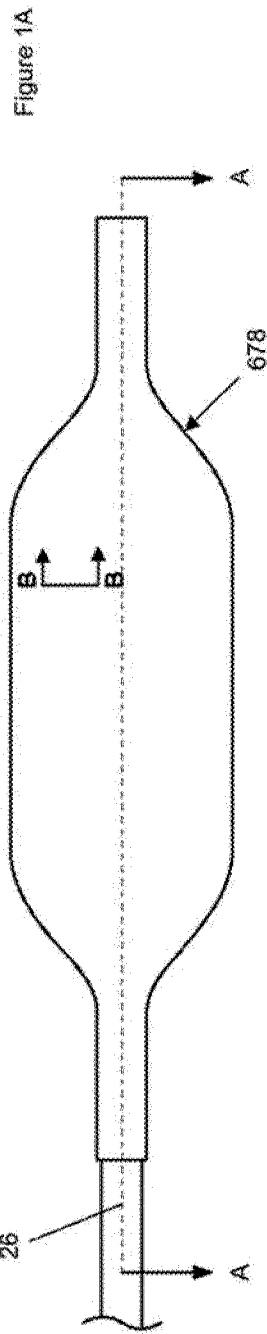
23. The apparatus of claim 1, wherein the valve comprises three leaflets.

24. An apparatus for performing a medical procedure in a vessel for transmitting a fluid flow, comprising:

a shaft;

an inflatable perfusion balloon supported by the shaft and comprising a plurality of inflatable cells in a single cross-section, the plurality of inflatable cells surrounding an internal passage for permitting the fluid flow in the vessel while the inflatable perfusion balloon is in an inflated condition; and

a valve for controlling the fluid flow within the internal passage.



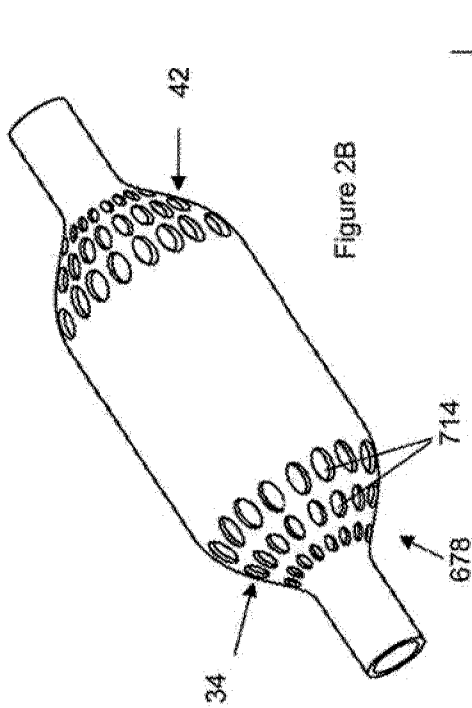


Figure 2B

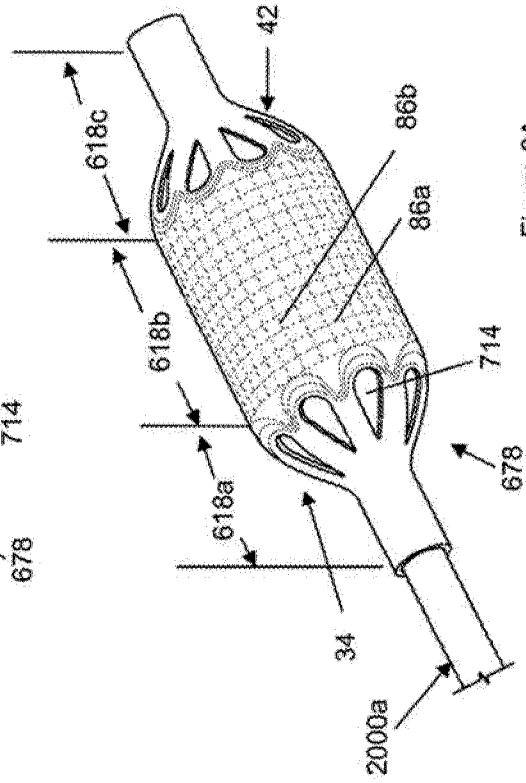


Figure 3A

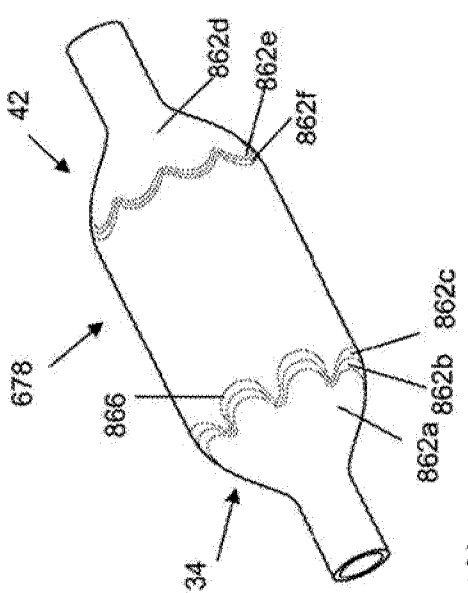


Figure 2A

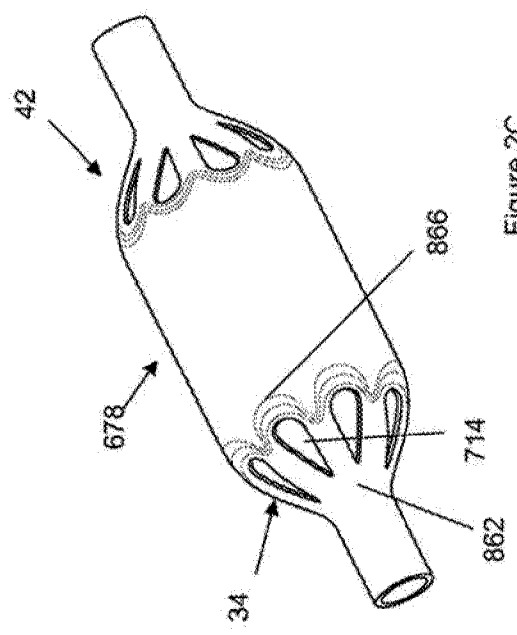
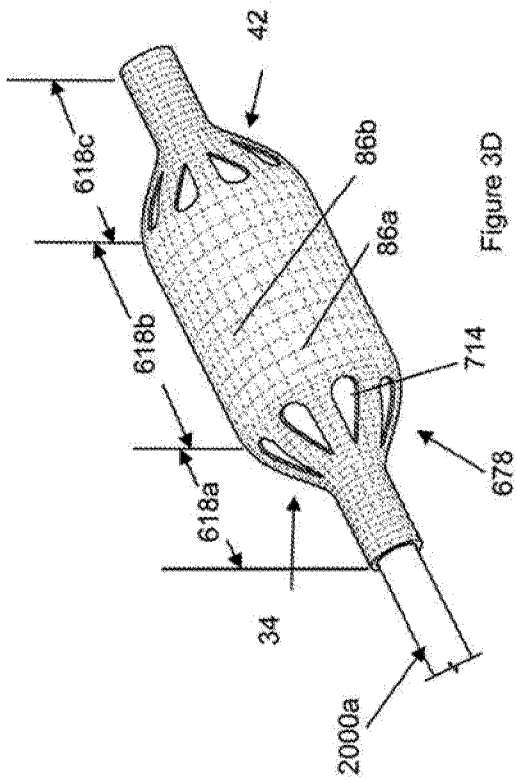
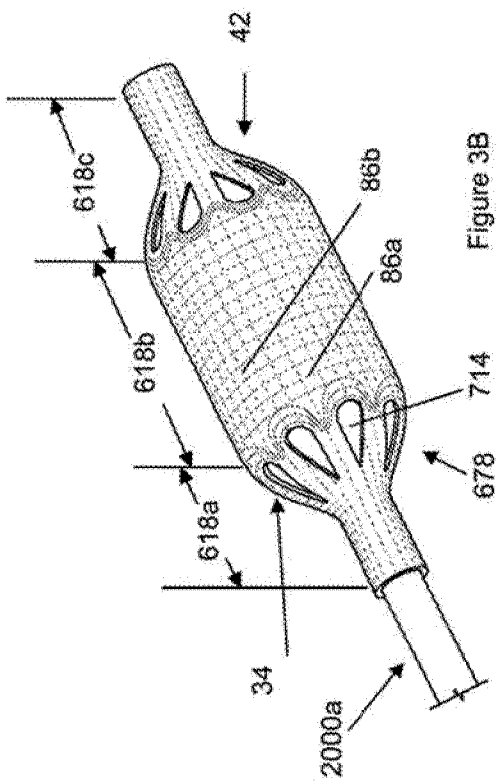
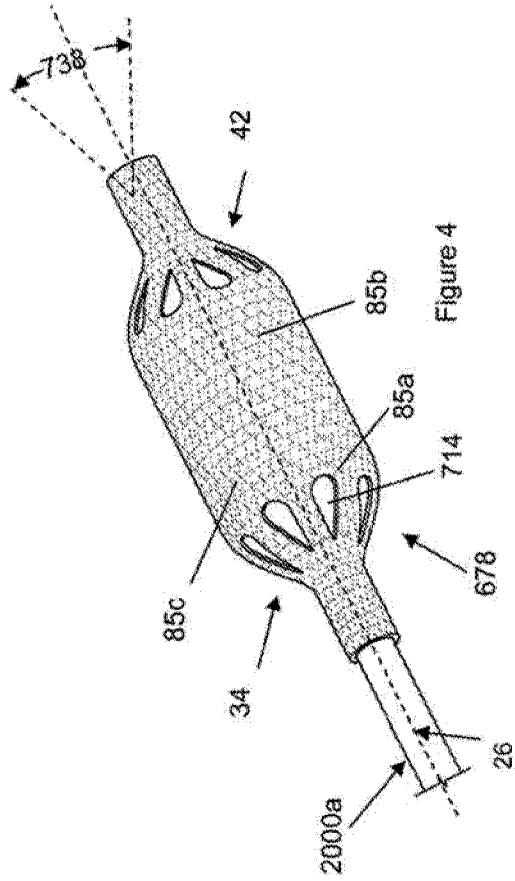
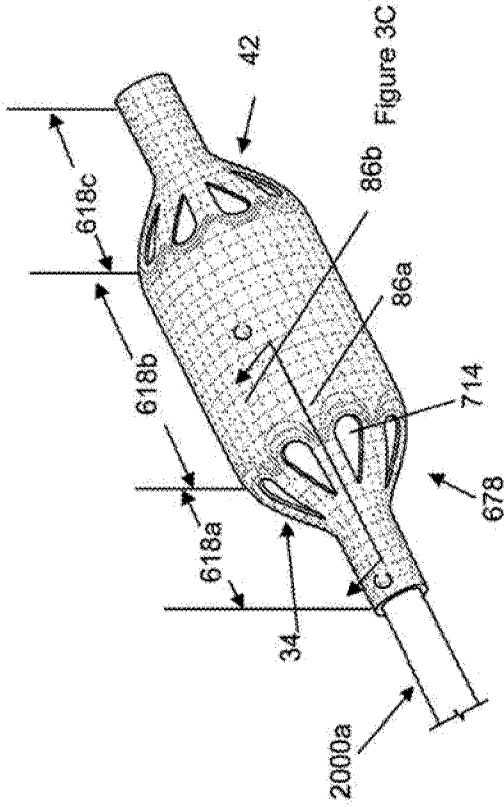


Figure 2C



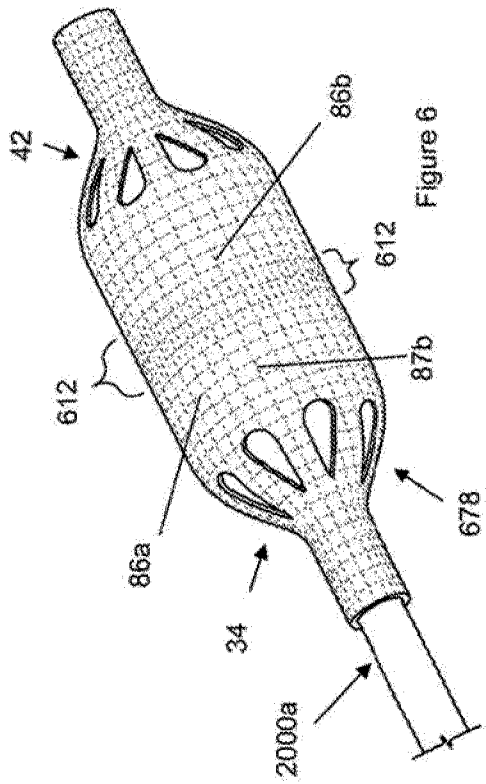


Figure 6

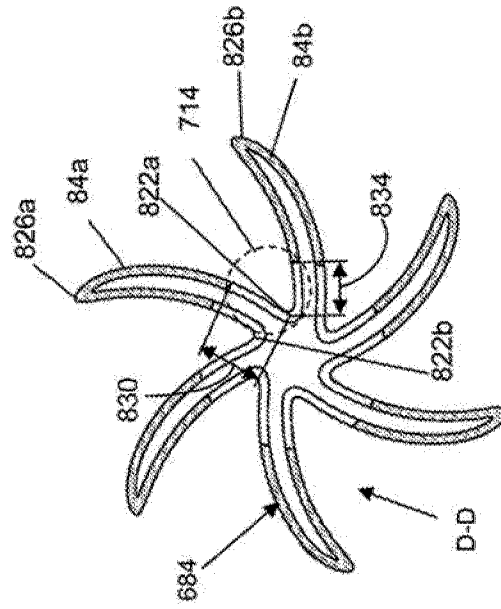


Figure 7B

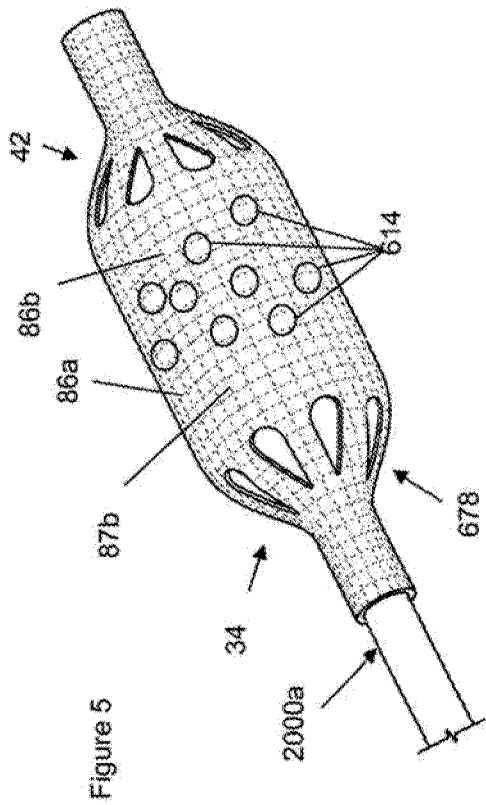


Figure 5

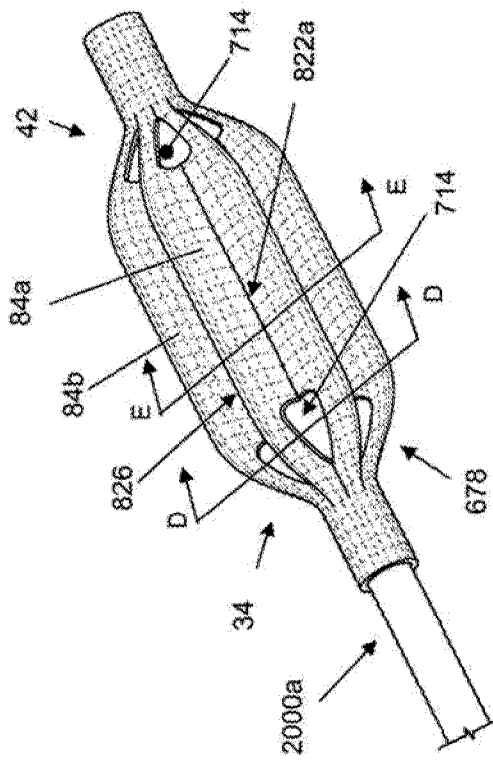
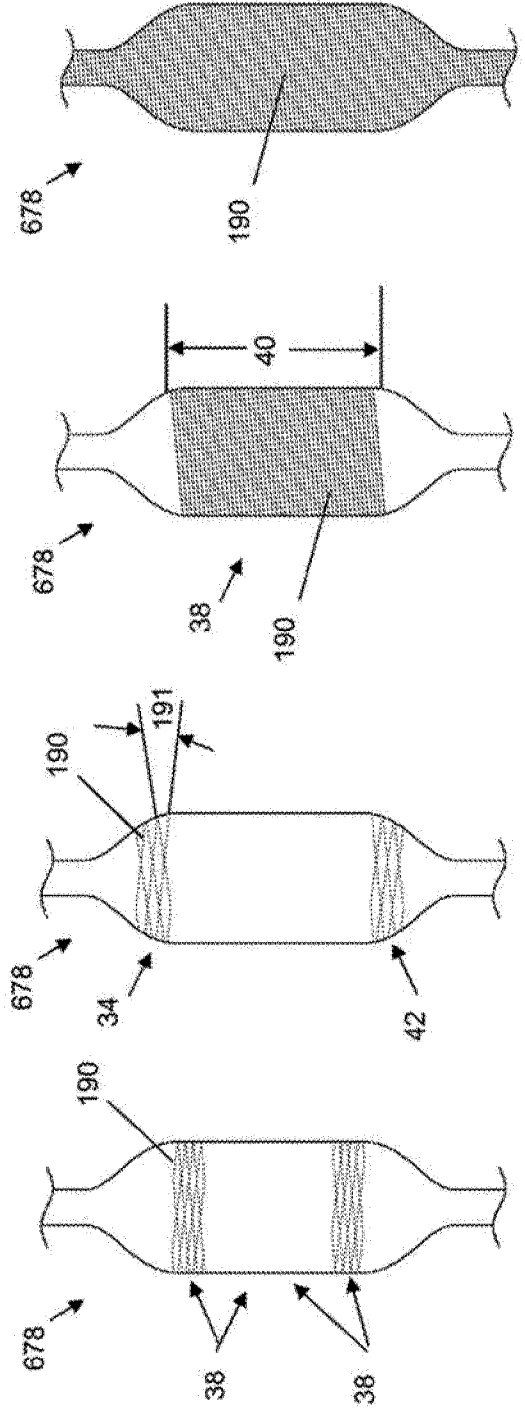
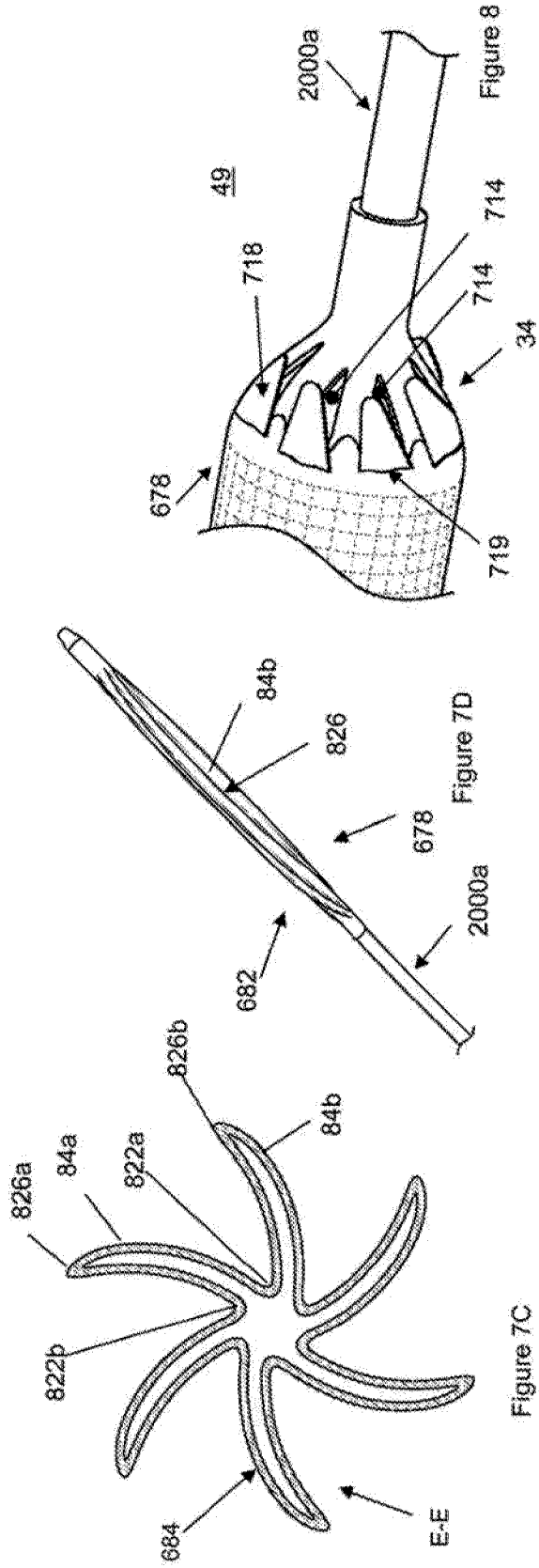


Figure 7A



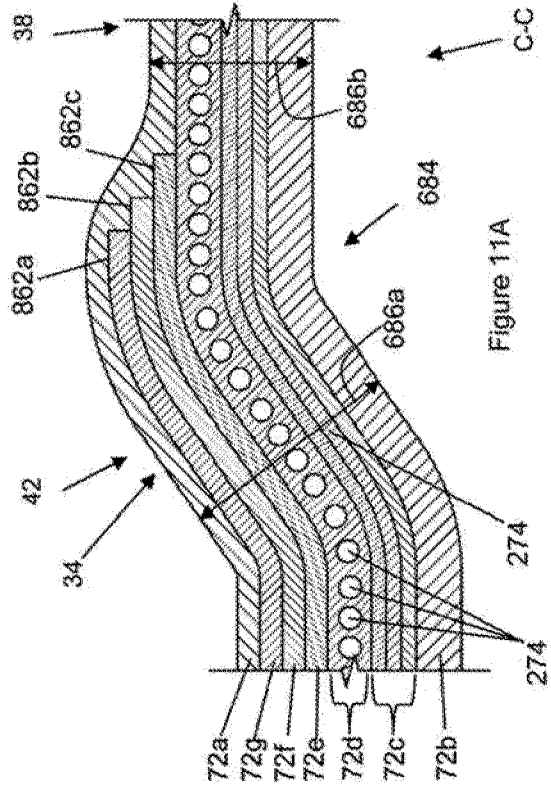


Figure 11A

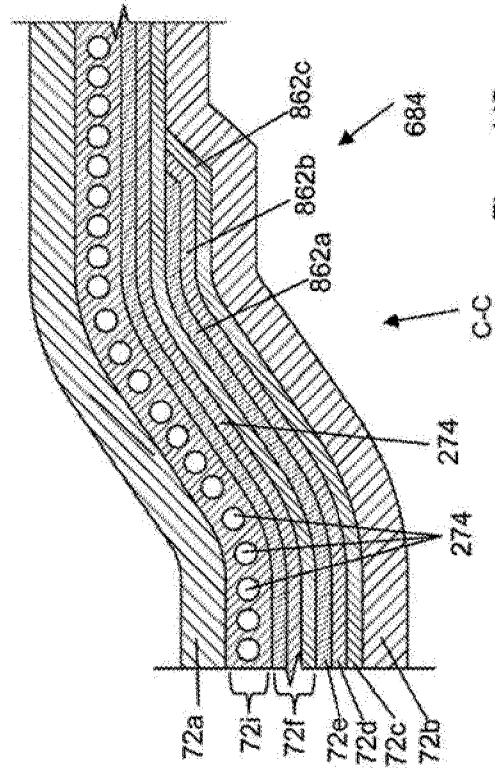


Figure 11B

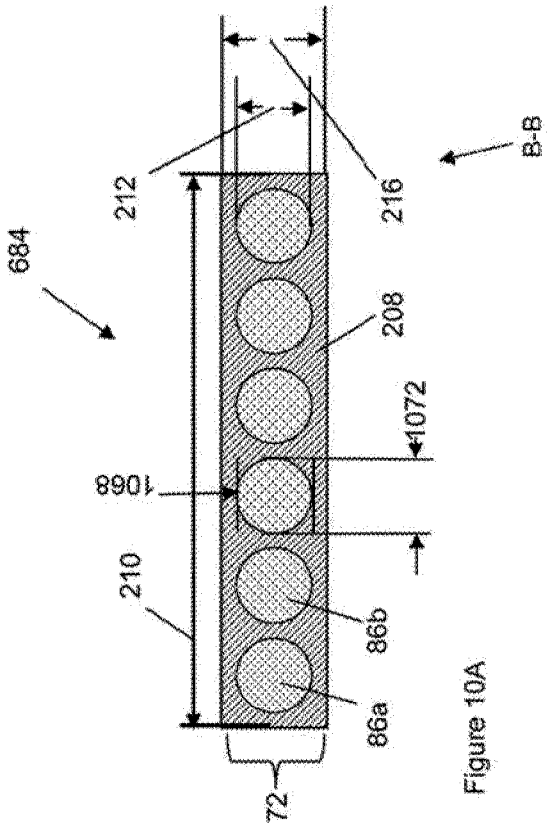


Figure 10A

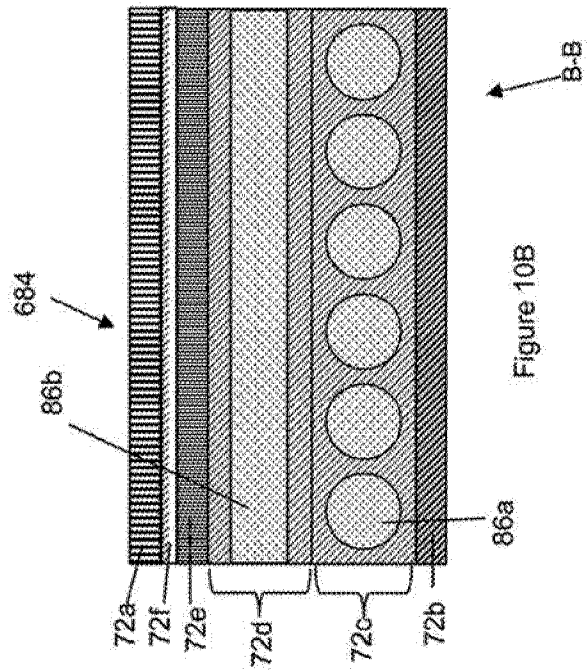
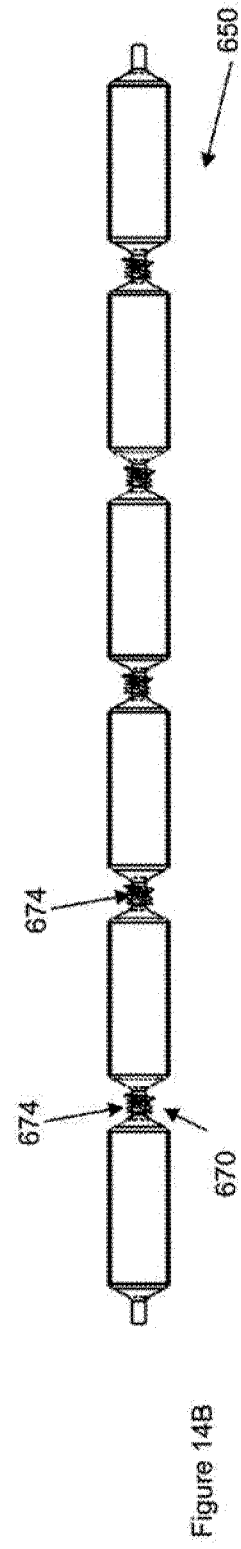
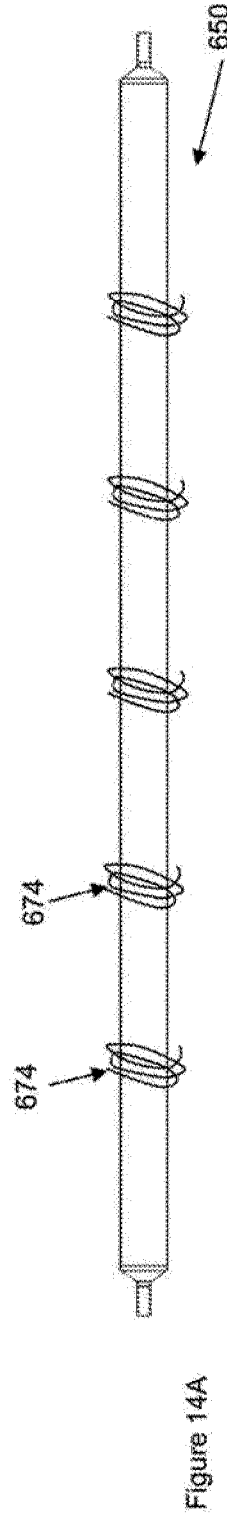
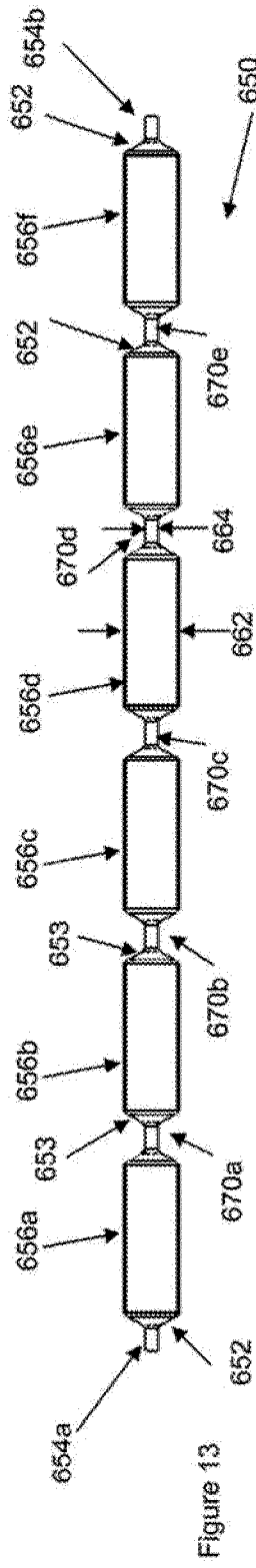
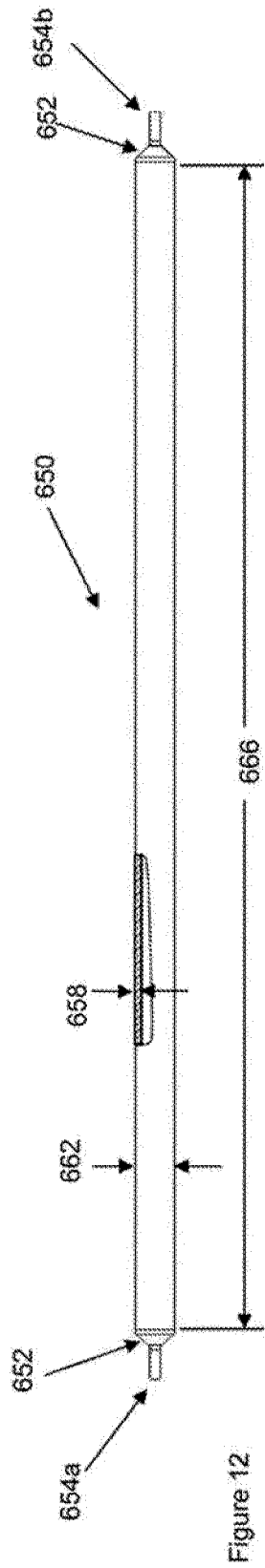


Figure 10B



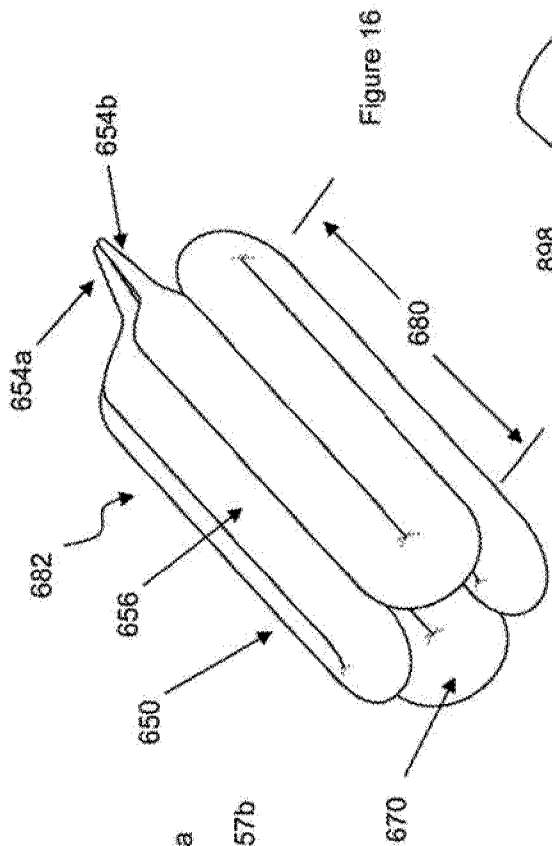


Figure 16

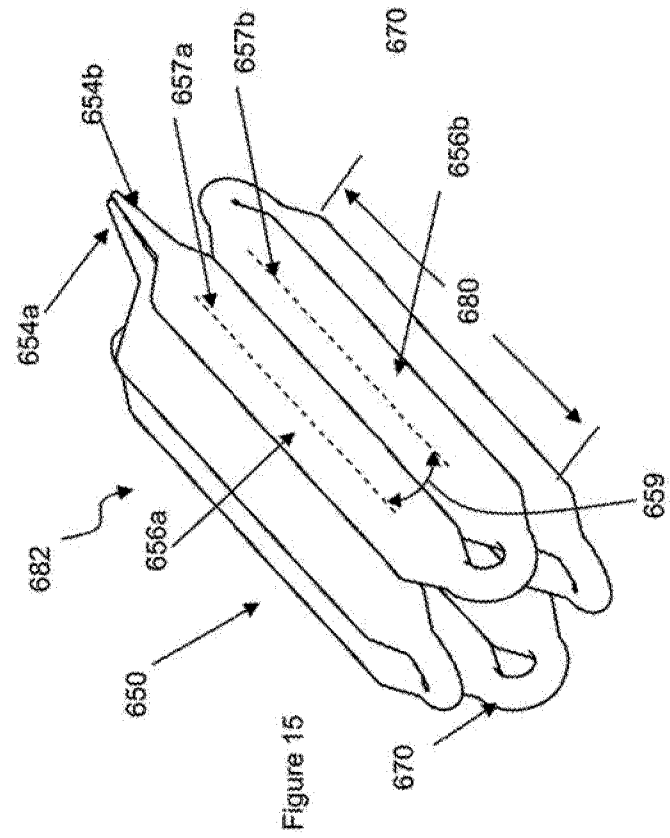


Figure 15

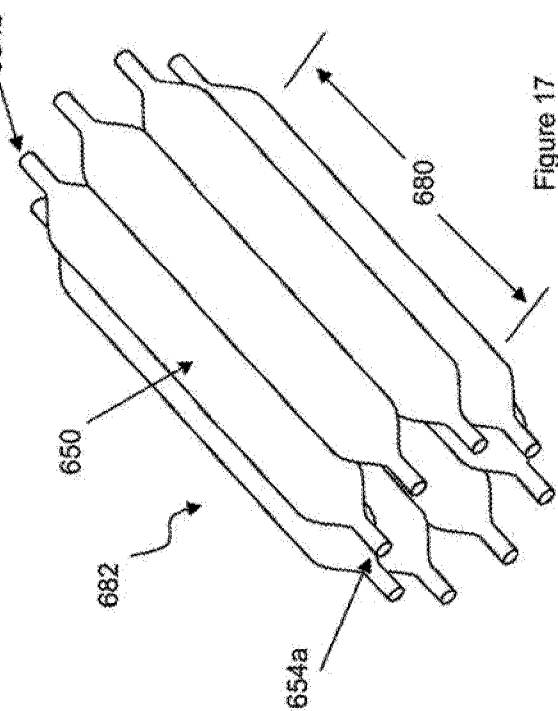


Figure 17

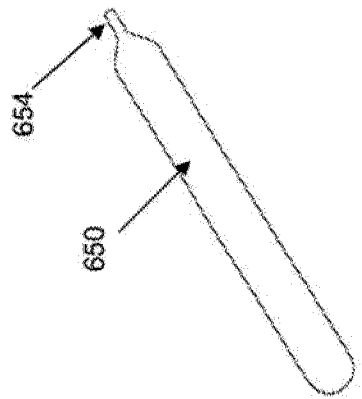


Figure 18

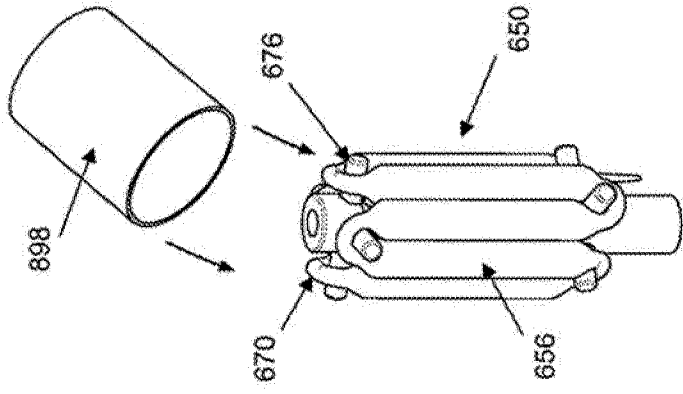
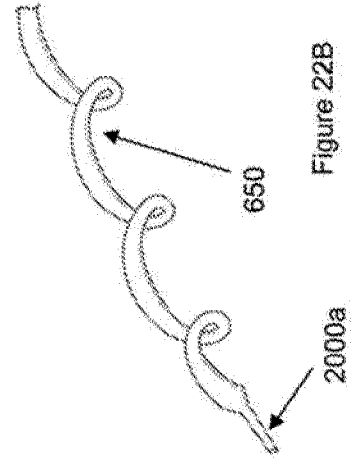
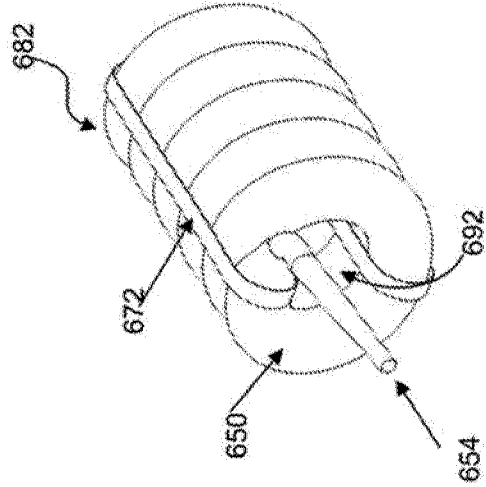
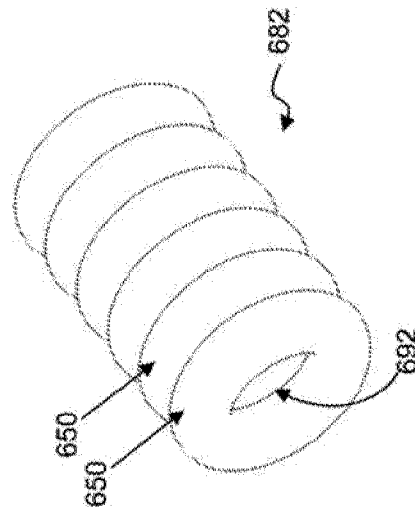
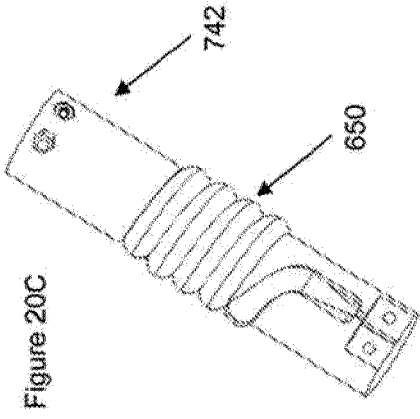
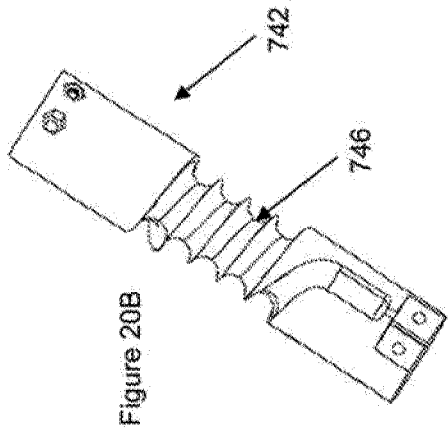
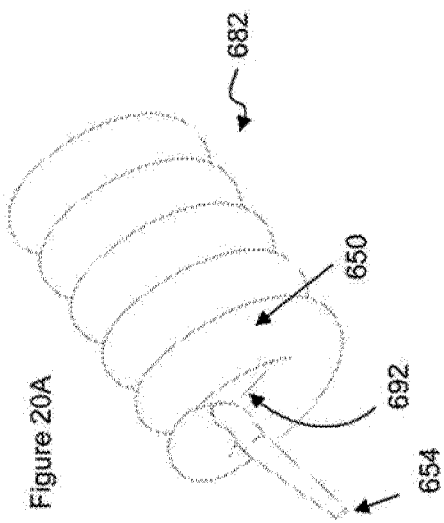


Figure 19



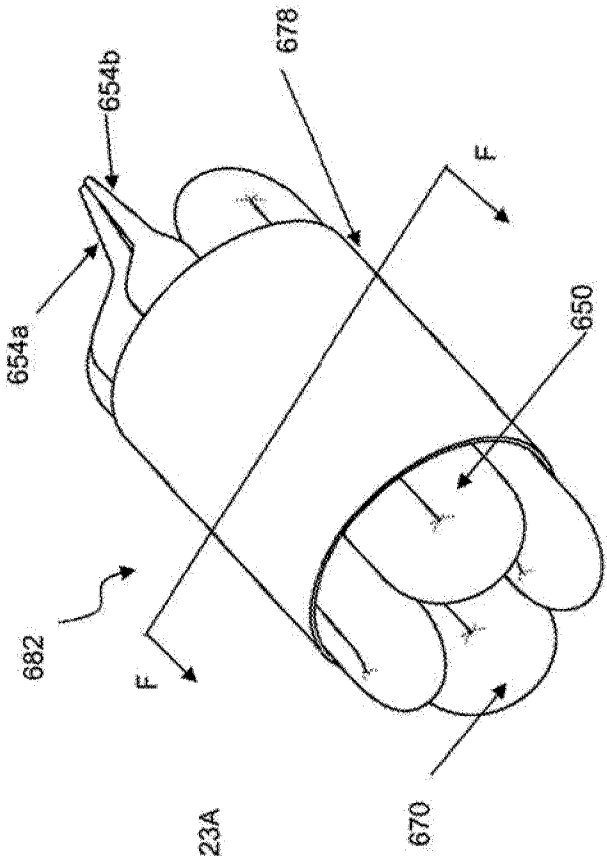


Figure 23A

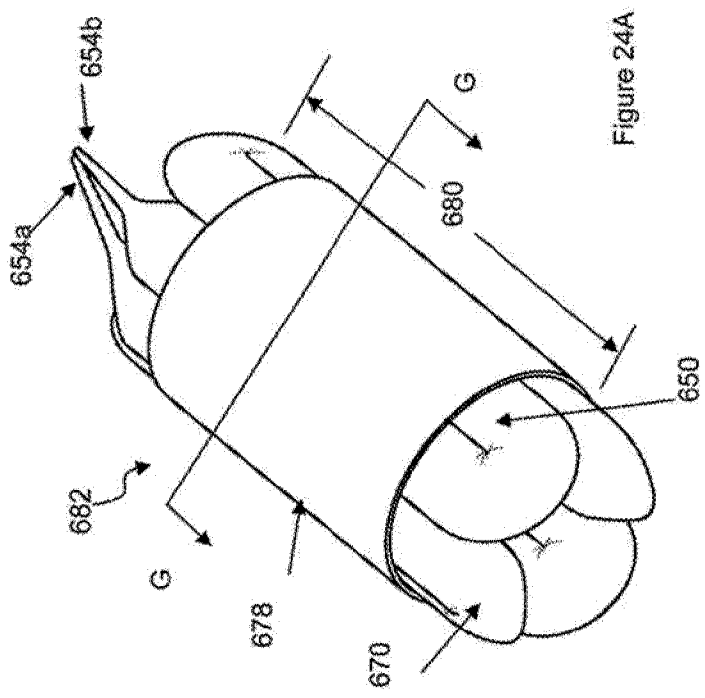


Figure 24A

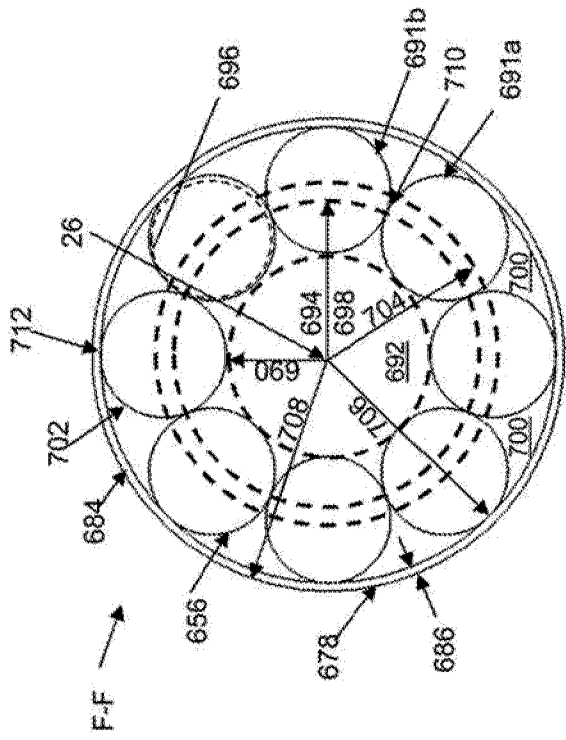


Figure 23B

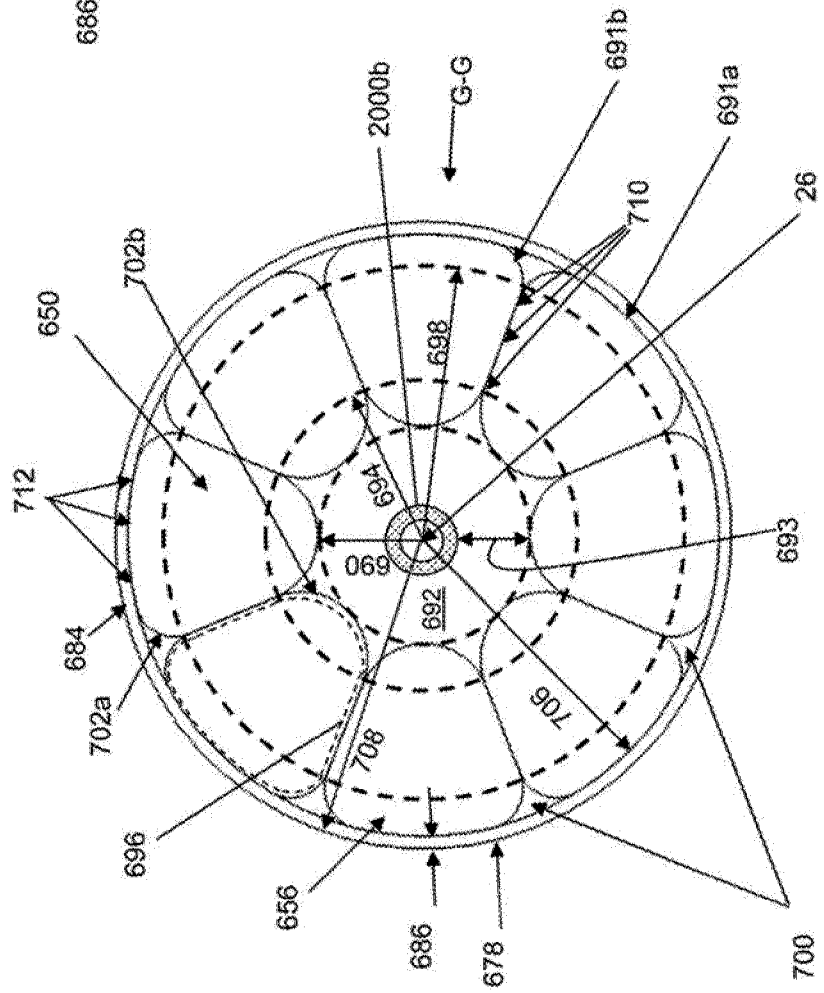


Figure 24B

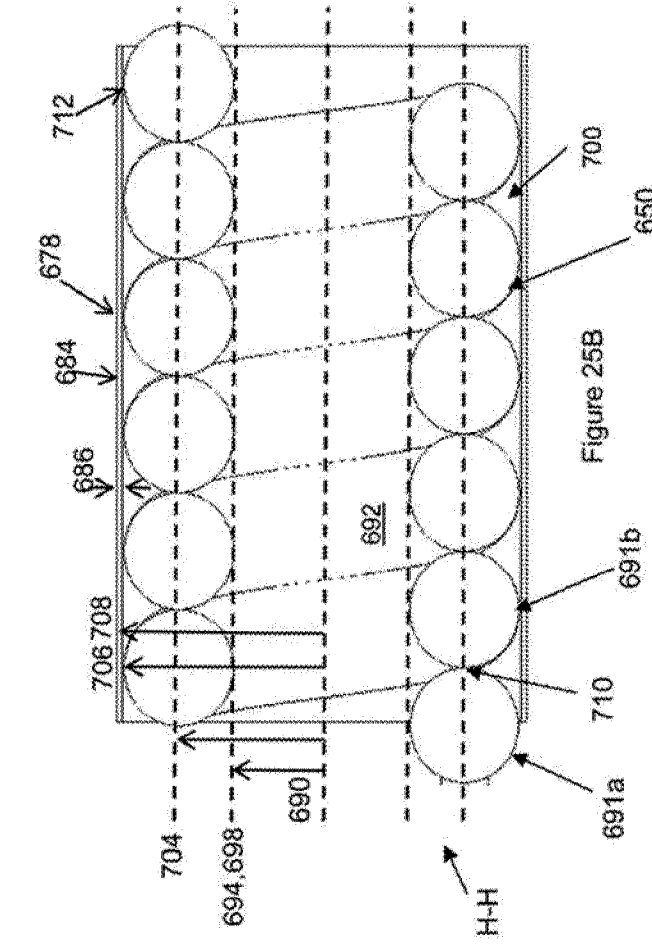


Figure 25A

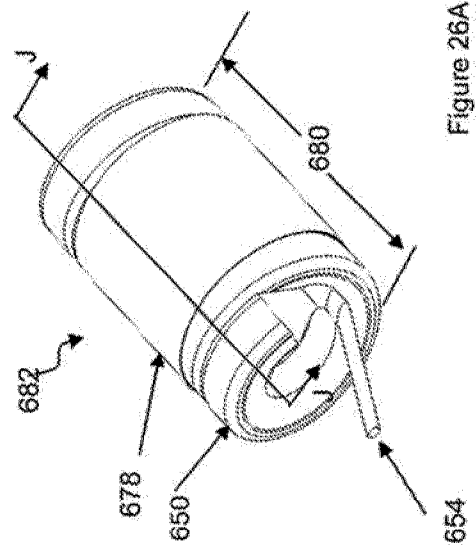


Figure 25B

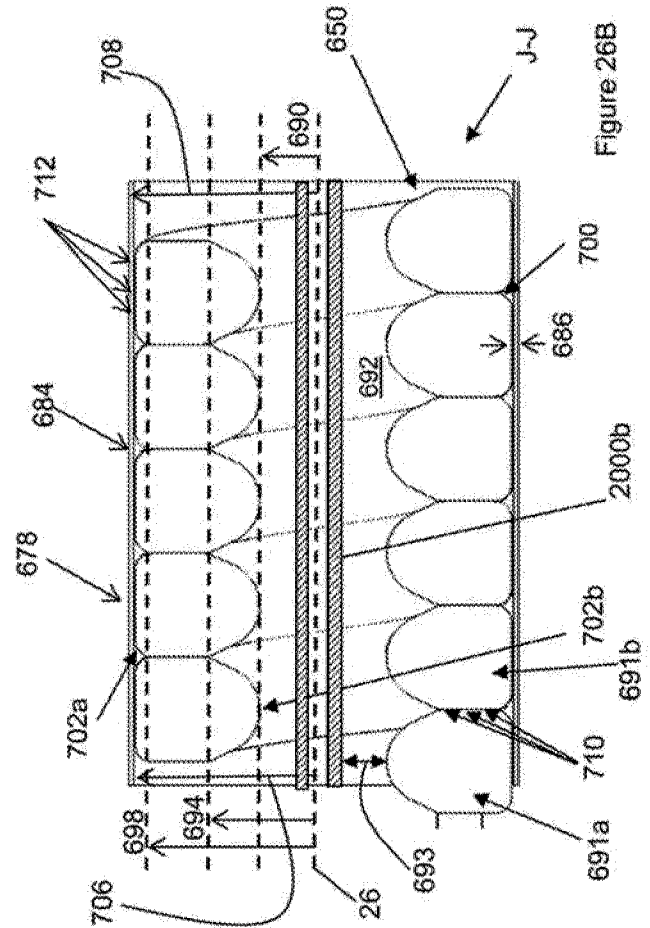


Figure 26A

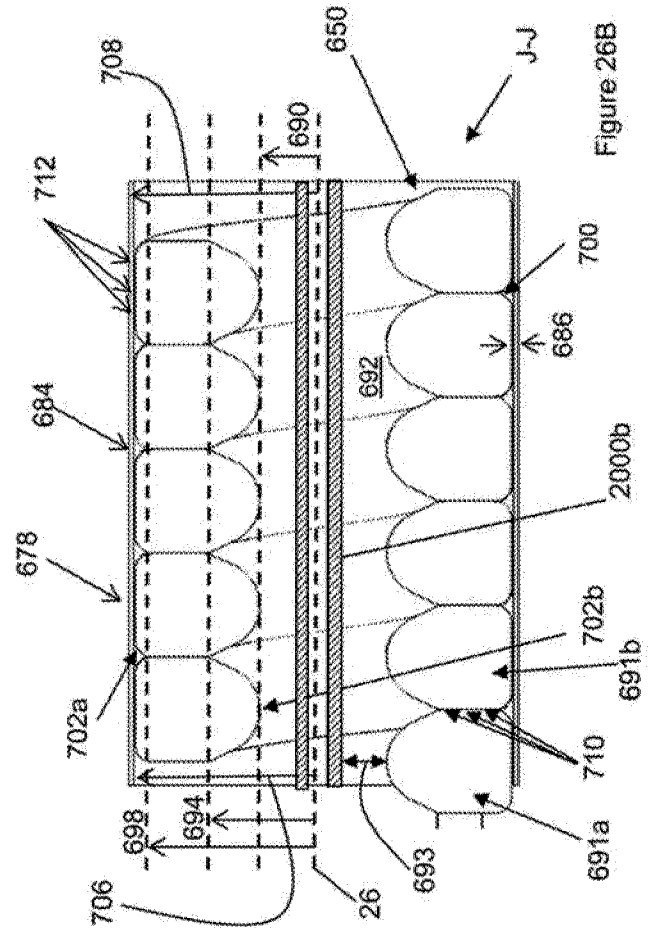
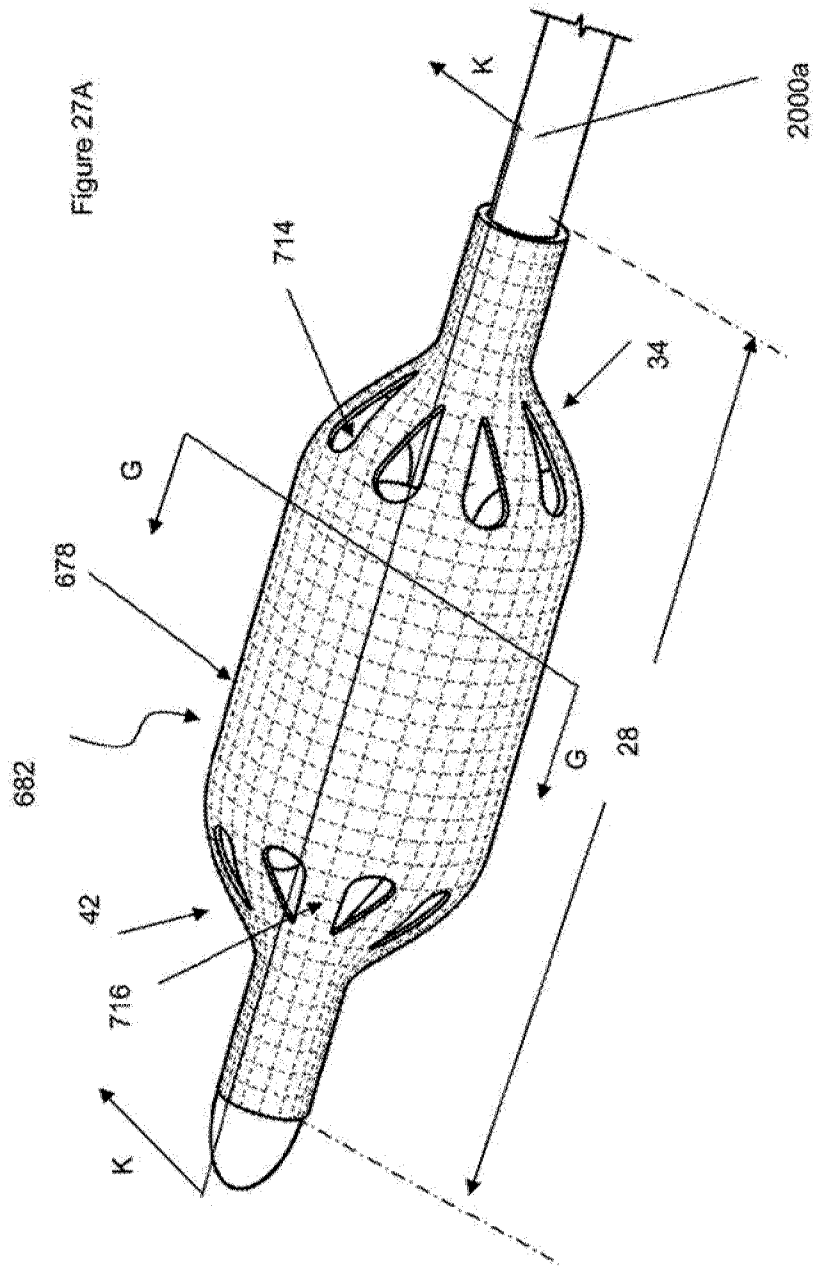


Figure 26B



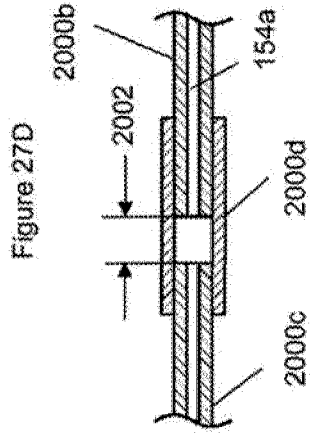
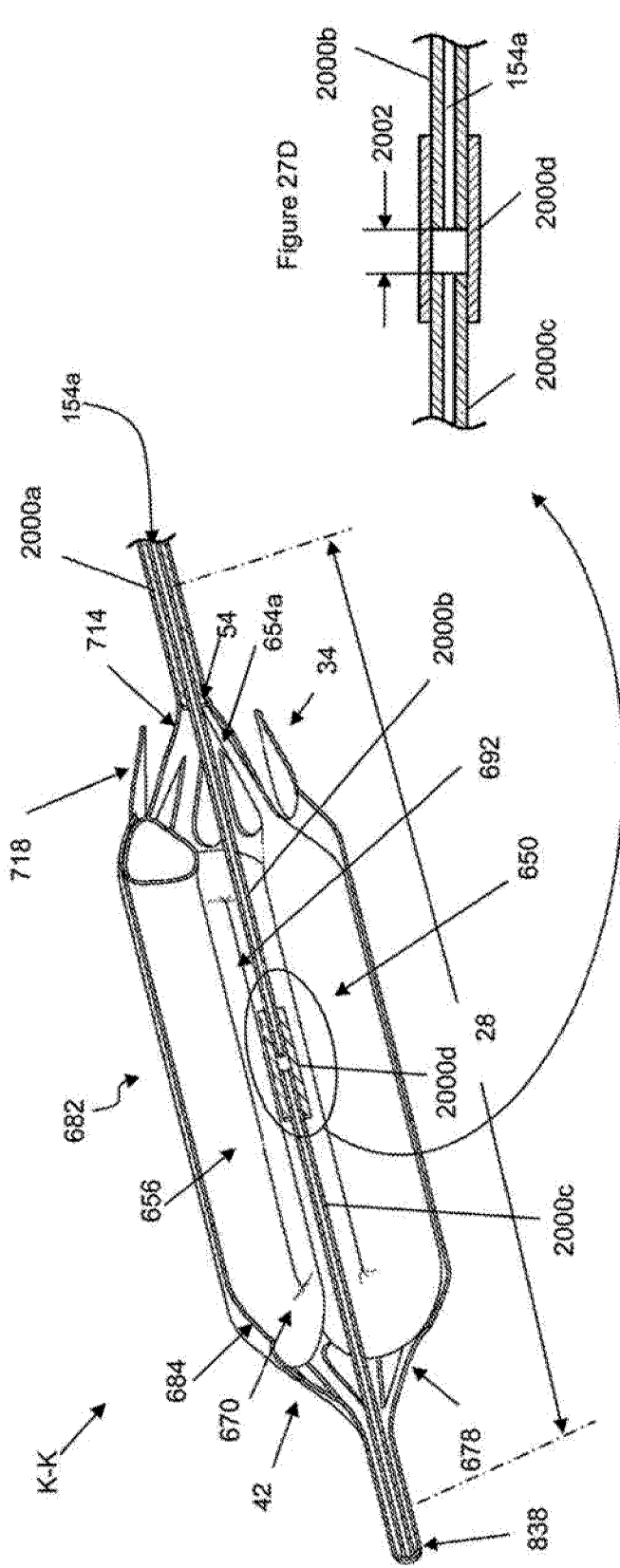


Figure 27D

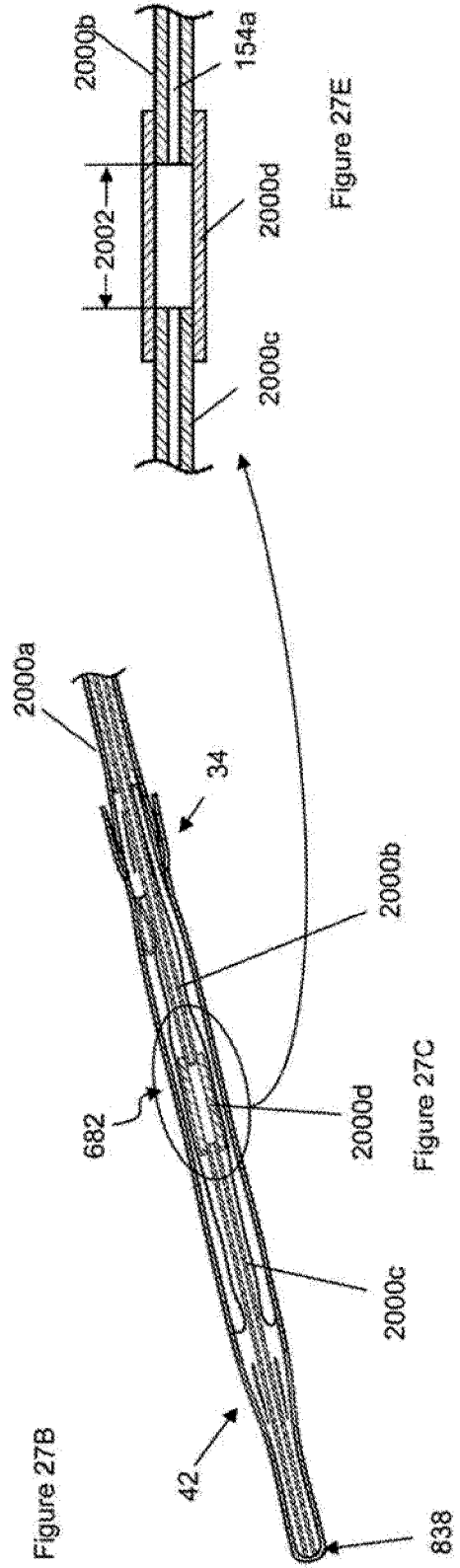


Figure 27B

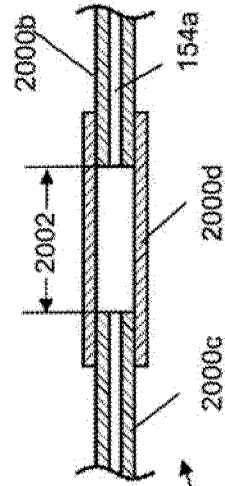


Figure 27E

Figure 27C

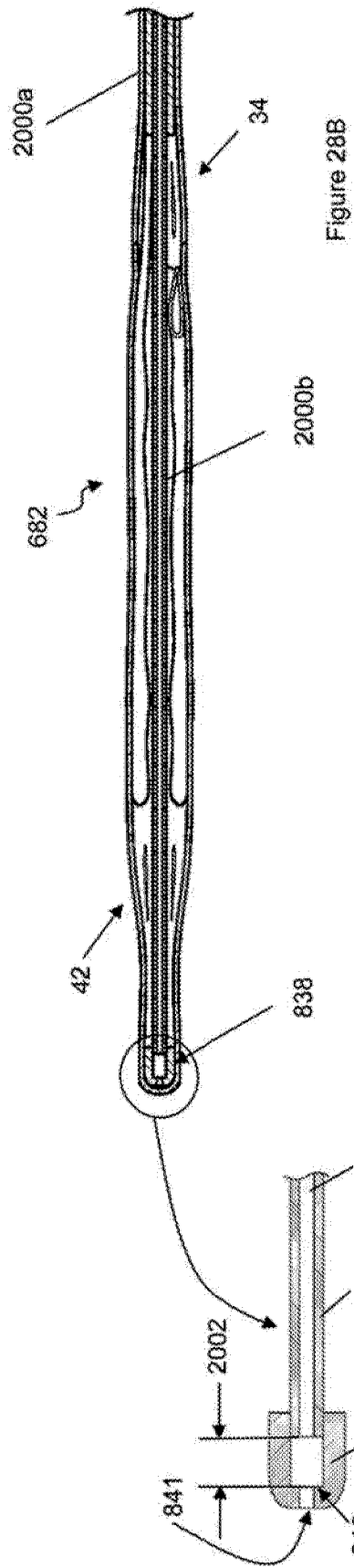
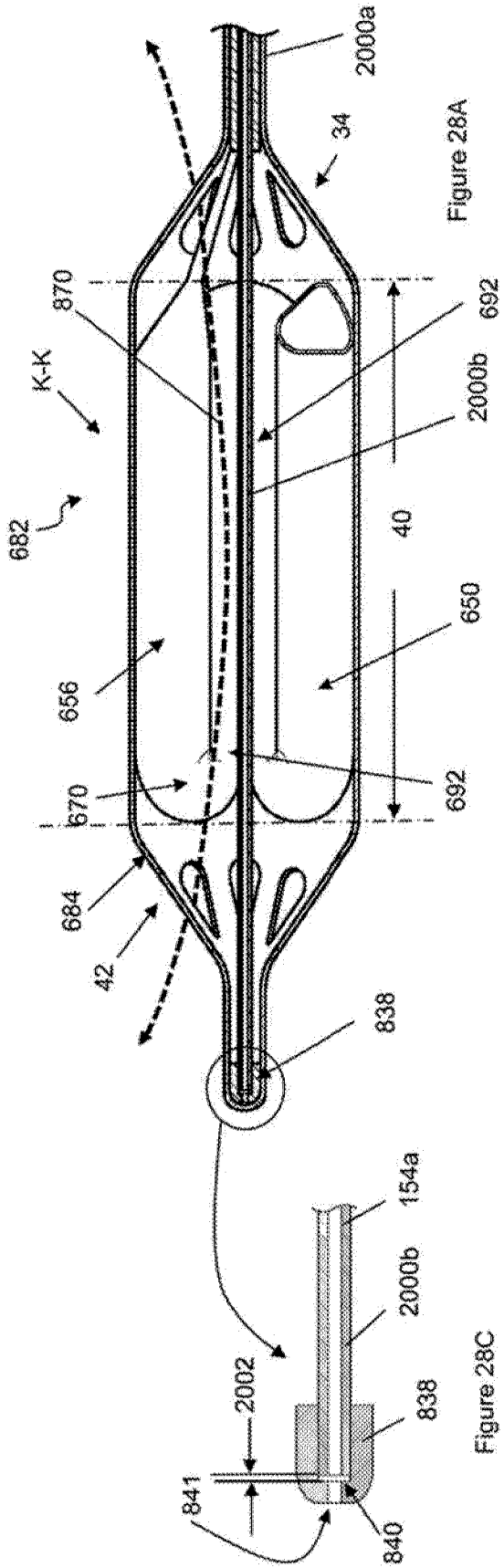


Figure 28C

Figure 28D

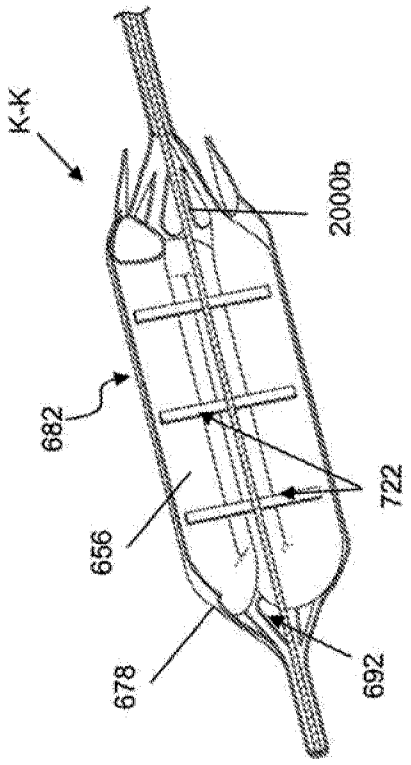


Figure 29

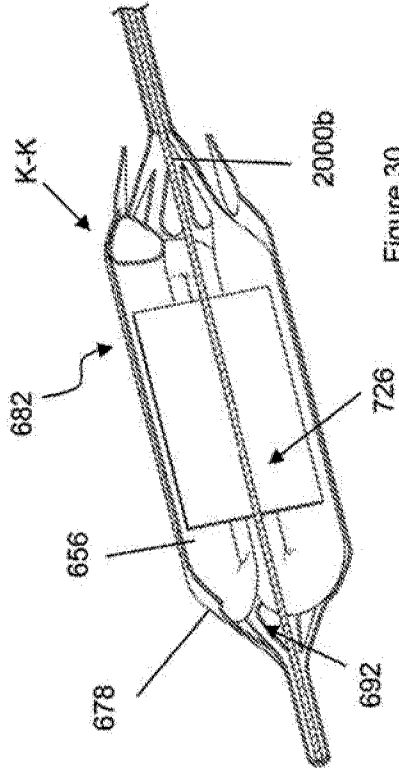


Figure 30

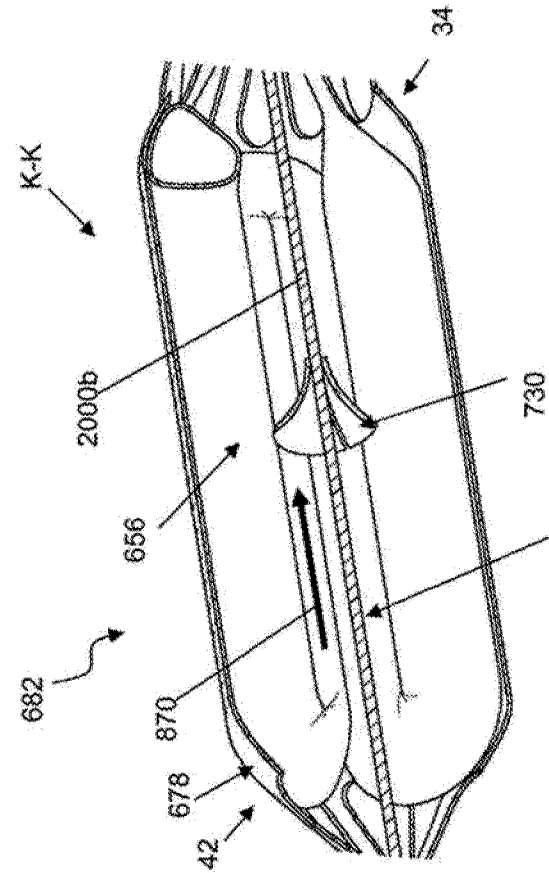


Figure 31A

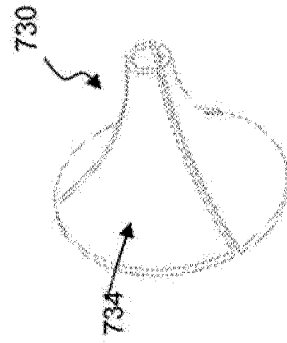


Figure 31B

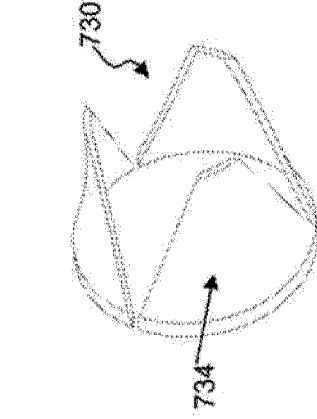


Figure 31C

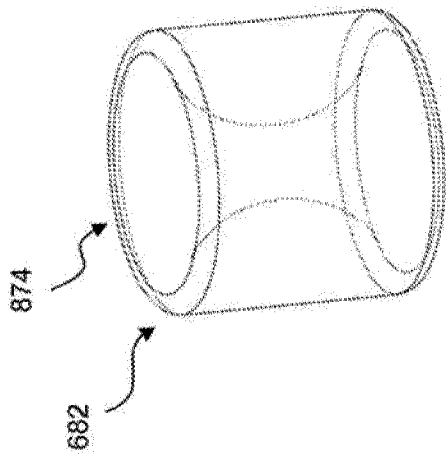


Figure 32A

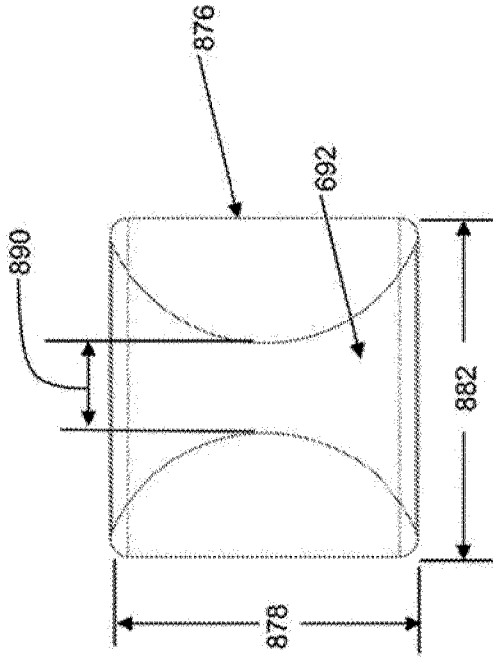


Figure 32B

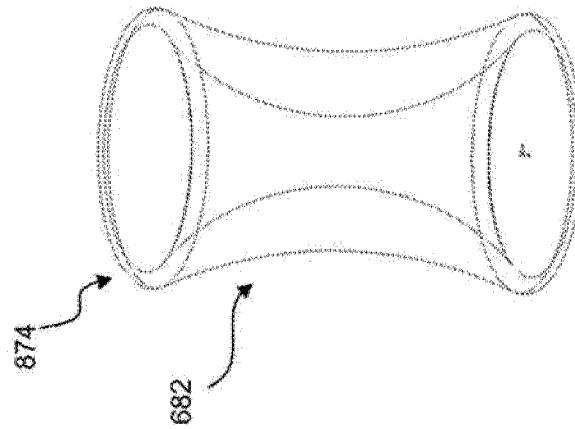


Figure 32C

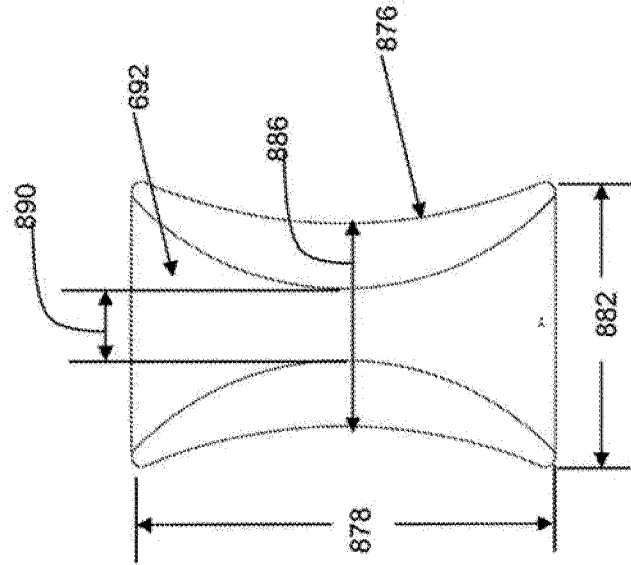


Figure 32D

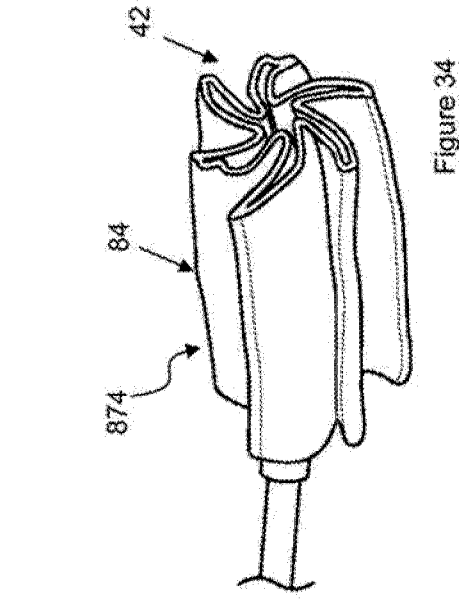


Figure 34

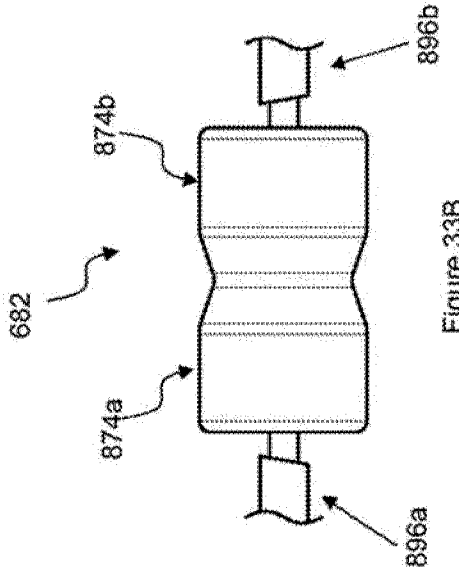


Figure 33B

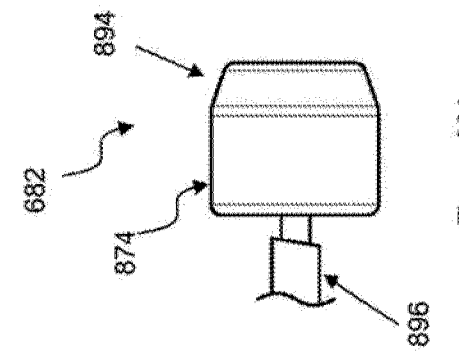


Figure 33A

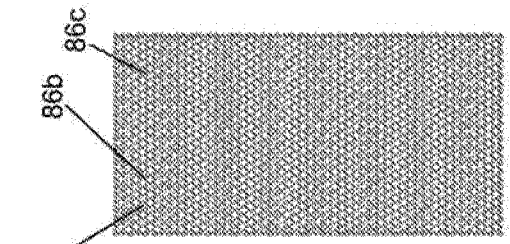


Figure 35d

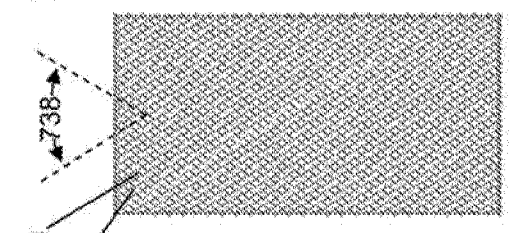


Figure 35c

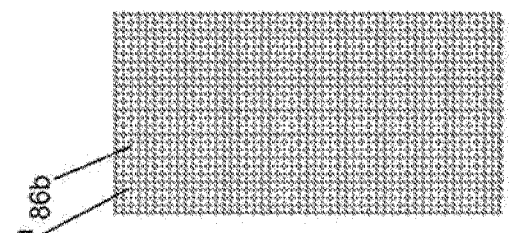


Figure 35b

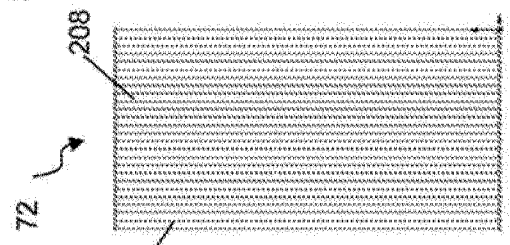


Figure 35a

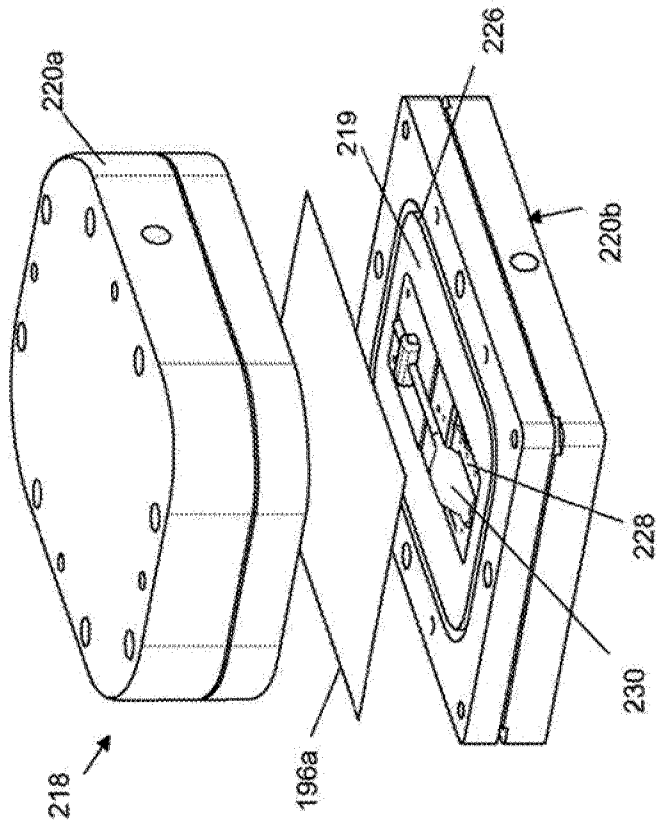


Figure 36

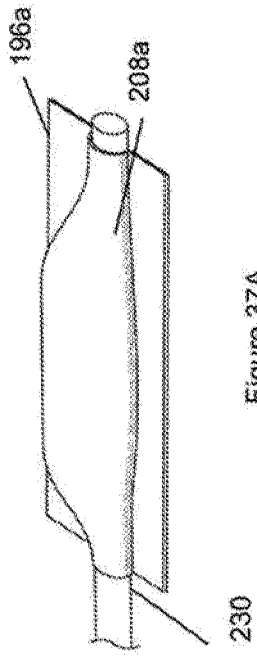


Figure 37A

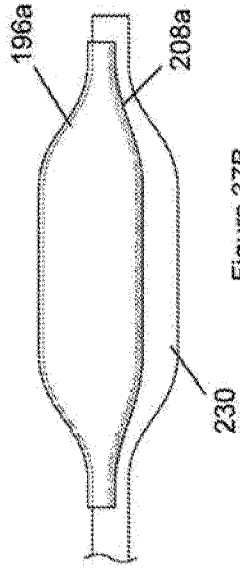


Figure 37B

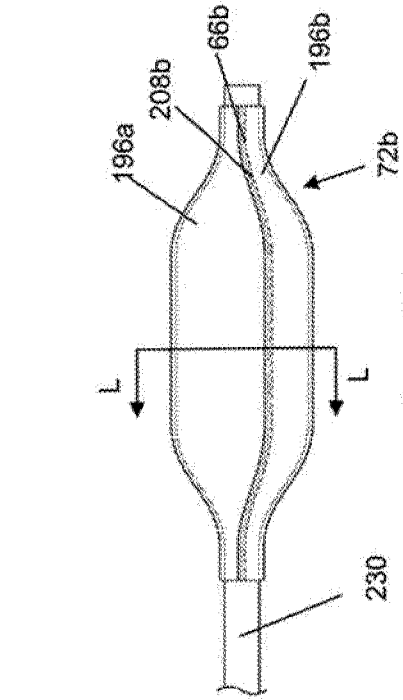


Figure 37C

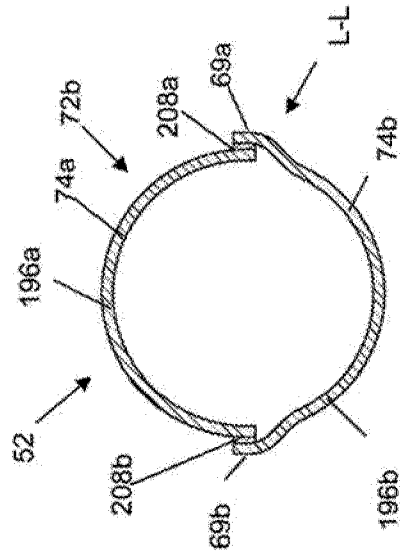


Figure 37D

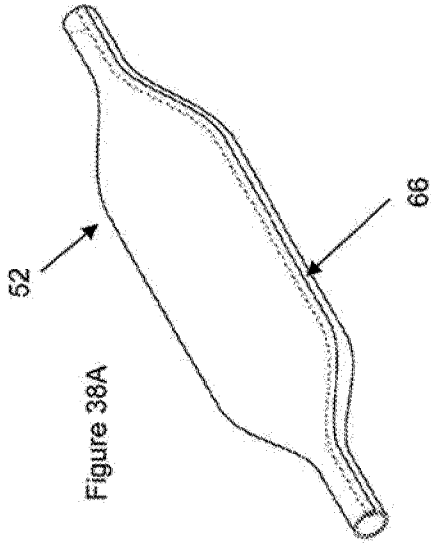


Figure 38A

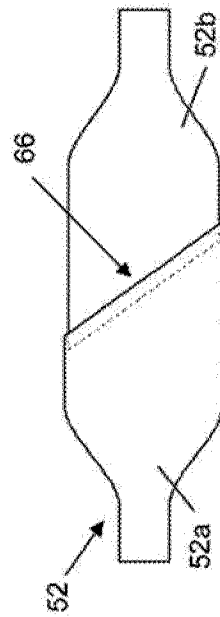


Figure 38B

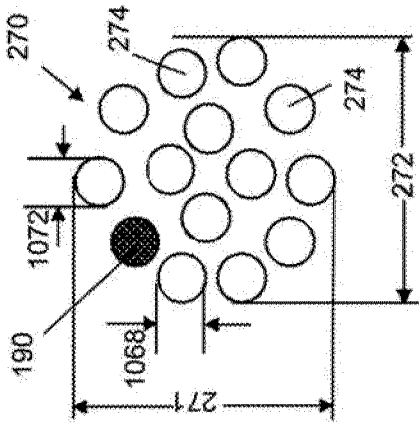


Figure 39A

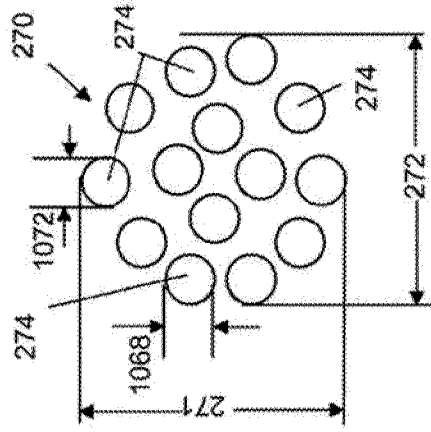


Figure 39B

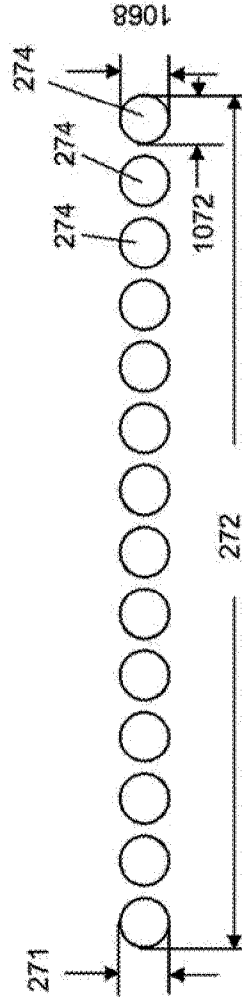
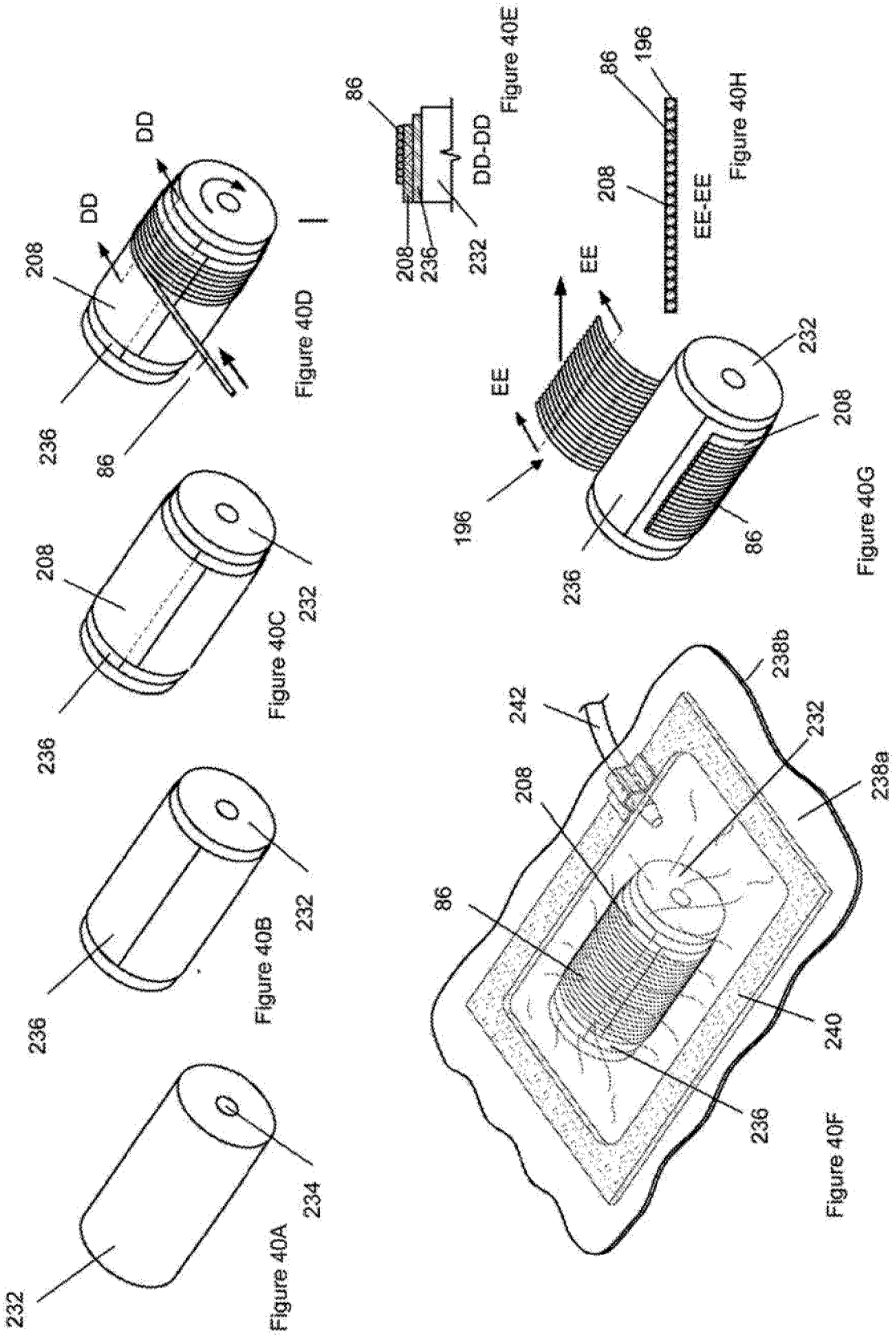


Figure 39C



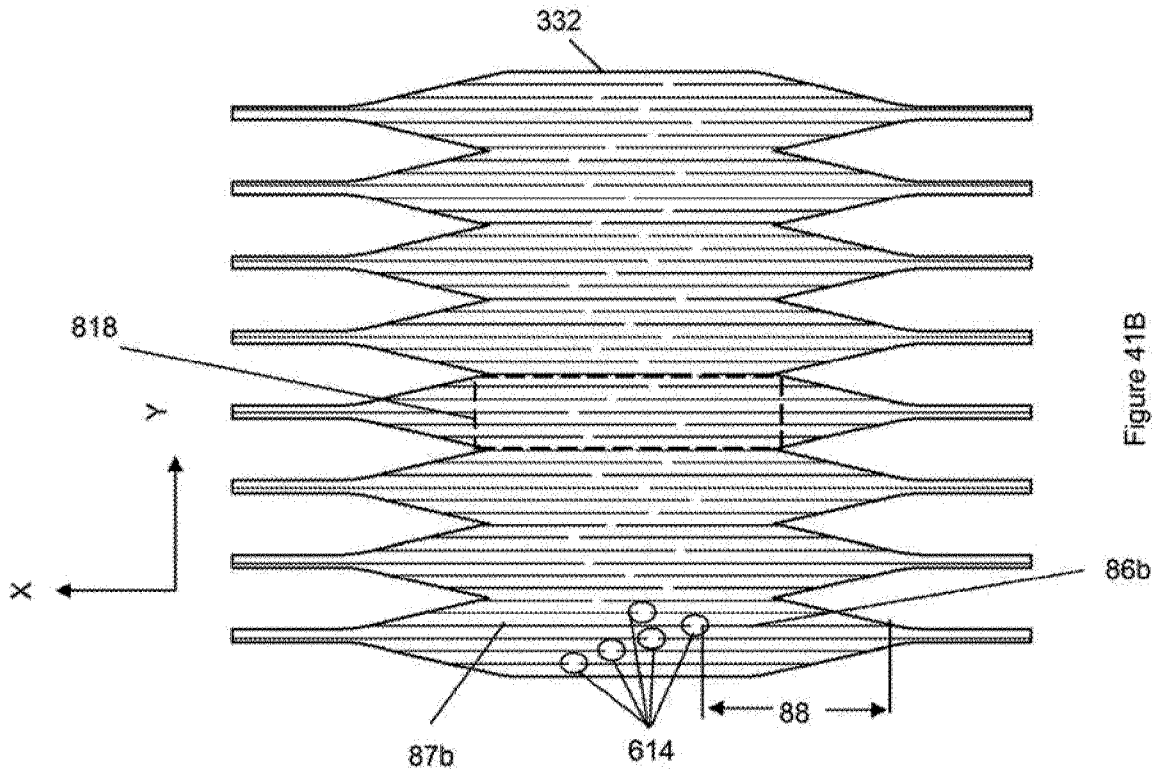


Figure 41B

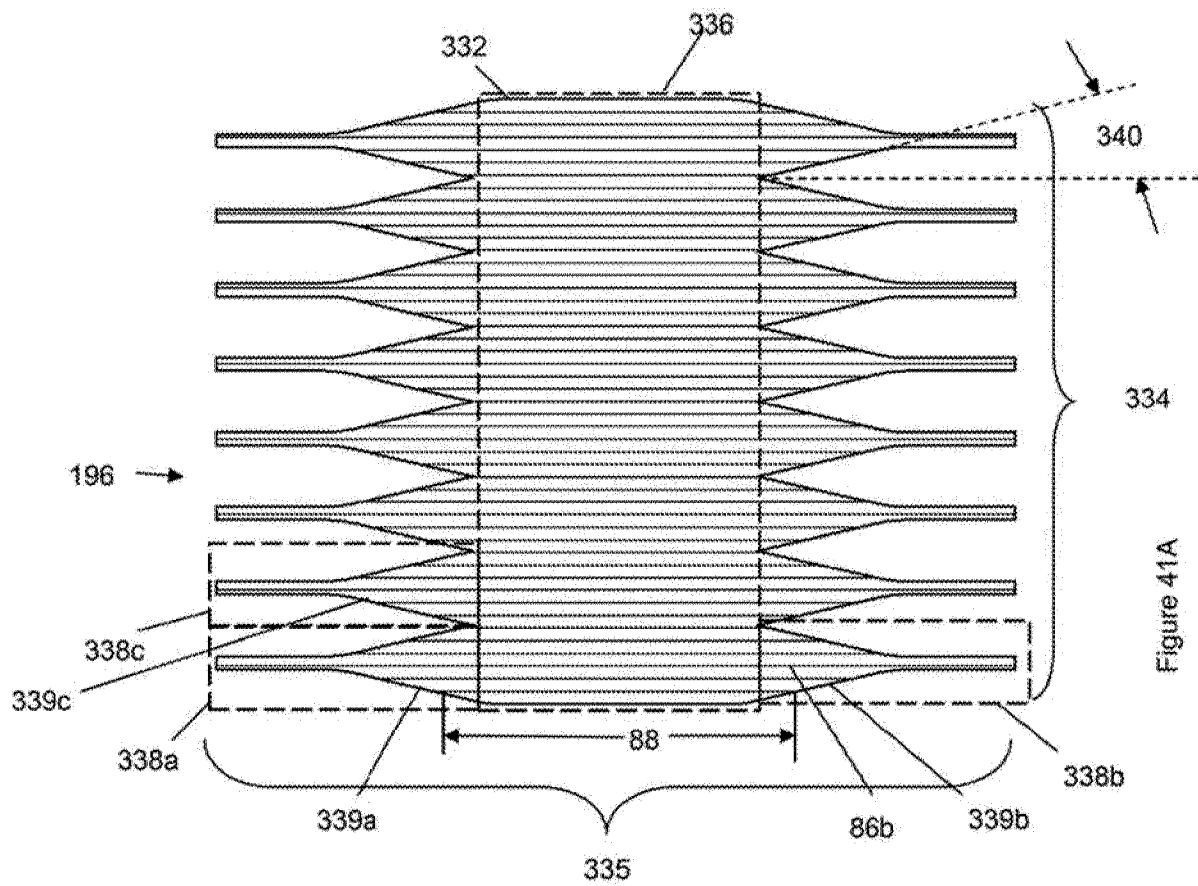


Figure 41A

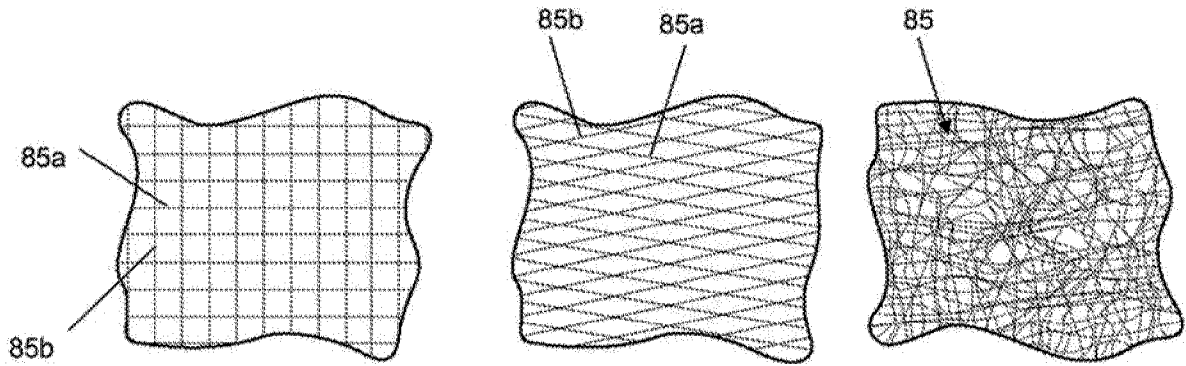


Figure 42A

Figure 42B

Figure 42C

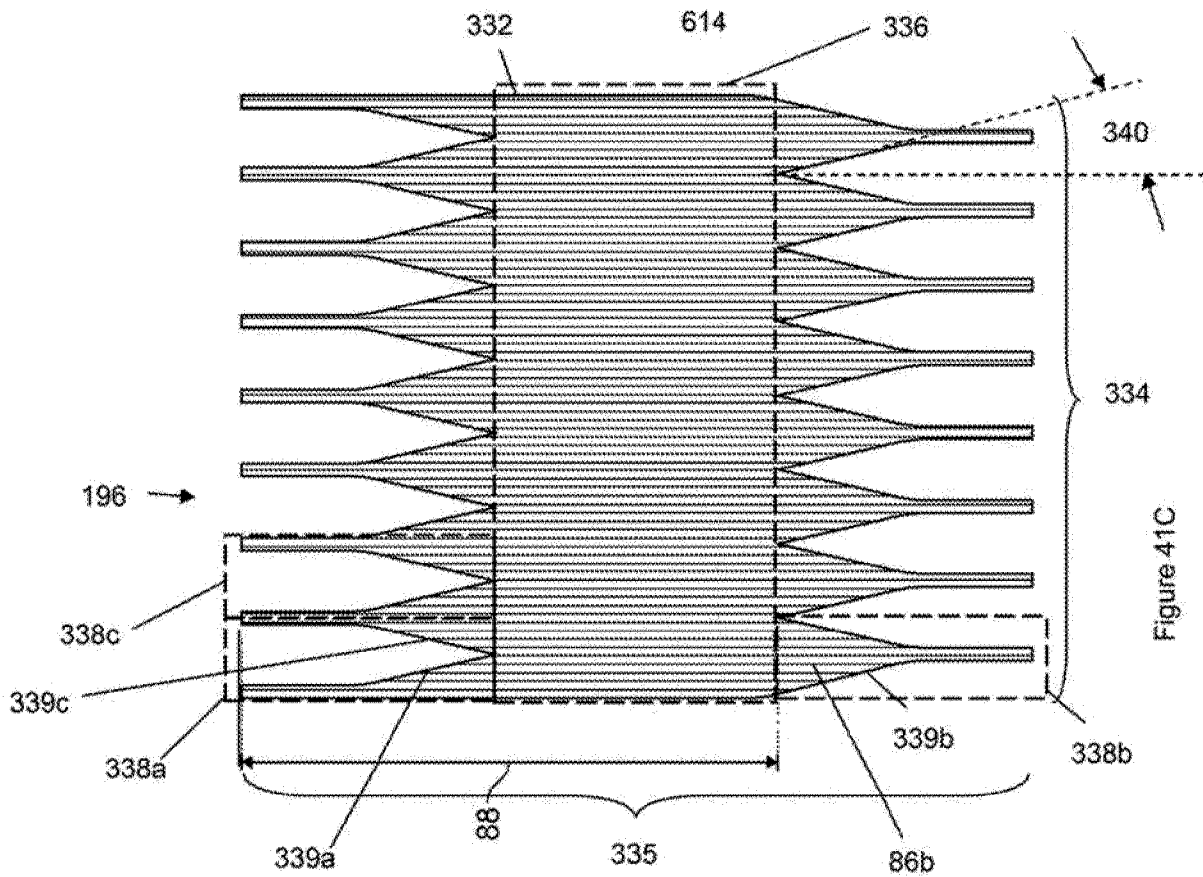


Figure 41C

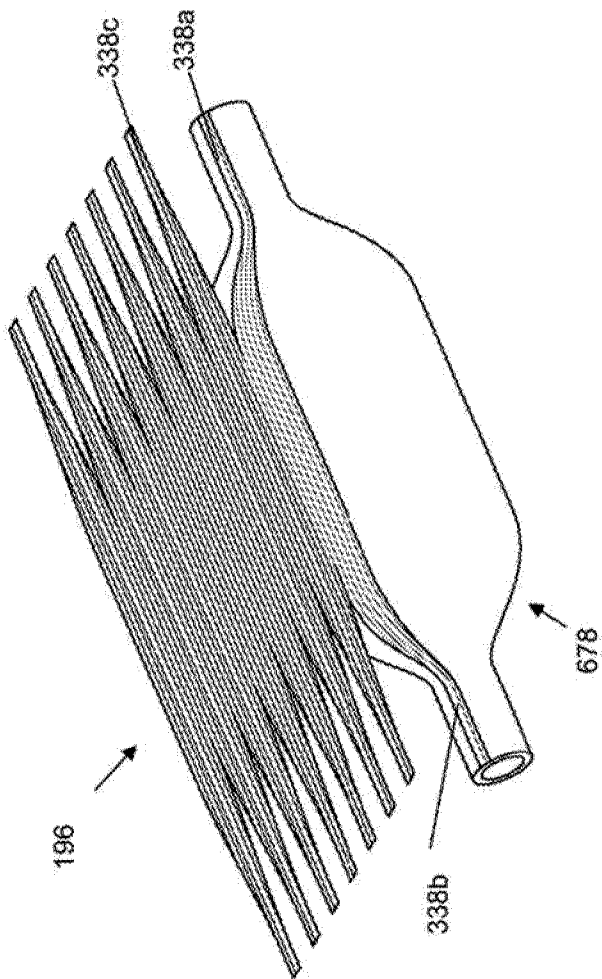


Figure 43A

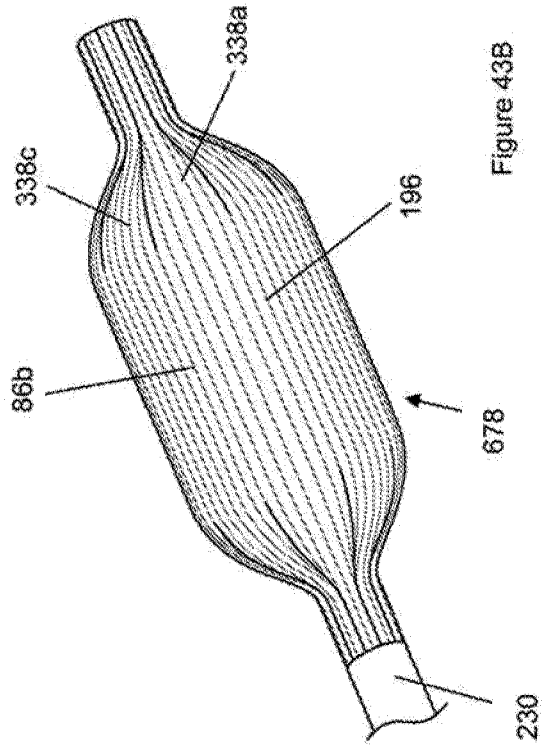
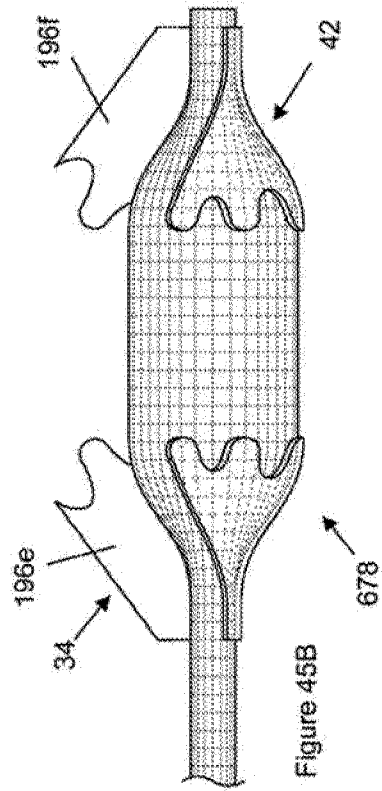
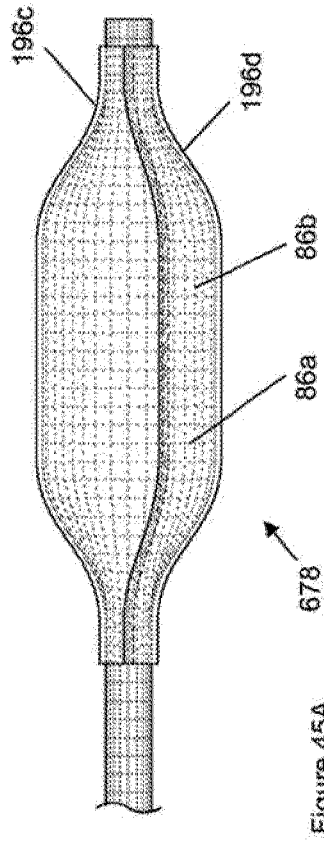
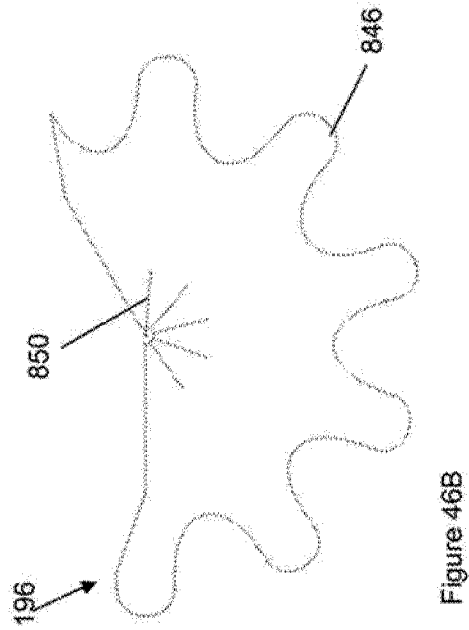
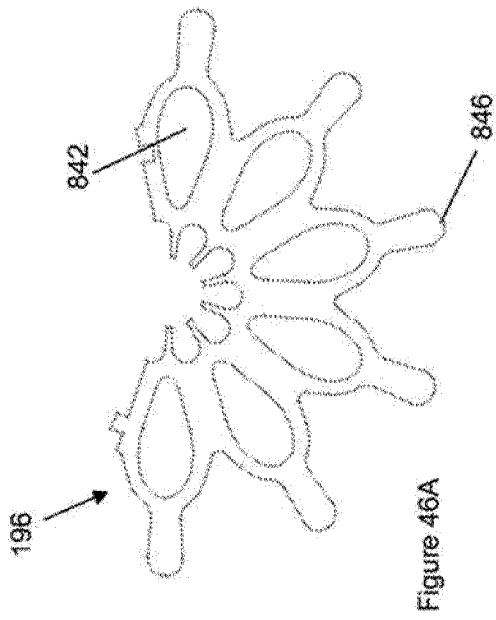
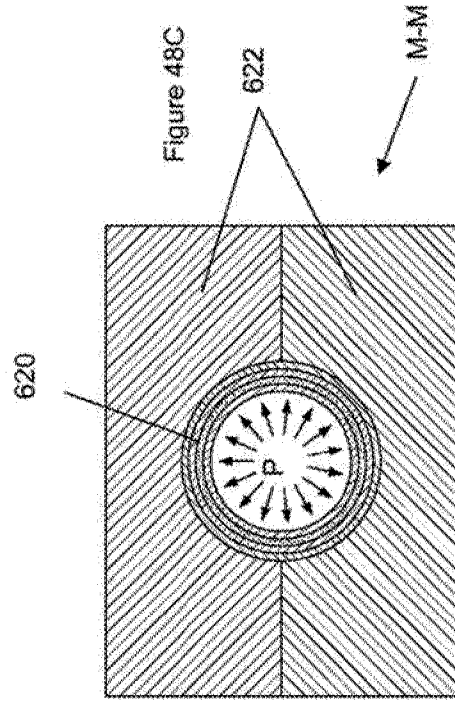
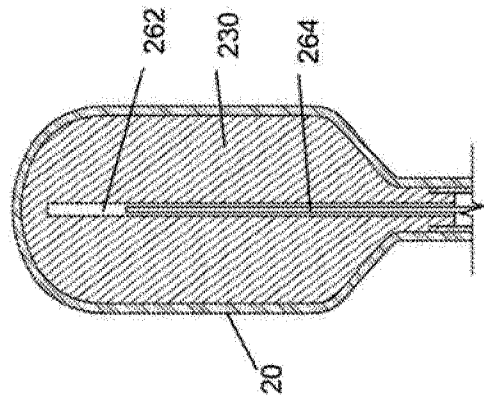
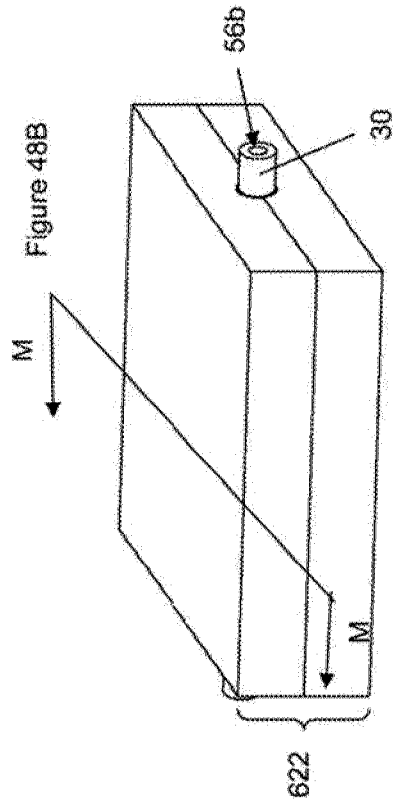
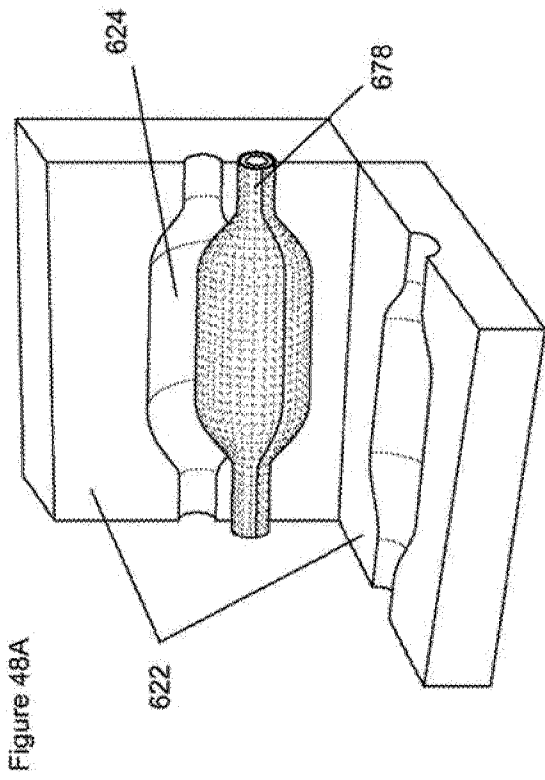


Figure 43B







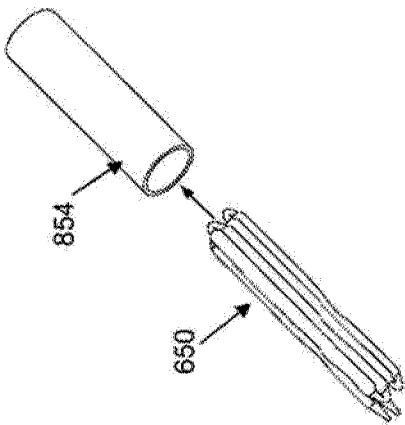


Figure 49A

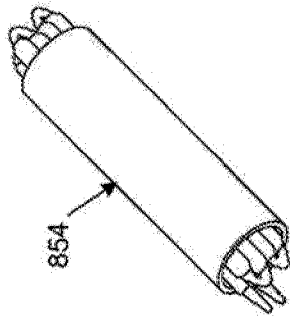


Figure 49B

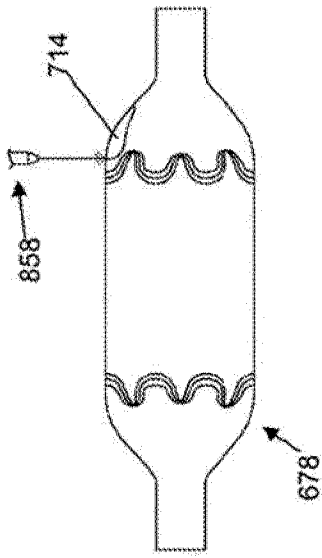


Figure 49C

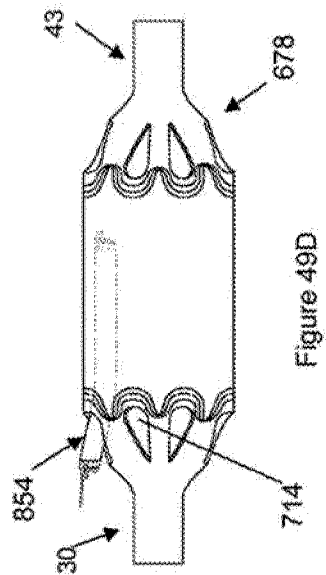


Figure 49D

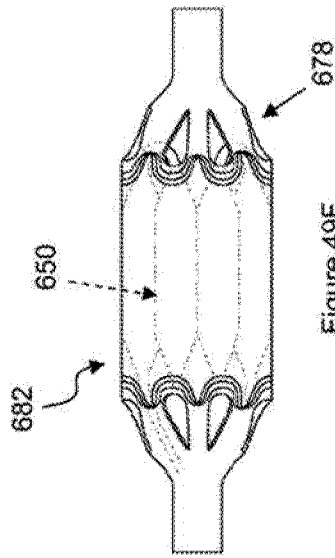


Figure 49F

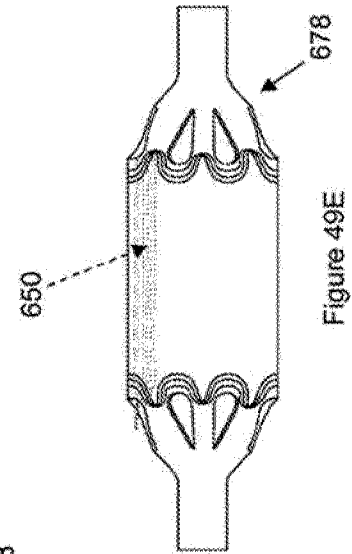


Figure 49E

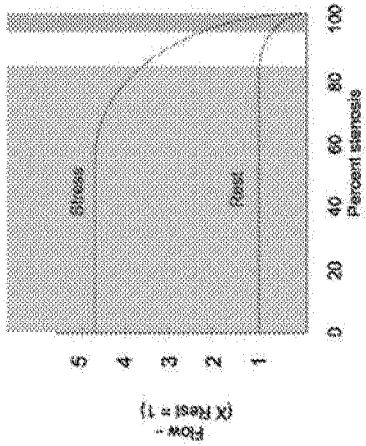


Figure 53

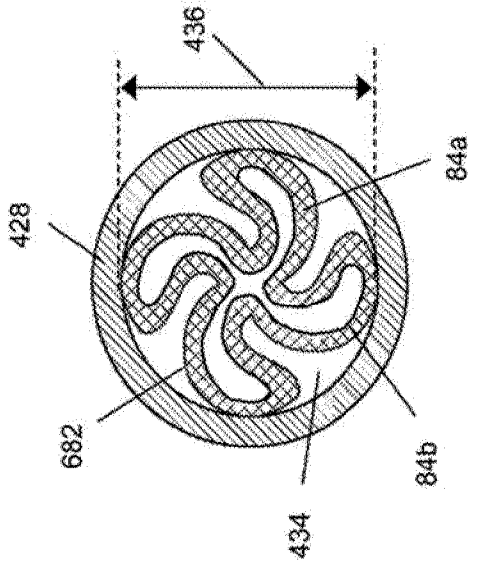


Figure 51

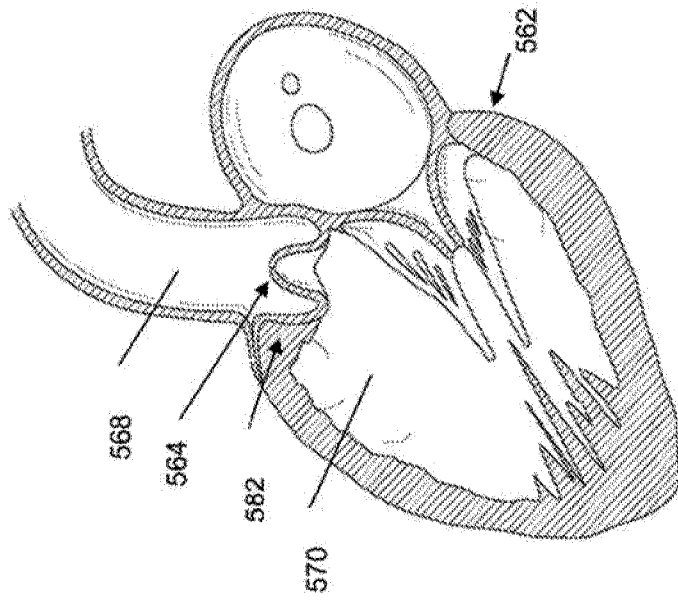


Figure 52

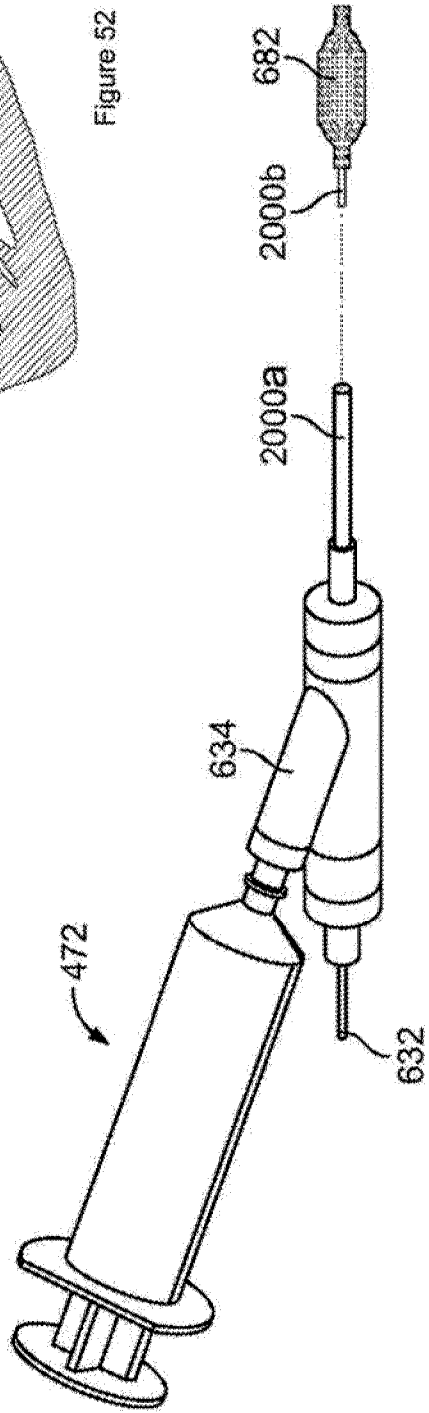


Figure 50

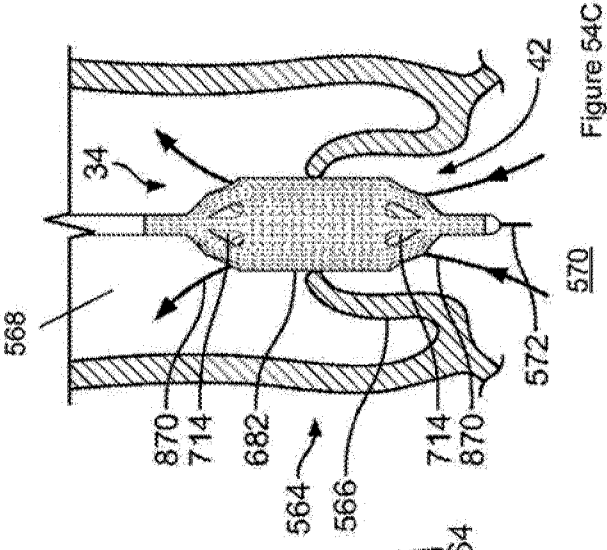


Figure 54C

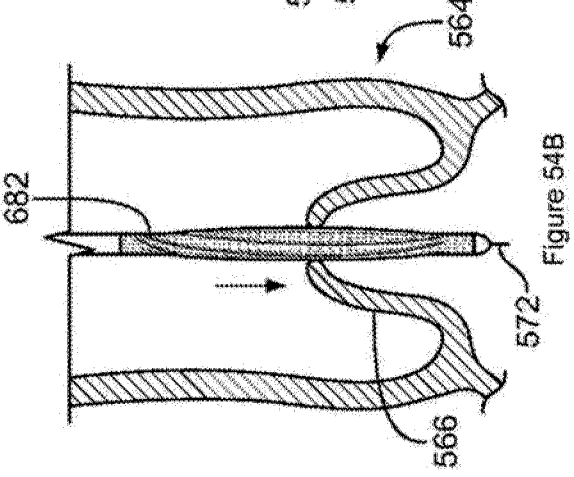


Figure 54B

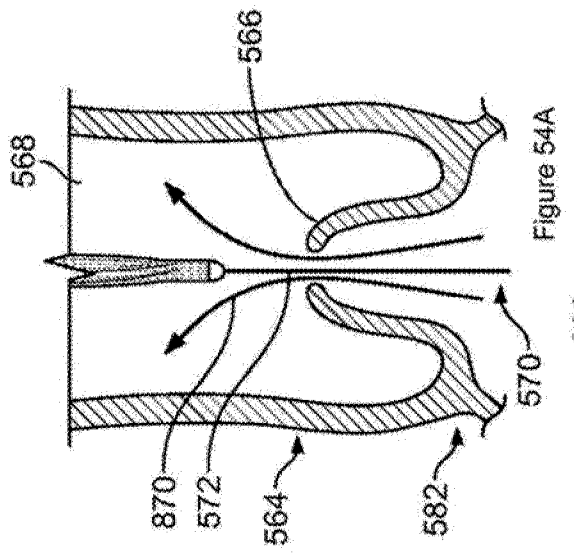


Figure 54A

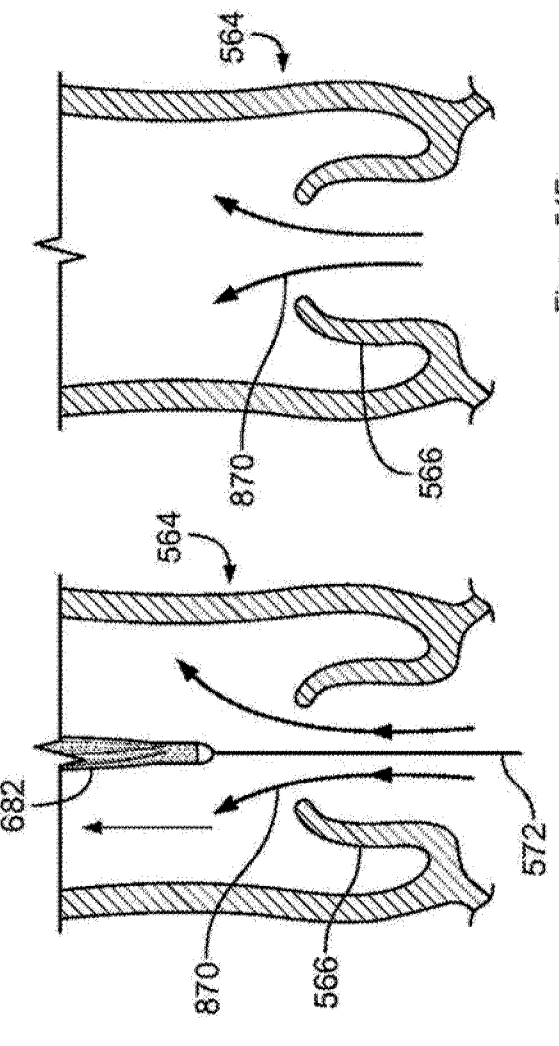


Figure 54D

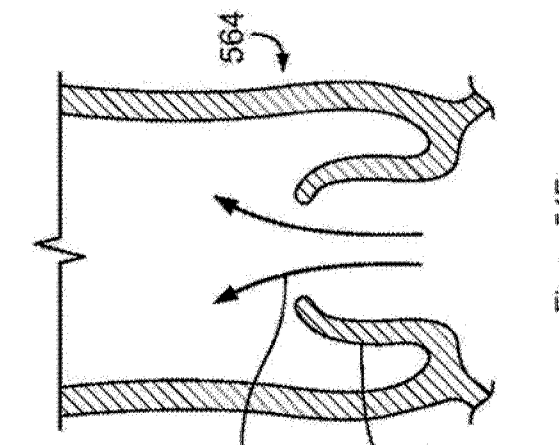


Figure 54E

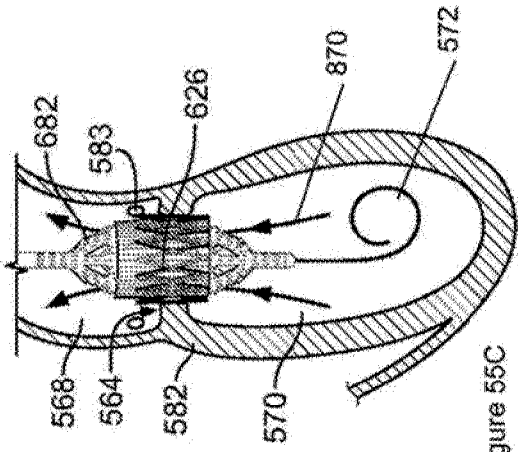


Figure 55C

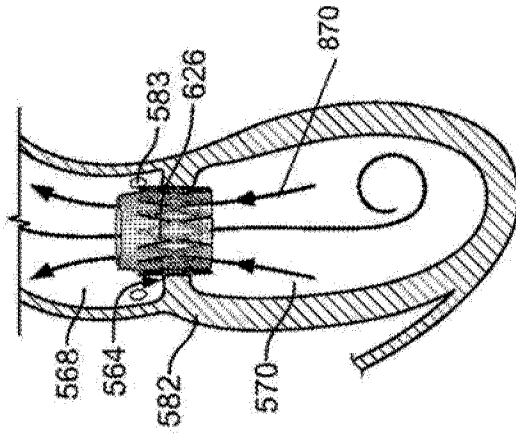


Figure 55F

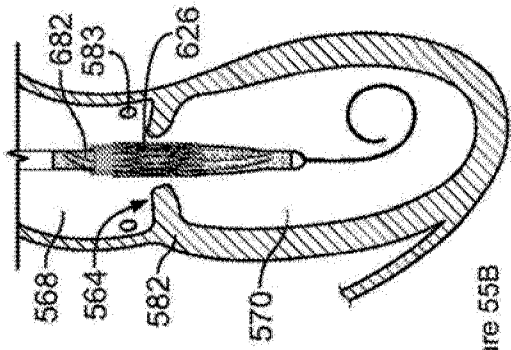


Figure 55B

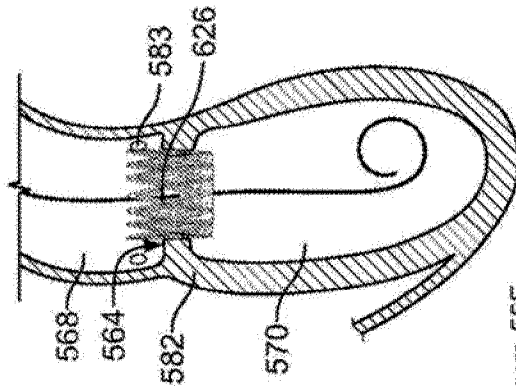


Figure 55E

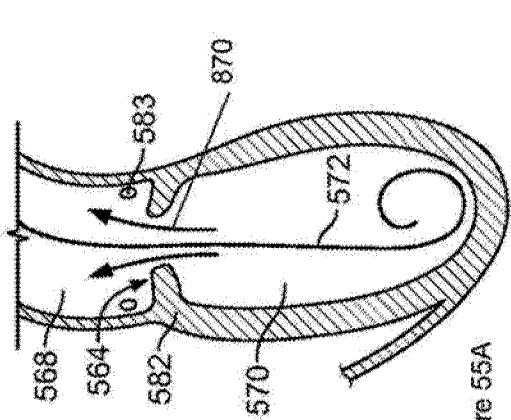


Figure 55A

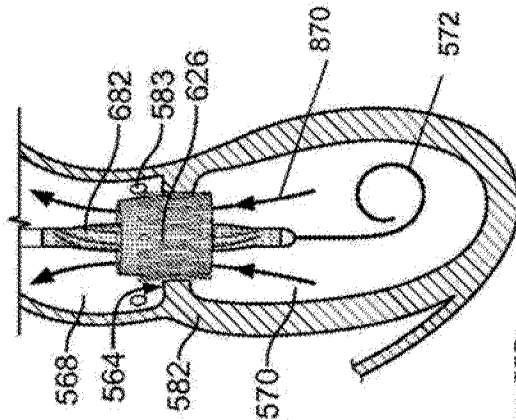


Figure 55D

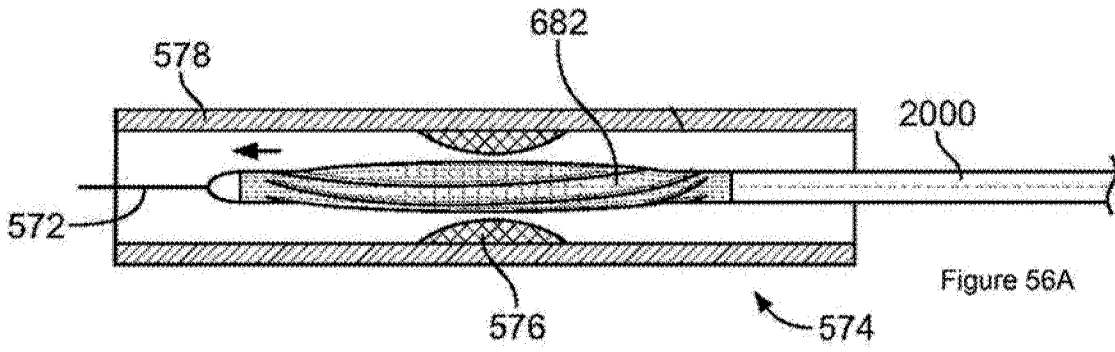


Figure 56A

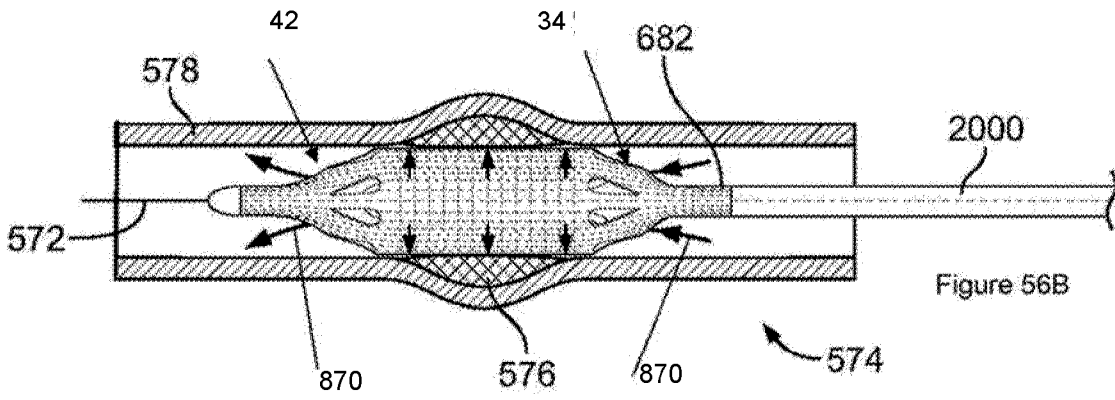


Figure 56B

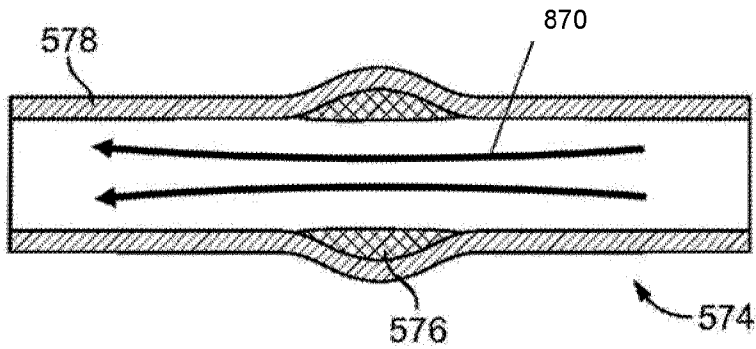


Figure 56C

