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(54) **METHOD AND DEVICE FOR CAVITY OBLITERATION**

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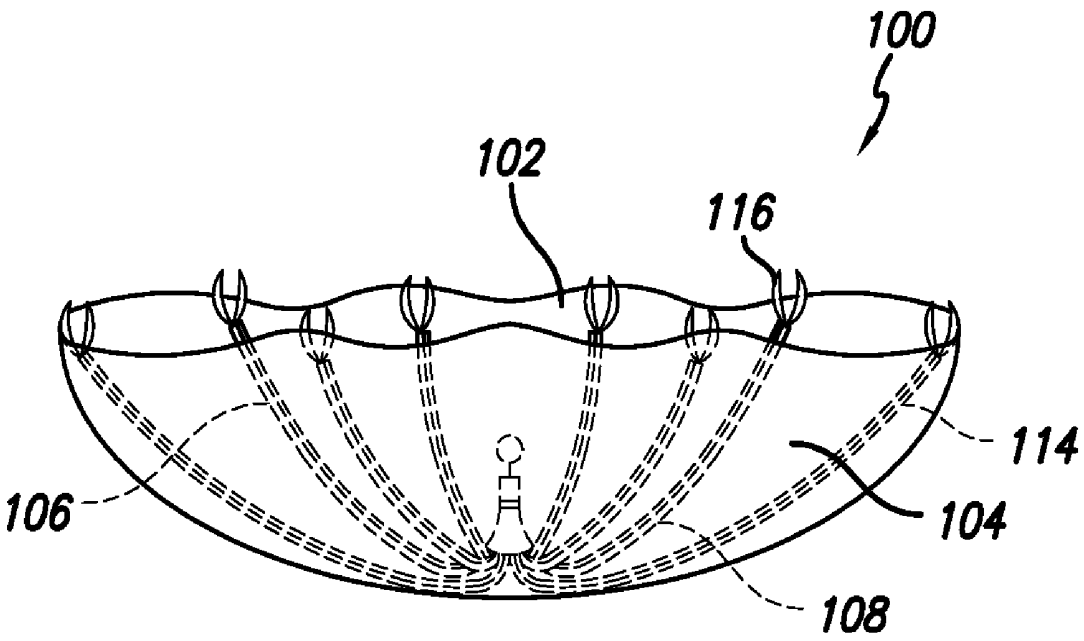
(52) **U.S. Cl.** **606/151**

(57) **ABSTRACT**

A device for the obliteration of an aberrant space or cavity. A method for the obliteration of an aberrant space or cavity comprising providing a device according to the present invention.



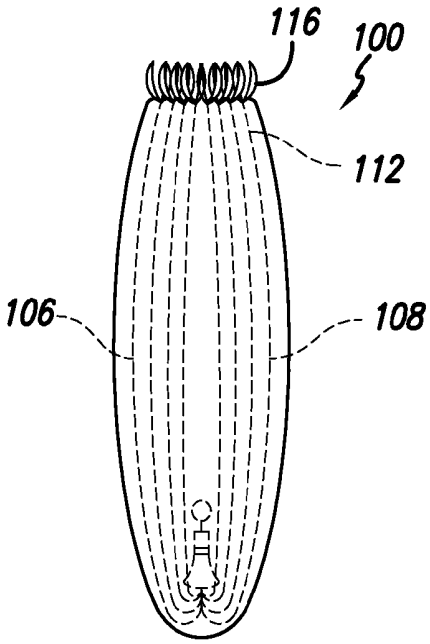


FIG. 1

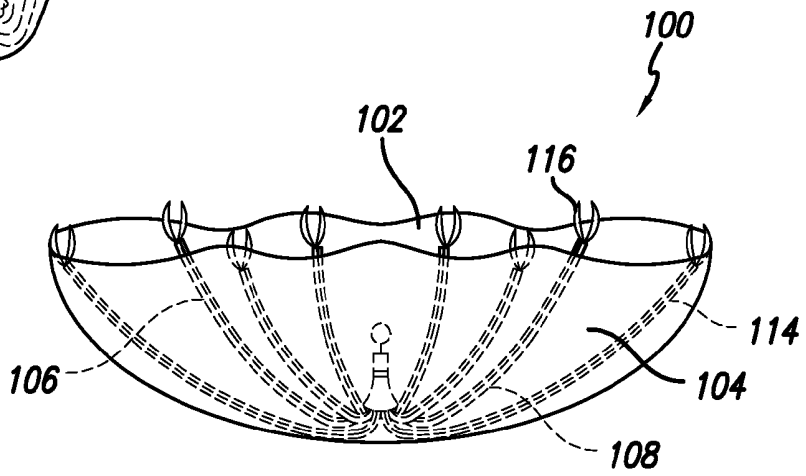
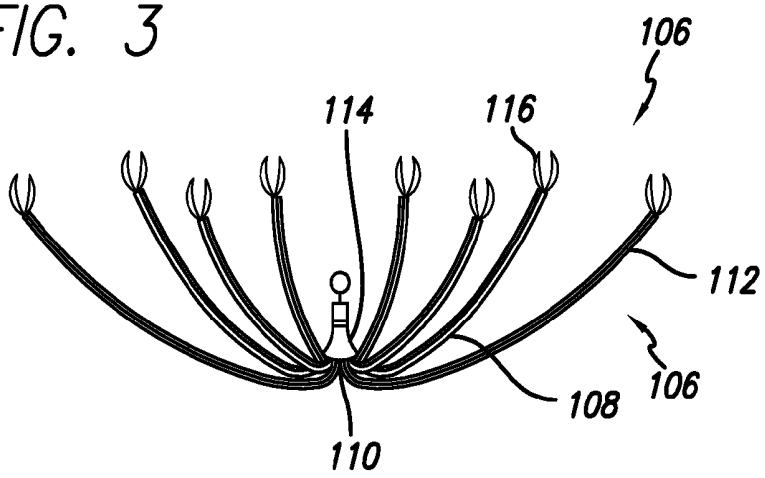
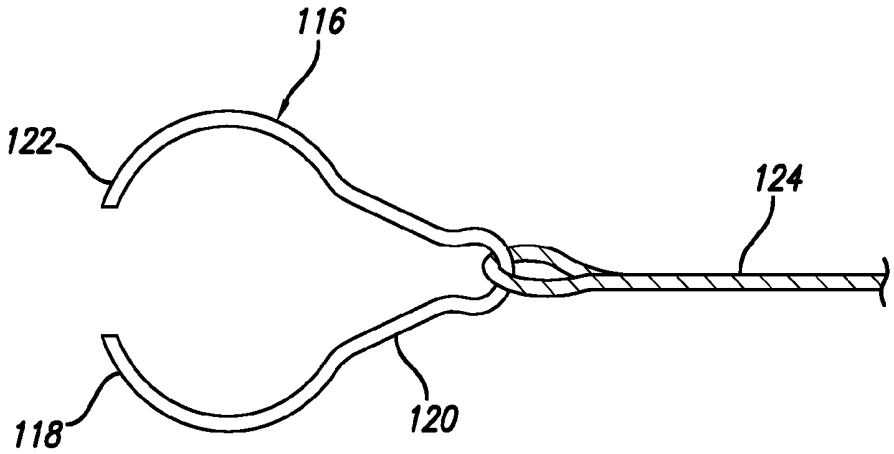


FIG. 2

FIG. 3





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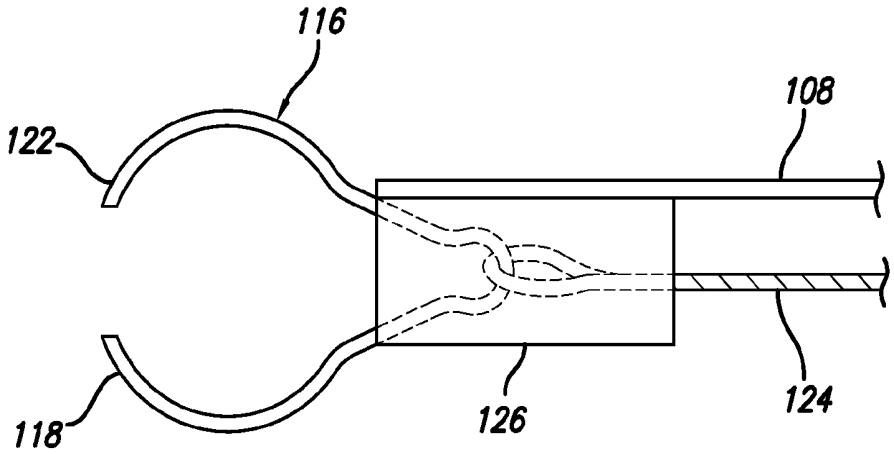
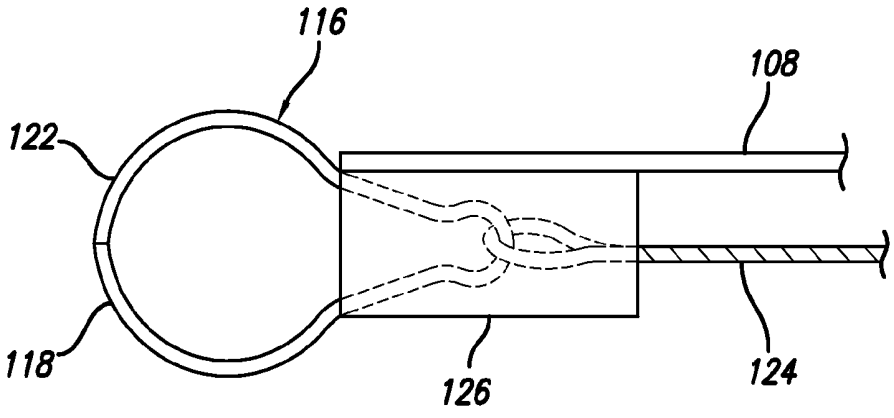


FIG. 5



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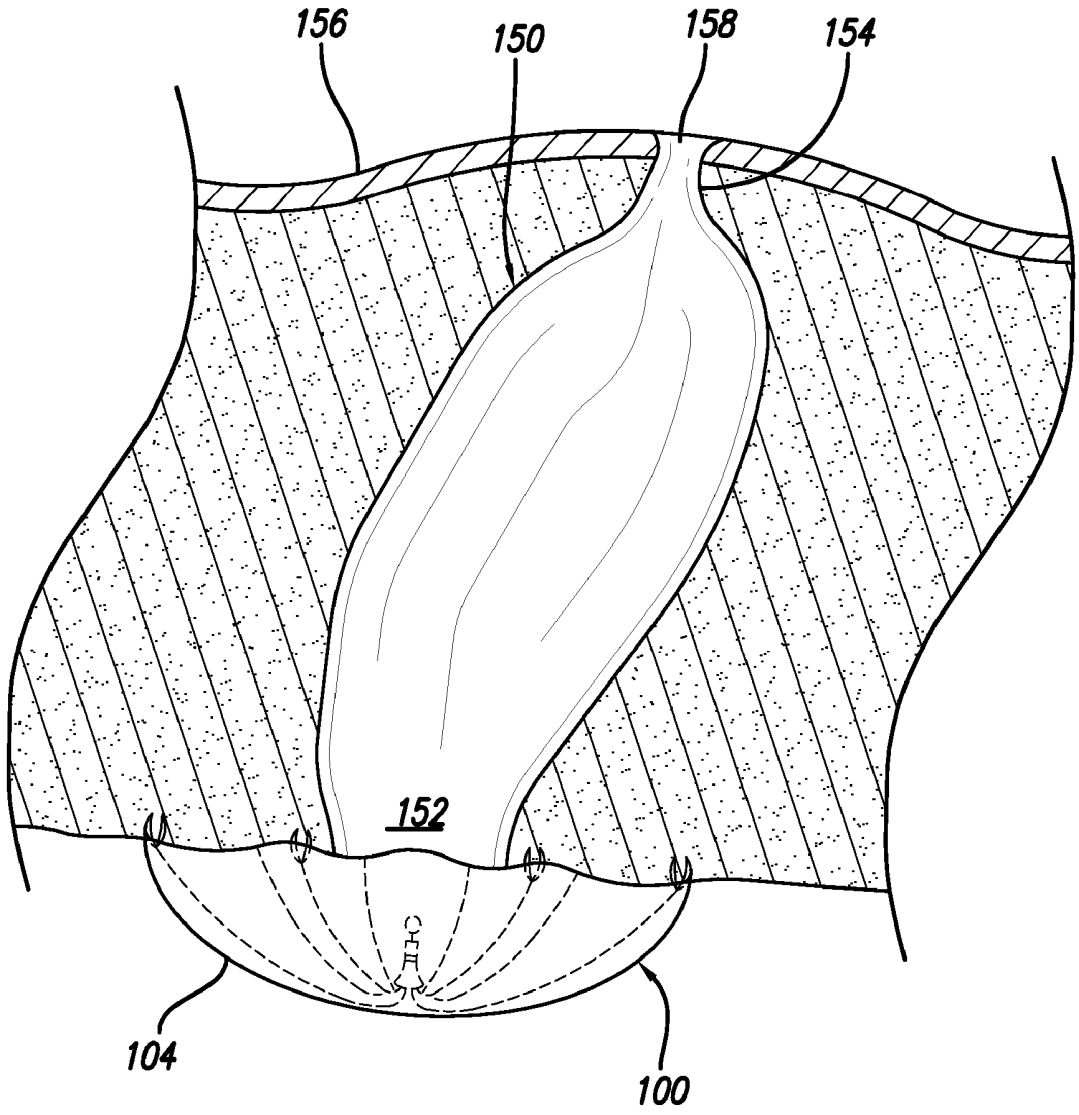

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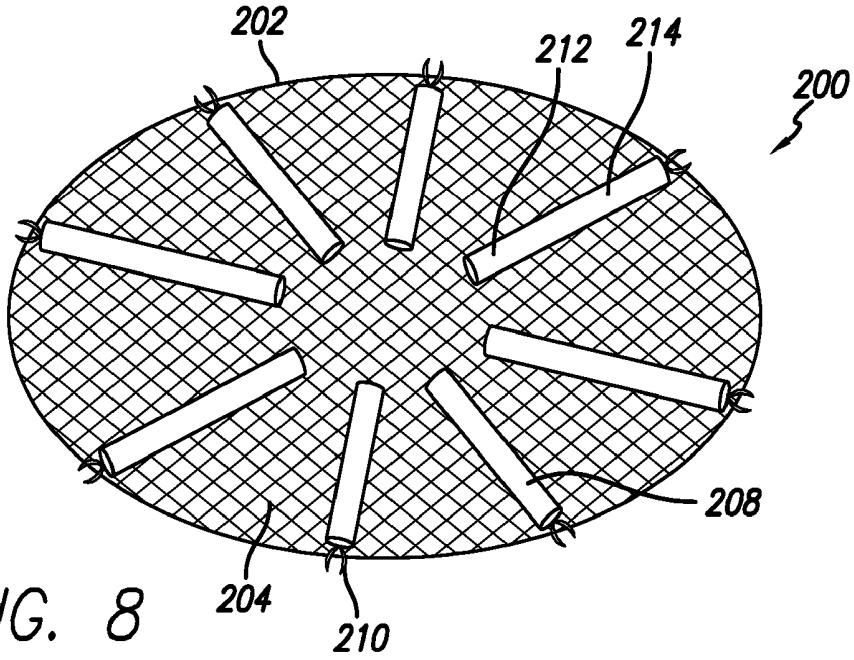

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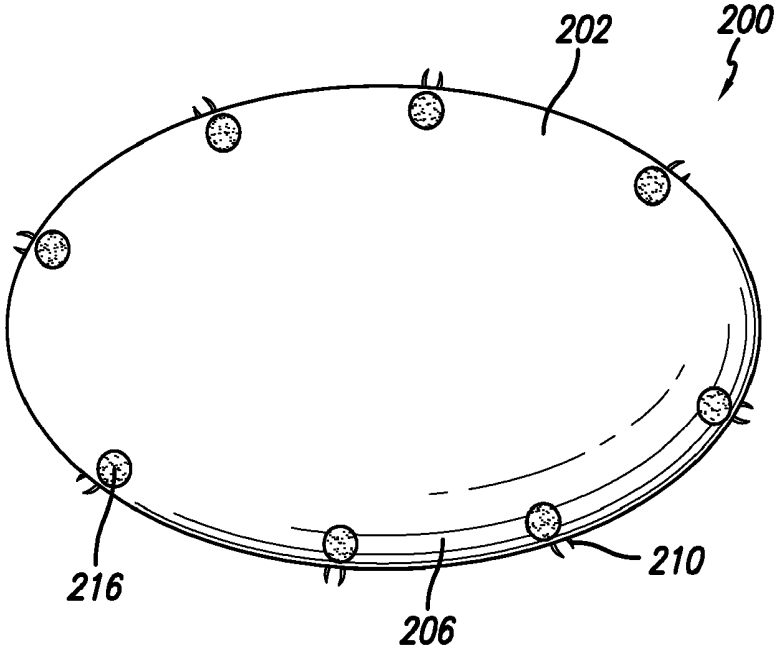

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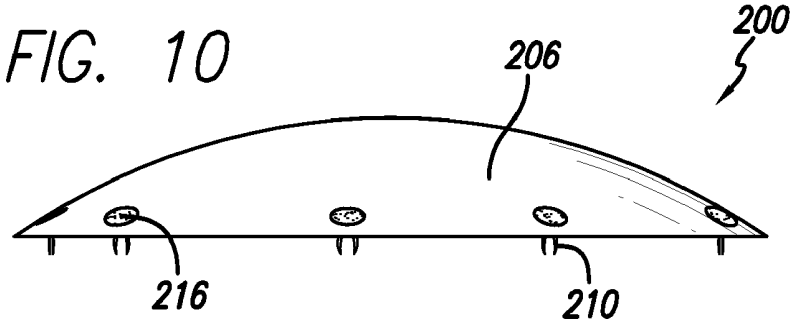

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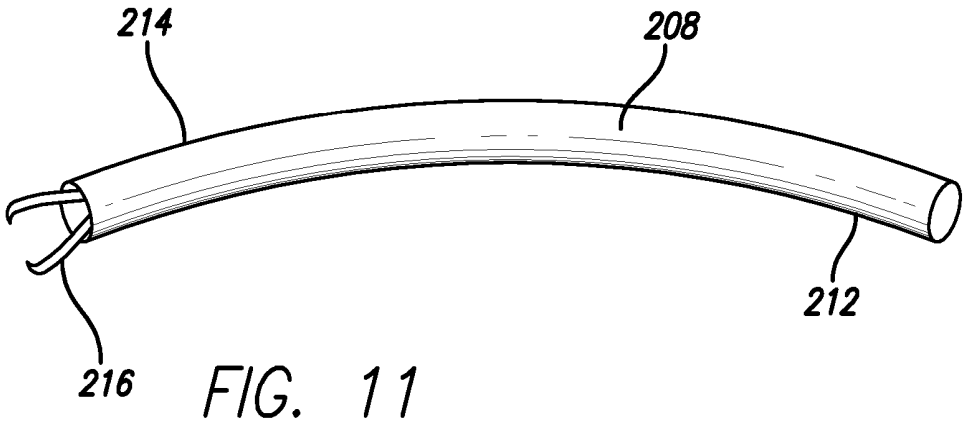

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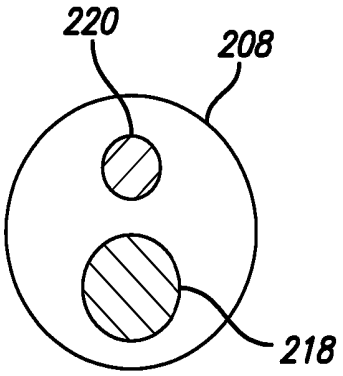

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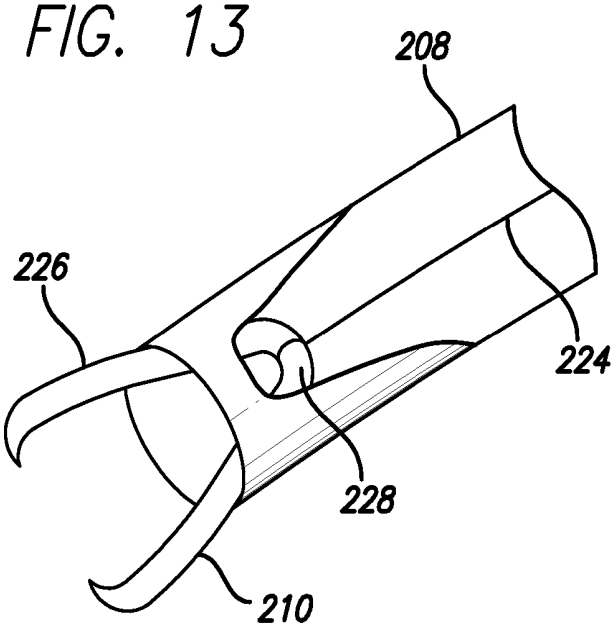

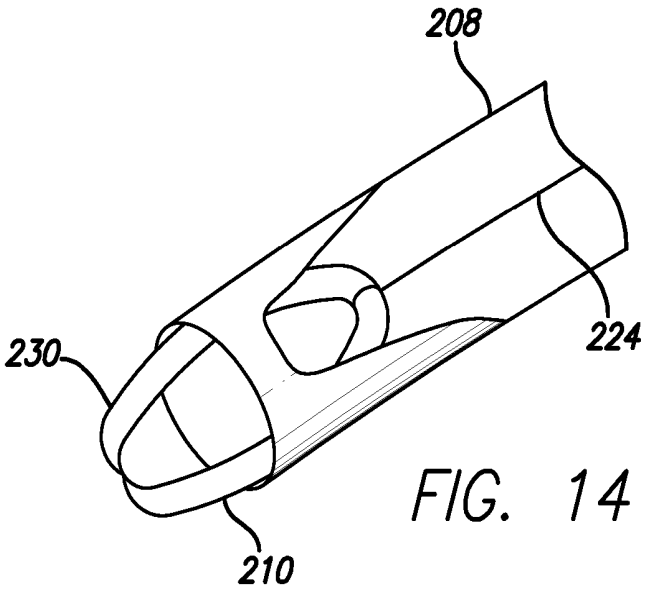

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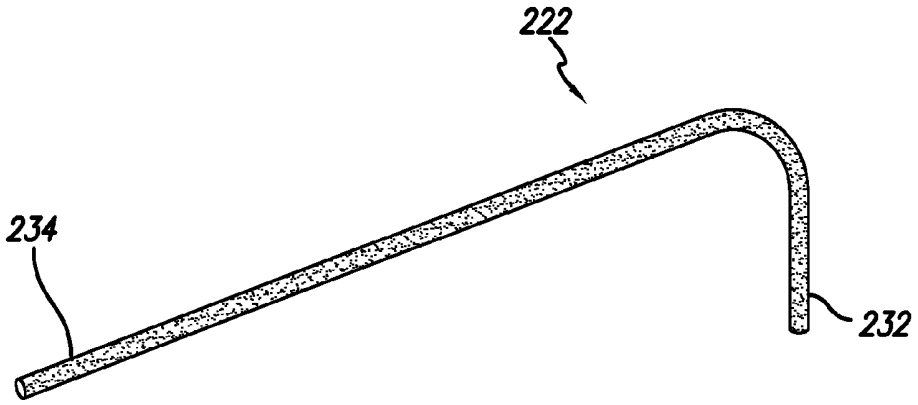

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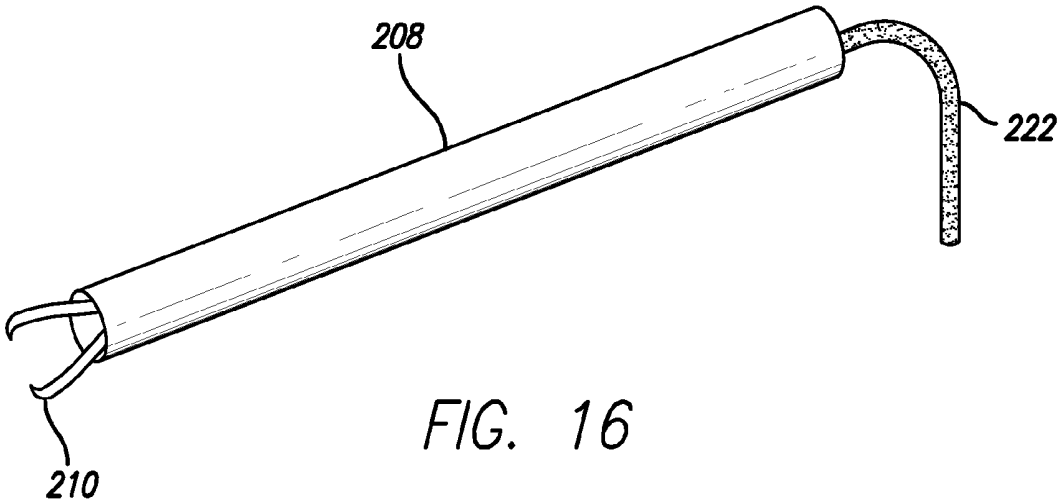

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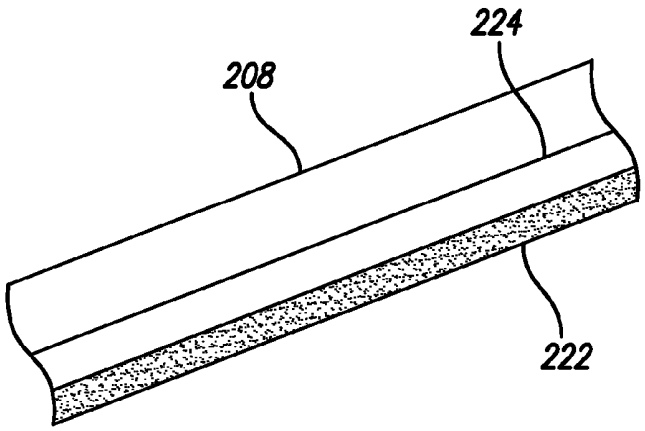

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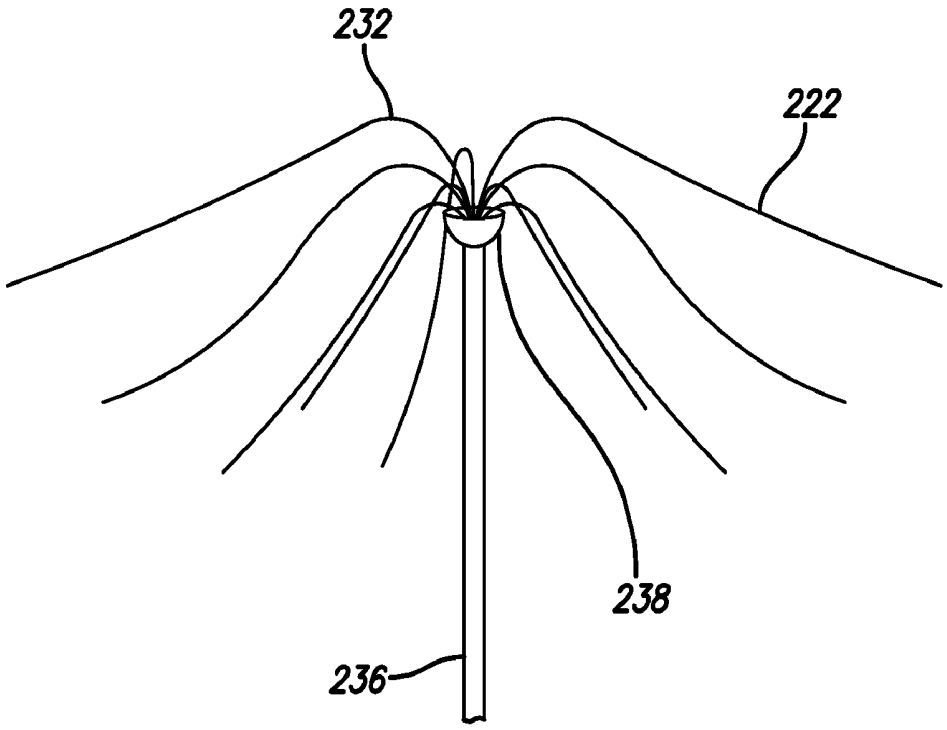

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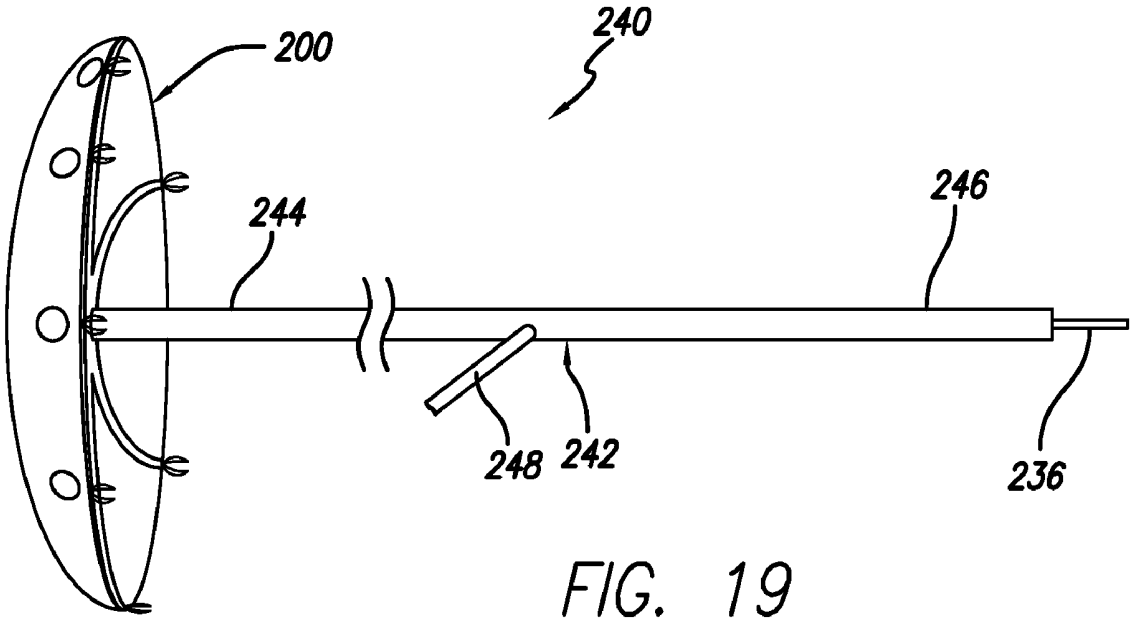

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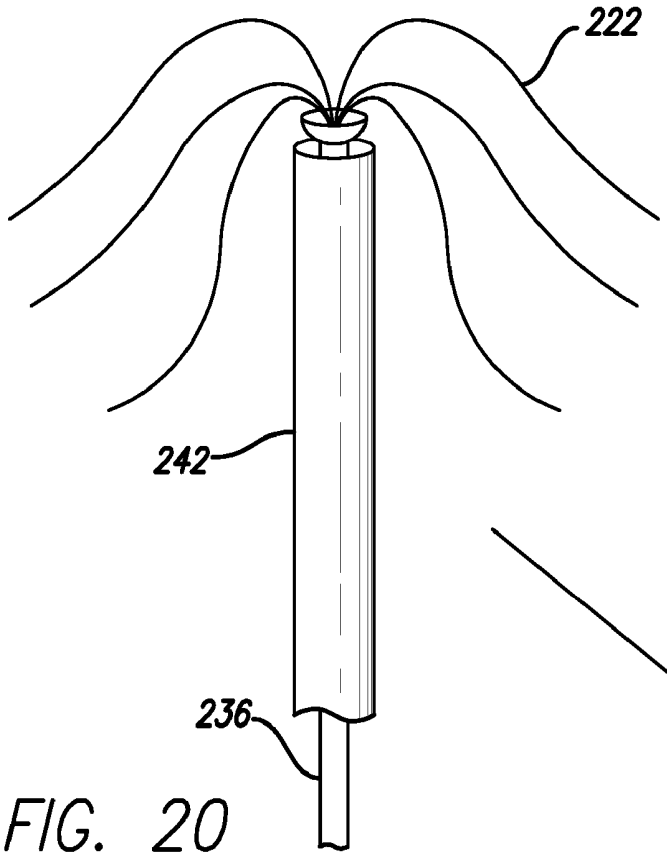

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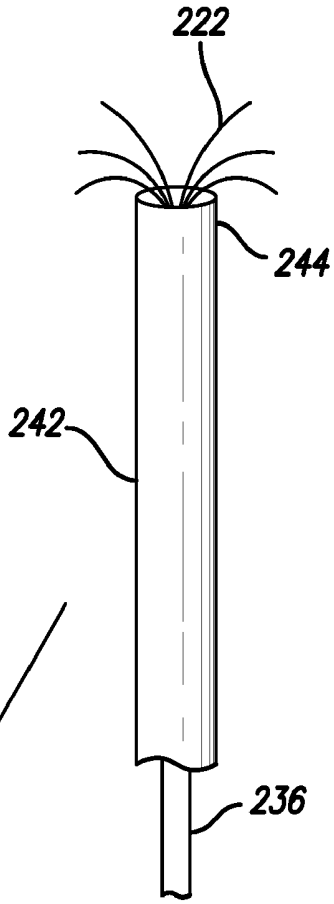

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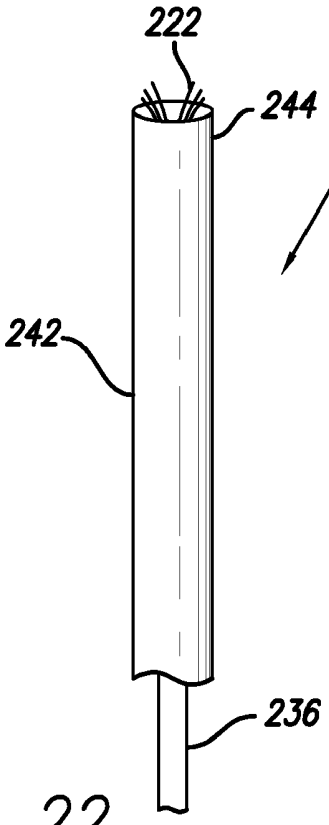

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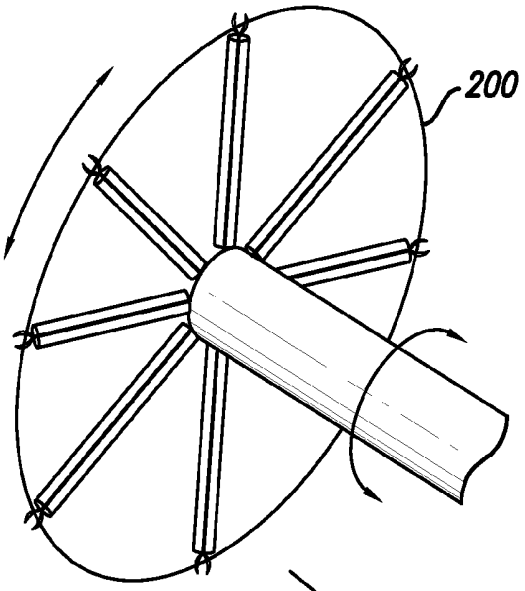

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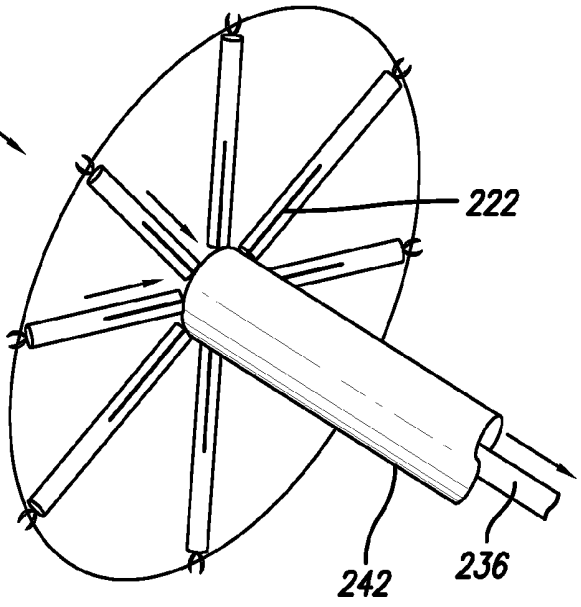

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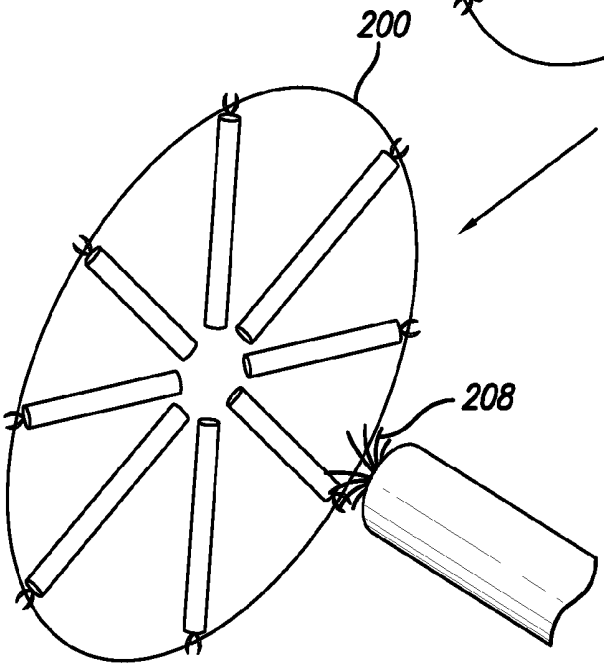

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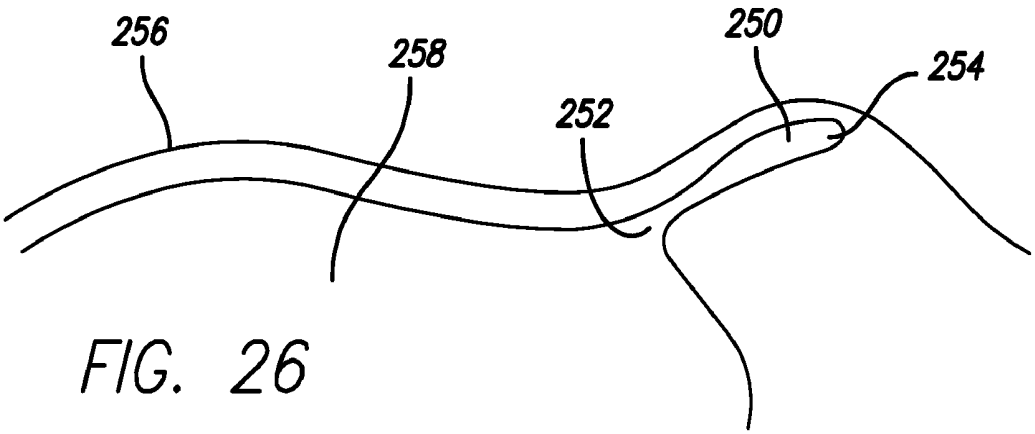

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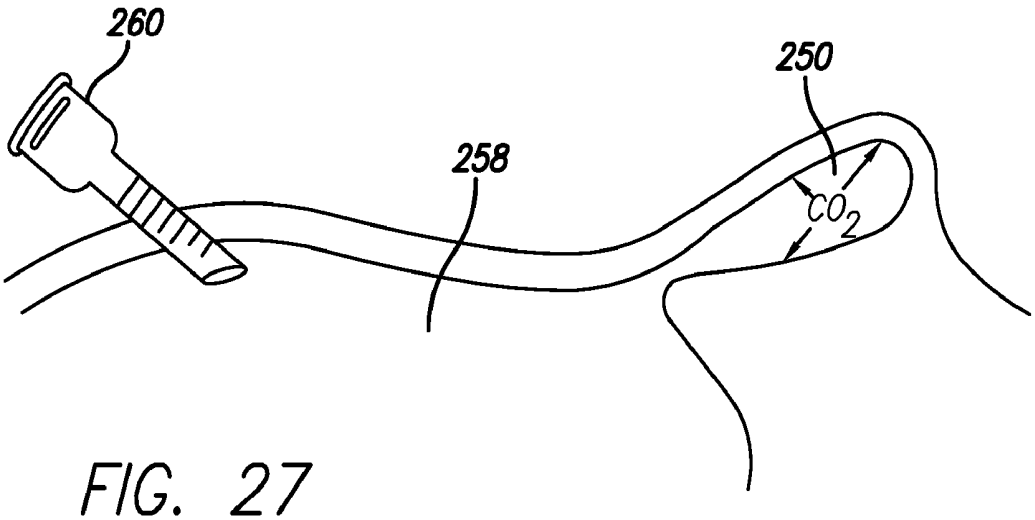

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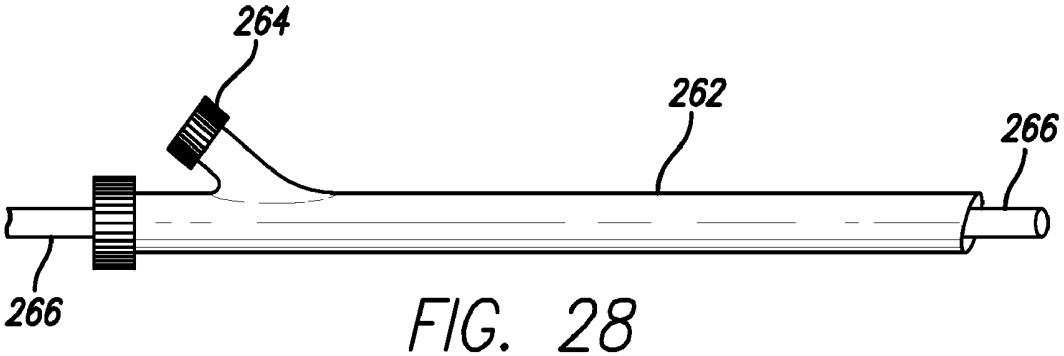

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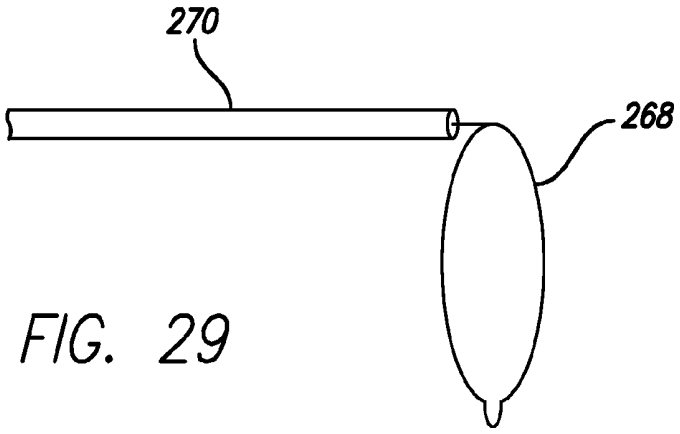

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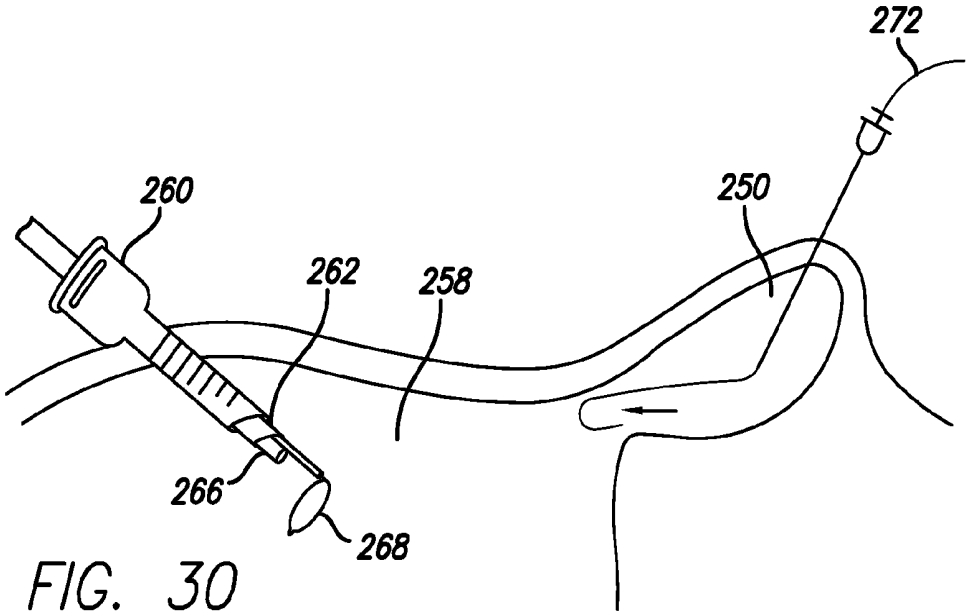

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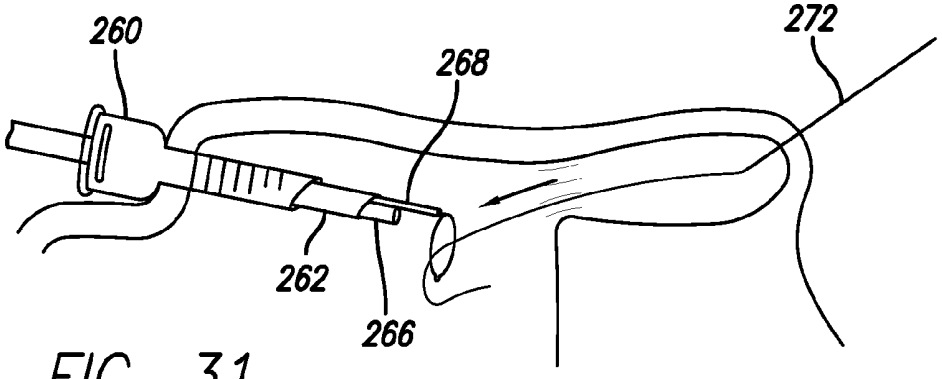

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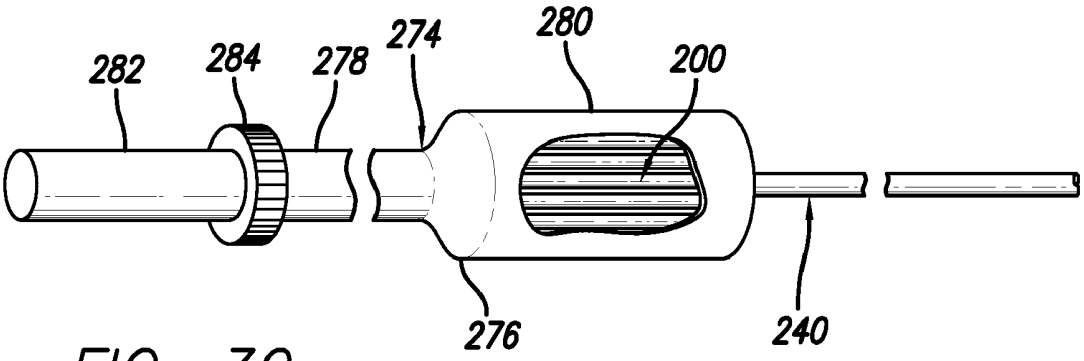

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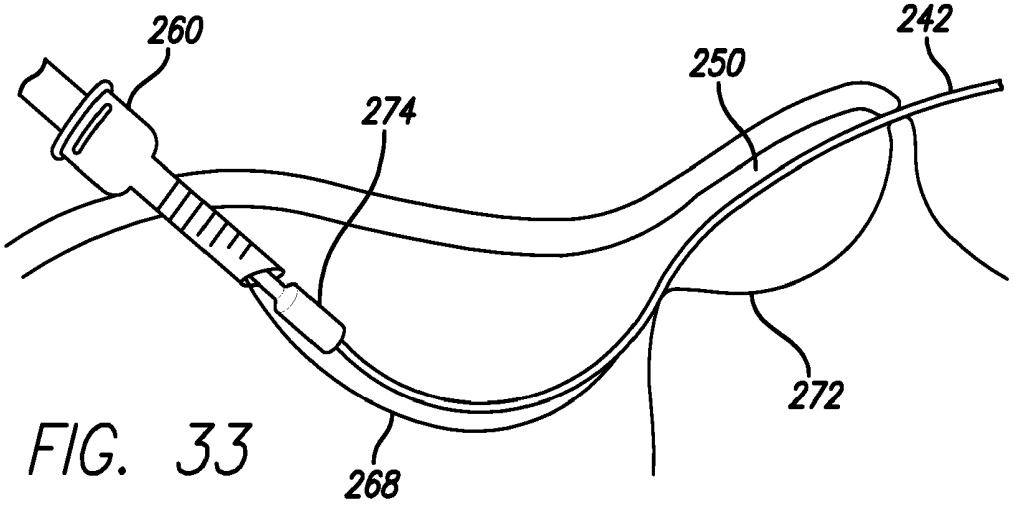

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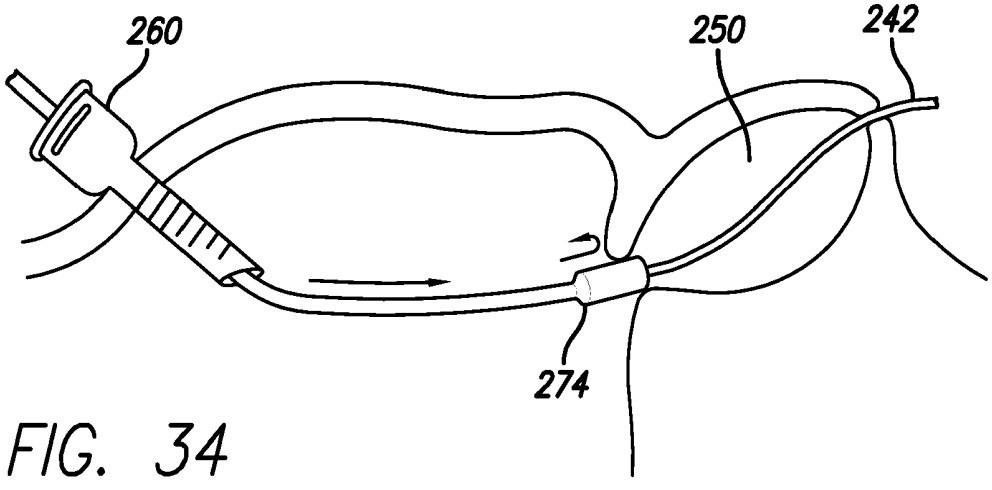

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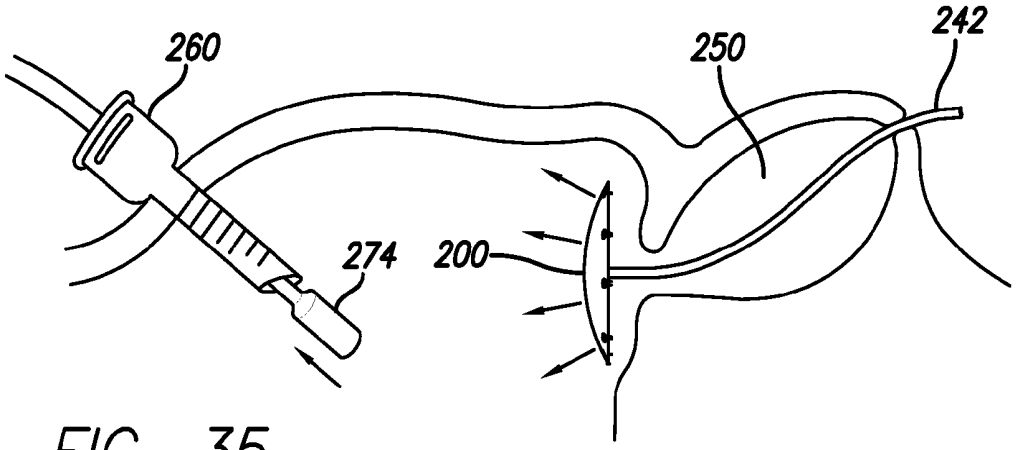

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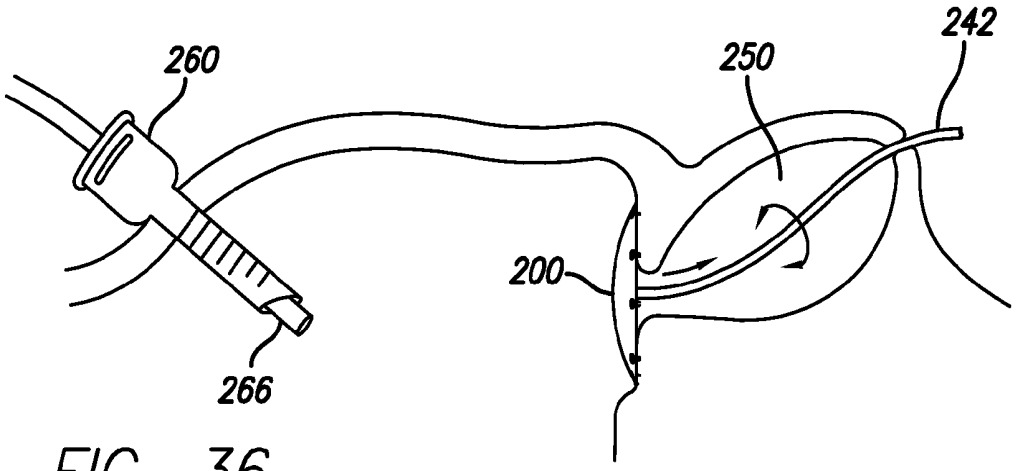

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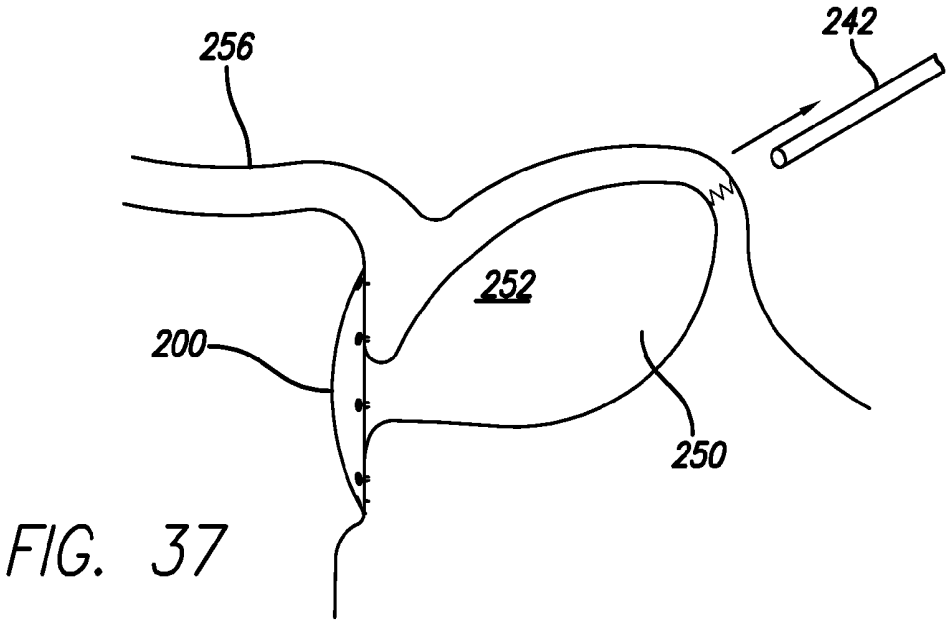

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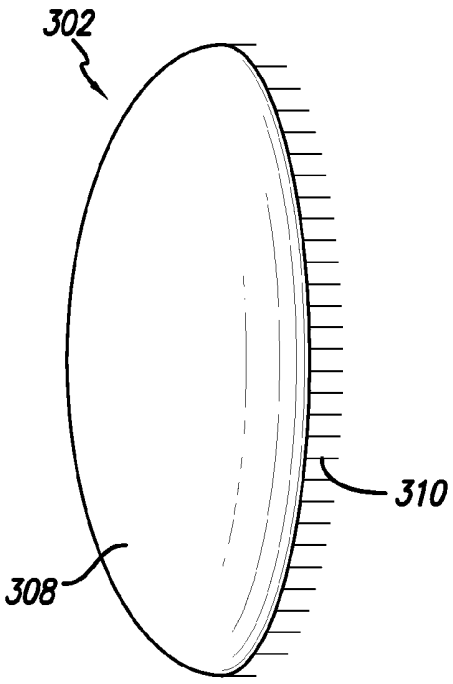

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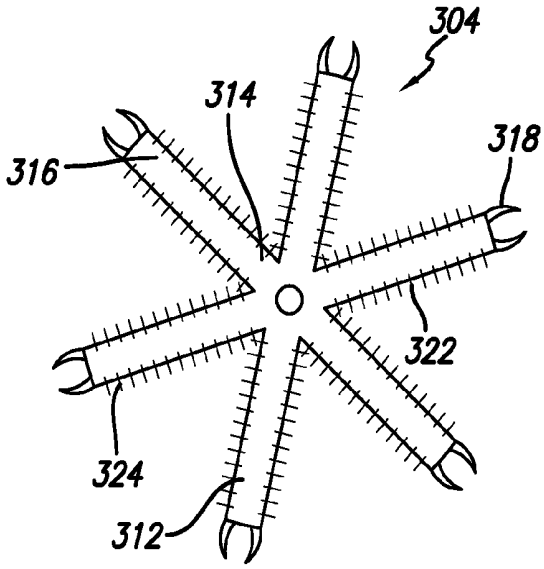

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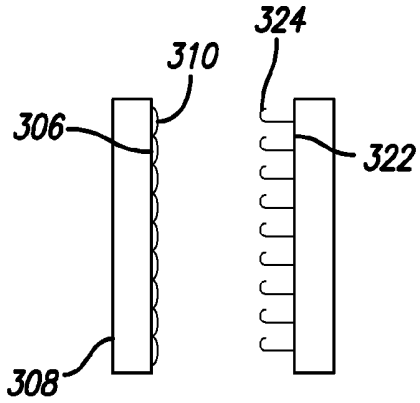

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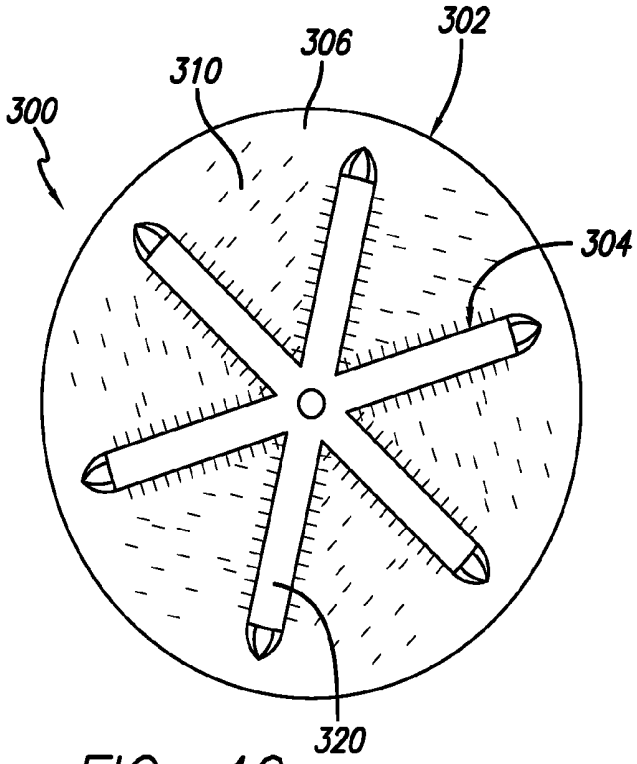

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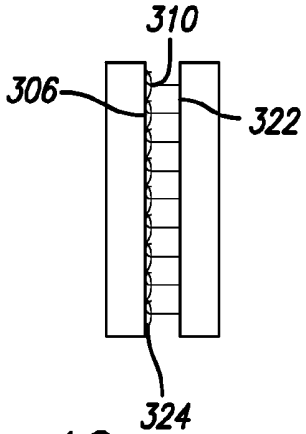

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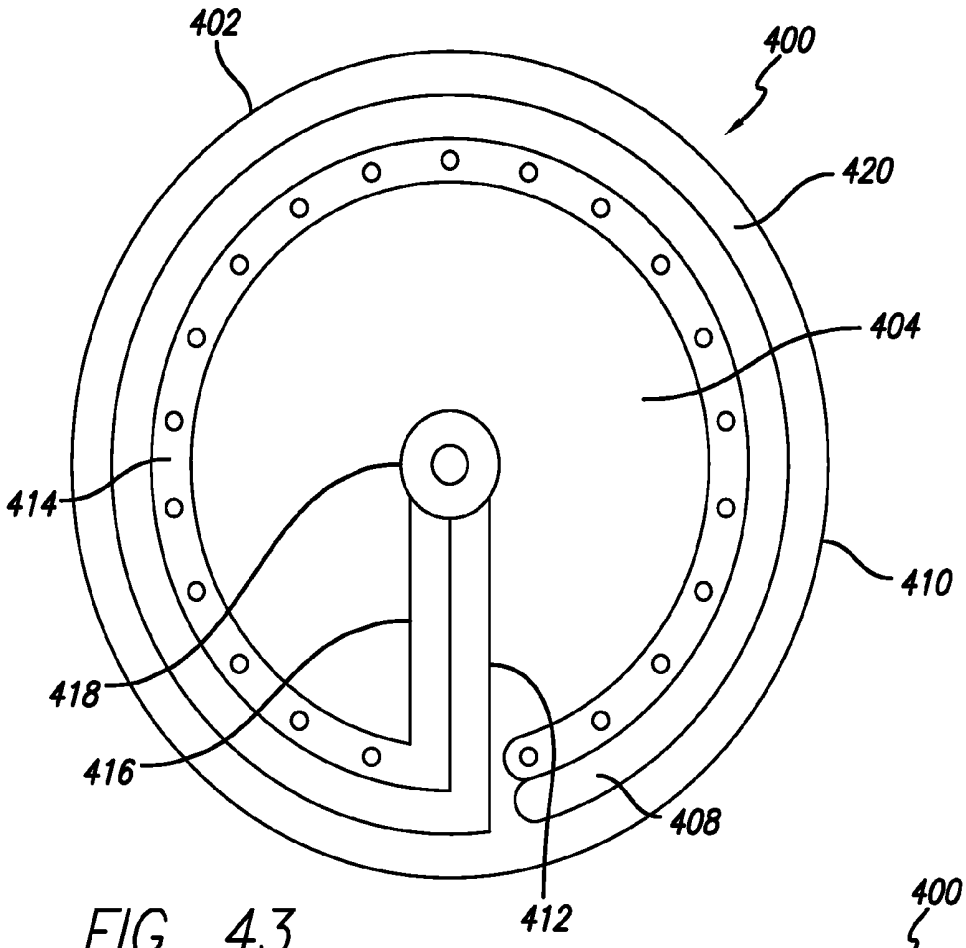
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FIG. 43

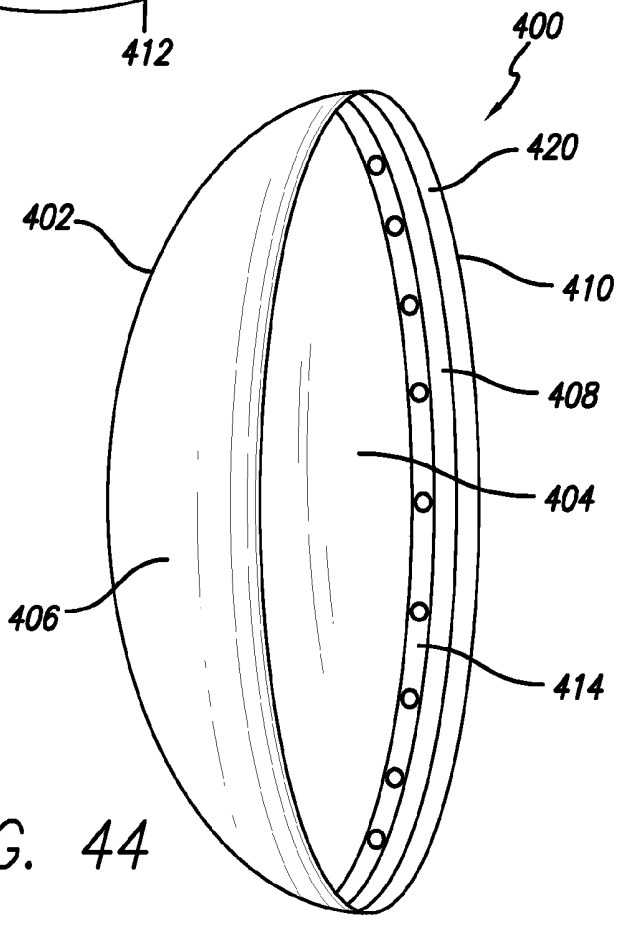
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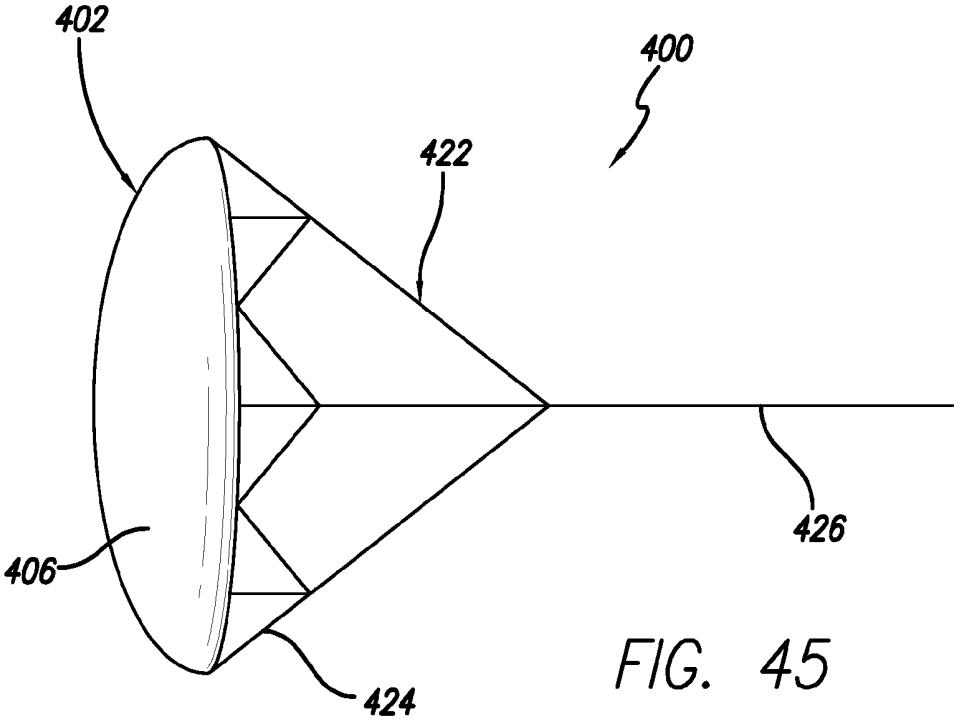
FIG. 44



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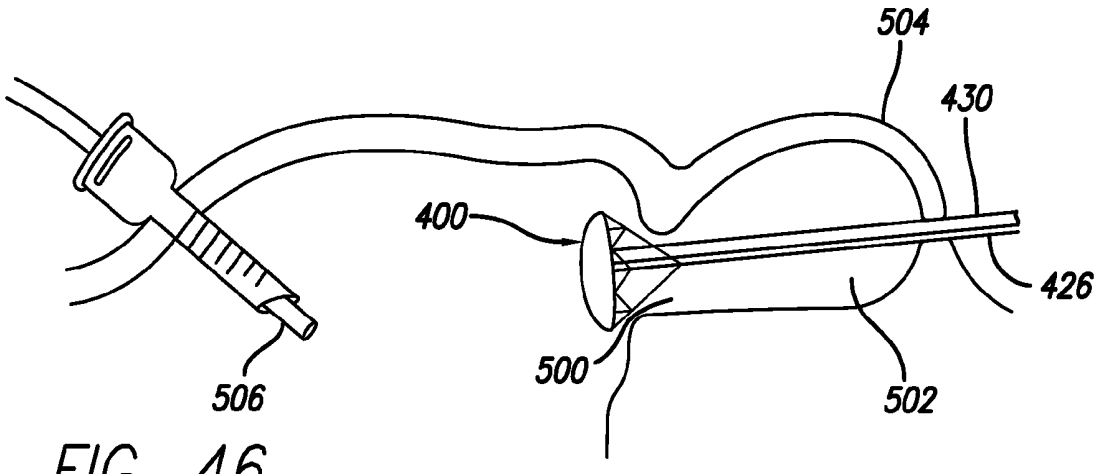

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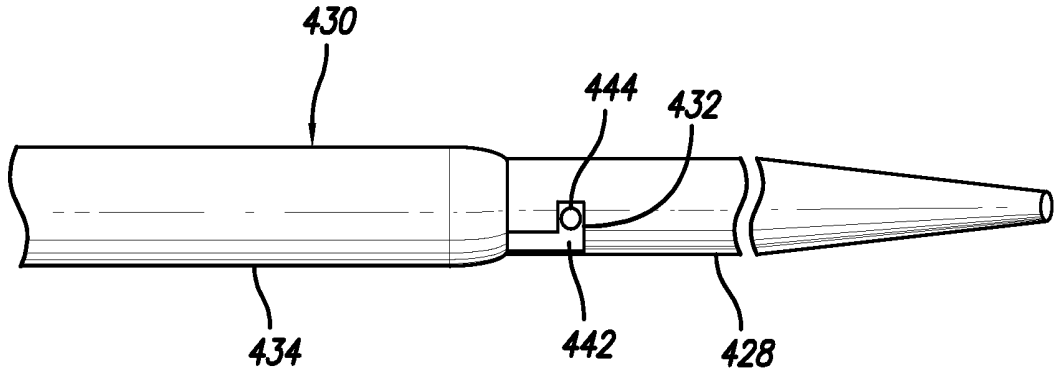


FIG. 47

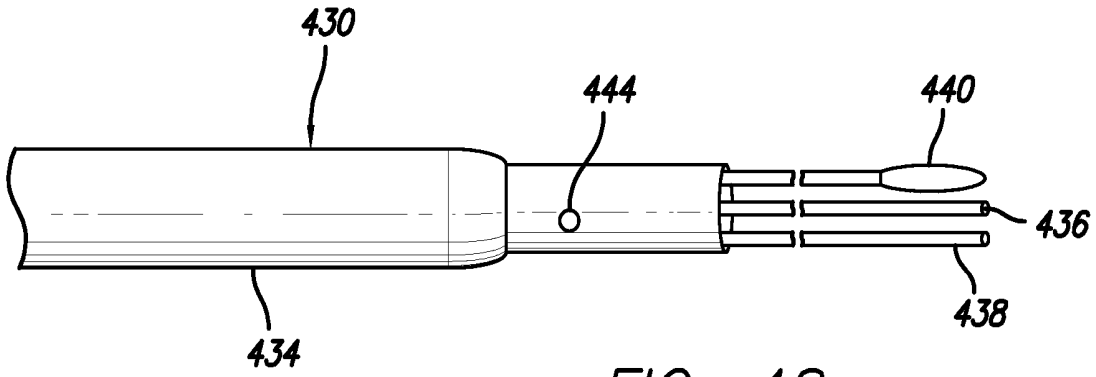
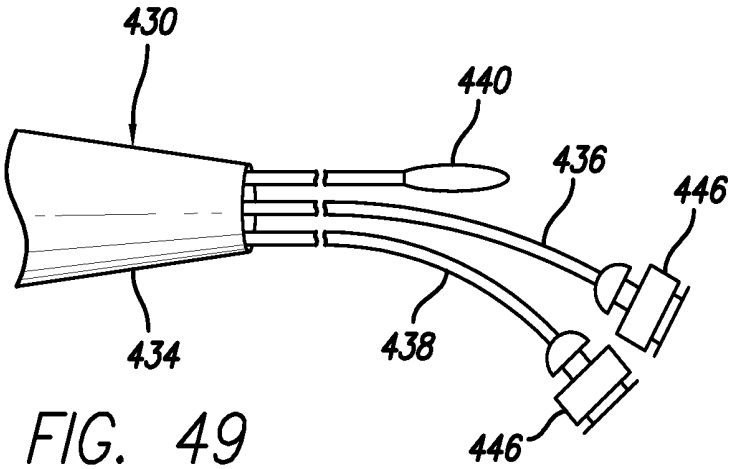


FIG. 48



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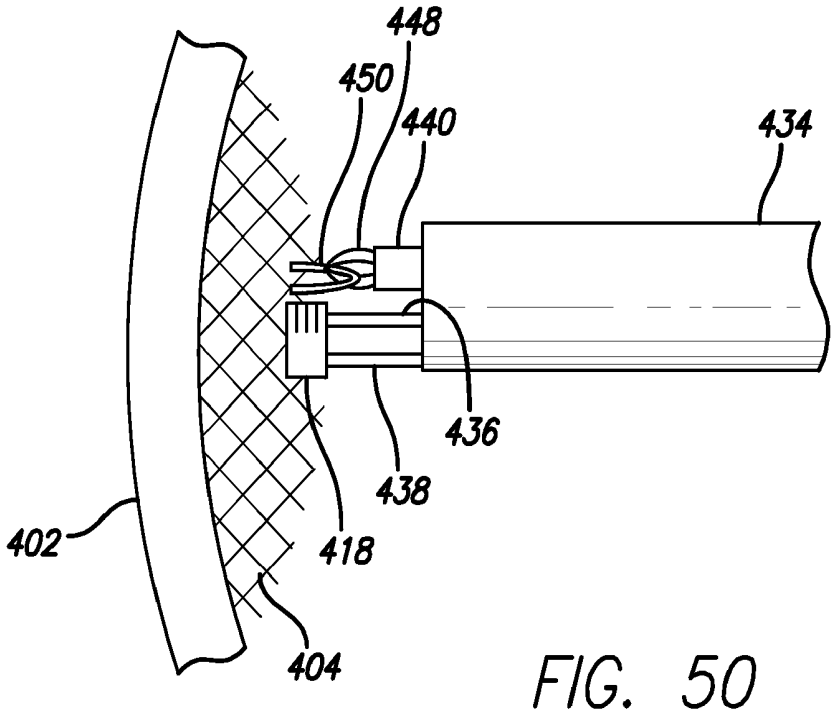
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FIG. 50

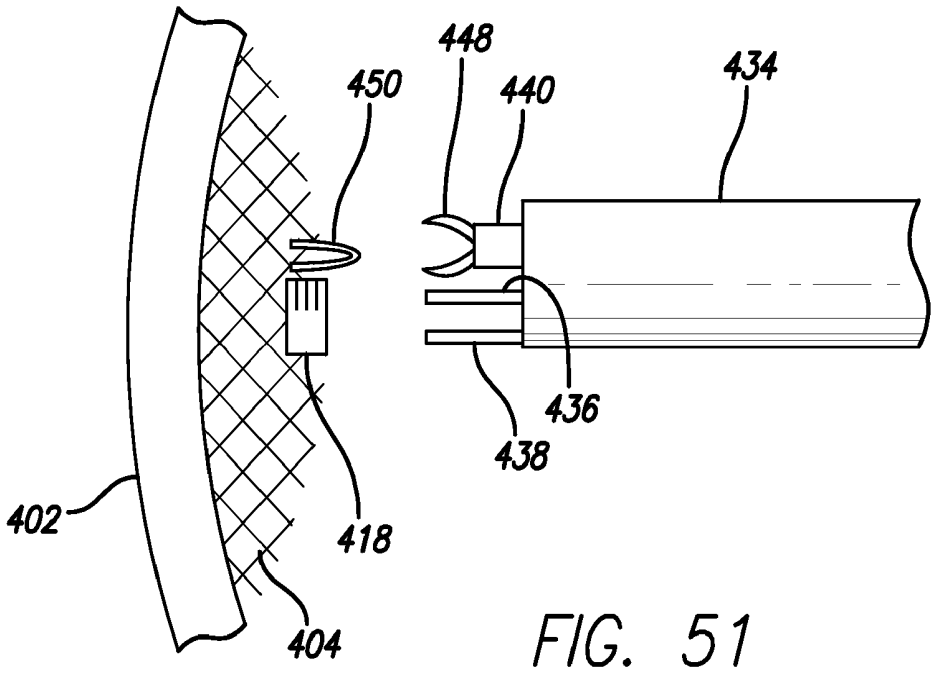
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FIG. 51

METHOD AND DEVICE FOR CAVITY OBLITERATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application No. 60/743,922 titled "Method and Device for Cavity Obliteration" filed Mar. 29, 2006; U.S. Provisional Patent Application No. 60/744,549 titled "Method and Device for Cavity Obliteration" filed Apr. 10, 2006; and U.S. Provisional Patent Application No. 60/745,349 titled "Method and Device for Cavity Obliteration" filed Apr. 21, 2006, the contents of which are incorporated in this disclosure by reference in their entirety.

BACKGROUND

[0002] There are a number of human diseases and conditions that include the existence of an aberrant space or cavity, such as, for example, a hernia sac of an inguinal hernia, and for which treatment of the disease or condition involves obliteration of the space or cavity. Generally, obliteration of the hernia sac of an inguinal hernia is accomplished by an open procedure where the connection between the sac and the peritoneal cavity is visualized, and the sac is then obliterated under direct visualization. There are, however, a number of disadvantages to open surgical approaches for the repair of inguinal hernias, including the need for a moderately sized skin incision that involves a significant risk of wound dehiscence, infection, post-operative pain, hernia recurrence, and an extended recuperative period.

[0003] Therefore, there remains a need for a new method for the obliteration of an aberrant space or cavity, such as the hernia sac of an inguinal hernia.

SUMMARY

[0004] According to one embodiment of the present invention, there is provided a device for the obliteration of an aberrant space or cavity. The device comprises: a) a patch portion comprising a first side and an opposing second side; b) a plurality of struts arranged radially between the first side and the second side, where each strut comprises a first end and a second end; and c) a clip associated with the second end of each strut; where the patch portion has a center and a circumference; where the first end of each strut is oriented toward the center of the patch portion, and the second end is oriented toward the circumference of the patch portion; where each clip is configured to attach the patch portion to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated; and where each strut comprises two lumens, a first lumen configured to contain a stabilization wire, and a second lumen configured to contain an attachment line. In one embodiment, the device comprises between 2 and 20 struts. In another embodiment, the device comprises between 5 and 8 struts. In one embodiment, the patch portion is convex toward the first side and comprises a generally circular circumference. In one embodiment, the second side comprises visually discernable markings corresponding to the position of each clip. In one embodiment, each strut is curved or bent to create the convex shape of the patch portion. In one embodiment, each clip comprises a plurality of arms comprising a first end and a second end, where the first ends of each arm of each clip are joined together, and are also connected to an attachment line. In one embodiment, the second end of each arm comprises one or more than one gripping tip. In one embodiment, each attachment line is joined at the proximal end to form a collective attachment line allowing simultaneous closing of the second ends of the arms of multiple clips.

[0005] According to another embodiment of the present invention, there is provided a deployment system for deploying a device according to the present invention. In one embodiment, the device comprises: a) a device according to the present invention; b) a deployment catheter comprising a proximal end and a distal end, and configured to advance over a guidewire; and c) one stabilization wire within each of the plurality of struts, where the stabilization wires are joined to a central pull wire within the deployment catheter.

[0006] According to another embodiment of the present invention, there is provided a device for the obliteration of an aberrant space or cavity, the device comprising: a) a patch portion comprising a first side and an opposing second side; and b) a frame portion comprising a first side and an opposing second side; where the first side of the patch portion comprises a first surface of two opposing surfaces of a hook and loop fastener; where the second side of the frame portion further comprises a second surface of two opposing surfaces of a hook and loop fastener configured to mate with the first surface of the first side of the patch portion; where the frame portion further comprises a plurality of peripherally radiating members, each of the peripherally radiating members comprising a first end and a second end; where the first ends of each radiating member are joined together; and where each of the second ends of the peripherally radiating members comprises a structure to attach the radiating member, and hence the frame portion, to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated.

[0007] According to another embodiment of the present invention, there is provided a device for the obliteration of an aberrant space or cavity, the device comprising: a) a patch portion comprising a first side, an opposing second side, and an outer edge; b) an inflation area or inflation channel, which when inflated, gives shape to the patch portion in a post-deployment configuration; c) an adhesive delivery channel comprising a series of perforations to allow adhesive to exit from the adhesive delivery channel; and d) one or more than one valve for introducing inflation material into the inflation area or inflation channel and for introducing adhesive into the adhesive delivery channel. In one embodiment, the inflation area or inflation channel is a circumferential conduit arrayed just central to the outer edge. In another embodiment, the inflation area or inflation channel comprises a single, centrally orientated inflation arm. In another embodiment, the inflation area or inflation channel comprises a single, centrally orientated inflation arm, and the adhesive delivery channel comprises a single, centrally orientated adhesive delivery arm, and the one or more than one valve is positioned in the center of the patch portion in continuity with the centrally orientated inflation arm and the centrally orientated adhesive delivery arm. In one embodiment, the patch portion further comprises a peripheral flange, oriented peripherally to the inflation area or inflation channel to allow the device to be fixed into position through the flange. In one embodiment, the device further comprises a suture harness attached to the first side of the patch portion. In one embodiment, the patch portion further comprises a peripheral flange, oriented peripherally to the inflation area or inflation channel to allow the

device to be fixed into position through the flange; where the device further comprises a suture harness attached to the first side of the patch portion.

[0008] In one embodiment, the first side, the second side or both the first side and the second side of the patch portion comprise material selected from the group consisting of polypropylene, polypropylene mesh, polytetrafluoroethylene (PTFE) graft material and silicone rubber.

[0009] According to another embodiment of the present invention, there is provided a method for the obliteration of an aberrant space or cavity comprising an open end and a closed end. The method comprises: a) selecting an aberrant space or cavity that is suitable for obliteration by the method; b) providing a device according to the present invention; and c) deploying the device to substantially seal the open end of the aberrant space or cavity. In one embodiment, the aberrant space or cavity obliterated by the method is within a living organism. In another embodiment, the aberrant space or cavity obliterated by the method is within a human. In another embodiment, the aberrant space or cavity obliterated by the method is a hernia sac of an inguinal hernia. In one embodiment, the method further comprises creating an opening in the closed end of the aberrant space or cavity and introducing the device through the opening in the closed end of the aberrant space or cavity. In one embodiment, the aberrant space or cavity is the hernia sac of an inguinal hernia, where the hernia sac is covered by skin, and where deploying the device comprises: a) inducing anesthesia; b) distending the hernia sac with carbon dioxide gas; and c) inserting a trocar into the intraperitoneal cavity adjacent the inguinal hernia. In another embodiment, the method further comprises: a) providing an adaptor sheath having two proximal self-sealing valves; b) introducing the sheath through a trocar; c) introducing a laparoscope through the sheath; d) introducing a wire snare into the intraperitoneal cavity through the sheath; e) providing a guidewire having a proximal end and a distal end, and inserting the proximal end of the guidewire through the skin over the hernia sac; f) advancing the proximal end of the guidewire into the intraperitoneal cavity; g) capturing the proximal end of the guidewire with the wire snare; h) pulling the proximal end of the guidewire through the trocar; i) providing a delivery device comprising a capsule having a proximal end and a distal end and a pusher, and containing a deployment system comprising the device in a pre-deployment configuration within the capsule; j) advancing the delivery device containing the deployment system over the guidewire through the trocar using the delivery catheter in monorail fashion until the distal end of the capsule contacts the area surrounding the hernia sac; k) releasing the deployment system with the device from the delivery device by maintaining the pusher in place and retracting the capsule proximally; l) changing the patch portion of the device to a post-deployment configuration; m) withdrawing the delivery device from the trocar; and n) positioning the patch portion of the device, thereby effecting the obliteration of the aberrant space or cavity.

[0010] According to another embodiment of the present invention, there is provided a method for the obliteration of an aberrant space or cavity comprising an open end and a closed end, the method comprising: a) selecting an aberrant space or cavity that is suitable for obliteration by the method; b) providing a device according to the present invention; c) deploying the device to substantially seal the open end of the aberrant space or cavity; d) inflating the inflation area or inflation channel of the patch portion of the device to impart structural rigidity to the patch portion; and e) introducing adhesive through the adhesive delivery conduit and allowing the adhesive to discharge from the series of perforations in the adhesive delivery channel.

FIGURES

[0011] These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying figures which depict various views and embodiments of the device, and some of the steps in certain embodiments of the method of the present invention, where:

[0012] FIG. **1** is a lateral perspective view of one embodiment of the device for the obliteration of an aberrant space or cavity in a pre-deployment configuration;

[0013] FIG. **2** is a lateral perspective view of the embodiment of the device shown in FIG. **1** in a post-deployment configuration;

[0014] FIG. **3** is a lateral perspective view of the frame portion of the device shown in FIG. **2** in a post-deployment configuration;

[0015] FIG. **4**, FIG. **5** and FIG. **6** are close-up, lateral perspective views of one embodiment of a clip suitable for incorporation into the embodiment shown in FIG. **1**, FIG. **2** and FIG. **3**;

[0016] FIG. **7** is a partial cross-sectional view of an aberrant space or cavity after having been sealed by the device as shown in FIG. **1** and FIG. **2**;

[0017] FIG. **8** is a top perspective view of the first side of the patch portion of another embodiment of the device for the obliteration of an aberrant space or cavity in a post-deployment configuration;

[0018] FIG. **9** is a bottom perspective view of the second side of the patch portion of the embodiment of the device shown in FIG. **8** in a post-deployment configuration;

[0019] FIG. **10** is a lateral perspective view of the patch portion of the device shown in FIG. **8** and FIG. **9** in a post-deployment configuration;

[0020] FIG. **11** is a lateral perspective view of a strut and clip of the device shown in FIG. **9**;

[0021] FIG. **12** is a cross-sectional view of the strut shown in FIG. **11**;

[0022] FIG. **13** is a close-up, partial, cutaway, perspective view of the second end of the strut shown in FIG. **11** shown in the pre-deployment configuration;

[0023] FIG. **14** is a close-up, partial, cutaway, perspective view of the second end of the strut shown in FIG. **11** shown in the post-deployment configuration;

[0024] FIG. **15** is a lateral perspective view of a stabilization wire used in the device;

[0025] FIG. **16** is a lateral perspective view of the strut and clip of the device shown in FIG. **11** with the stabilization wire shown in FIG. **15** in position within the strut;

[0026] FIG. **17** is a cross-sectional view of the mid section of the strut shown in FIG. **16**;

[0027] FIG. **18** is a lateral perspective view of a group of stabilization wires, as shown in FIG. **15**, joined together centrally by a fitting to a central pull wire;

[0028] FIG. **19** is a partial, lateral perspective view of a deployment system according to the present invention;

[0029] FIG. **20**, FIG. **21** and FIG. **22** are partial, lateral perspective views of the stabilization wires, central pull wire and metal fitting as they are retracted into the proximal end of the deployment catheter;

[0030] FIG. **23**, FIG. **24** and FIG. **25** are partial lateral perspective views of the proximal end of the deployment system, showing the device of the present invention being rotated for proper placement, the stabilization wires being withdrawn from the struts into the proximal end of the deployment catheter, and the deployment catheter with the struts inside being separated from the device;

[0031] FIG. **26** is a cross-sectional view of an aberrant space or cavity suitable for obliteration by a method for the obliteration of an aberrant space or cavity according to the present invention;

[0032] FIG. **27**, FIG. **30**, FIG. **31** and FIG. **33** through FIG. **37** are cross-sectional views of various steps in a method for the obliteration of an aberrant space or cavity according to the present invention;

[0033] FIG. **28** is a lateral perspective view of an adaptor sheath for use in the present method;

[0034] FIG. **29** is a lateral perspective view of a wire snare for use in the present method;

[0035] FIG. **32** is a partial, lateral perspective view of a delivery device suitable for use in the present method;

[0036] FIG. **38** is a lateral perspective view of the second side of the patch portion of another embodiment of the device for the obliteration of an aberrant space or cavity in a post-deployment configuration;

[0037] FIG. **39** is a top perspective view of the frame portion of the embodiment of the device shown in FIG. **38** in a post-deployment configuration;

[0038] FIG. **40** is a bottom perspective view of the patch portion of the device shown in FIG. **38** and the frame shown in FIG. **39** in a post-deployment configuration, where the patch portion and frame portion are joined together;

[0039] FIG. **41** is a partial lateral perspective view of the opposing surfaces of a hook and loop fastener with the two sides in the unattached configuration;

[0040] FIG. **42** is a partial lateral perspective view of the opposing surfaces of a hook and loop fastener as shown in FIG. **41** with the two sides in the attached configuration;

[0041] FIG. **43** is a top perspective view of the first side of the patch portion of another embodiment of the device for the obliteration of an aberrant space or cavity in a post-deployment configuration;

[0042] FIG. **44** is a lateral perspective view of the patch portion of the device shown in FIG. **43** in a post-deployment configuration;

[0043] FIG. **45** is a lateral perspective view of the patch portion and optional suture harness of the device shown in FIG. **43** in a post-deployment configuration;

[0044] FIG. **46** is a cross-sectional view of one step in the present method for the obliteration of an aberrant space or cavity according to the present invention;

[0045] FIG. **47** is a partial, close-up lateral perspective view of the distal end of the deployment catheter as shown in FIG. **46**;

[0046] FIG. **48** is a partial, close-up lateral perspective view of the distal end of the deployment catheter as shown in FIG. **47** with the distal portion of the deployment catheter removed;

[0047] FIG. **49** is a partial, close-up lateral perspective view of the distal end of the deployment catheter as shown in FIG. **48** with luer lock hubs attached to the inflation material delivery conduit and to the adhesive delivery conduit;

[0048] FIG. **50** and FIG. **51** are sequential, partial close-up lateral perspective views of the patch portion of the device in the post-deployment configuration being separated from the proximal portion of the deployment catheter, the inflation material delivery conduit, the adhesive delivery conduit and the pusher rod according to the embodiment of the method shown in FIG. **46**.

DESCRIPTION

[0049] According to one embodiment of the present invention, there is provided a device for the obliteration of an aberrant space or cavity. In a preferred embodiment, the aberrant space or cavity is within a living organism, such as within a human. In another preferred embodiment, the aberrant space or cavity is a hernia sac of an inguinal hernia. In another preferred embodiment, the aberrant space or cavity is a vascular or cardiac aneurysm. According to another embodiment of the present invention, there is provided a method for the obliteration of an aberrant space or cavity comprising an open end and a closed end. In a preferred embodiment, the aberrant space or cavity obliterated by the method is within a living organism, such as within a human. In another preferred embodiment, the aberrant space or cavity obliterated by the method is a hernia sac of an inguinal hernia. In another preferred embodiment, the aberrant space or cavity is a vascular or cardiac aneurysm. In one embodiment, the method comprises providing a device according to the present invention. In another embodiment, the method comprises deploying a device through the opening created in the closed end of the aberrant space or cavity.

[0050] As used in this disclosure, the term "comprise" and variations of the term, such as "comprising" and "comprises," are not intended to exclude other additives, components, integers or steps.

[0051] As used in this disclosure, the term "closed end of the aberrant space or cavity" means any position on the wall of the aberrant space or cavity other than through the open end of the aberrant space or cavity.

[0052] As used in this disclosure, the term "obliterate" means to substantially seal the open end of the aberrant space or cavity.

[0053] All dimensions specified in this disclosure are by way of example only and are not intended to be limiting. Further, the proportions shown in these Figures are not necessarily to scale. As will be understood by those with skill in the art with reference to this disclosure, the actual dimensions of any device or part of a device disclosed in this disclosure will be determined by its intended use.

[0054] The method steps disclosed in this disclosure are not intended to be limiting nor are they intended to indicate that each step depicted is essential to the method, but instead are exemplary steps only.

[0055] According to one embodiment of the present invention, there is provided a device for the obliteration of an aberrant space or cavity. In a preferred embodiment, the aberrant space or cavity is within a living organism, such as within a human. In another preferred embodiment, the aberrant space or cavity is a hernia sac of an inguinal hernia. In another preferred embodiment, the aberrant space or cavity is a vascular or cardiac aneurysm.

[0056] Referring now to FIG. **1**, FIG. **2** and FIG. **3**, there are shown, respectively, a lateral perspective view of one embodiment of the device for the obliteration of an aberrant space or cavity in a pre-deployment configuration (FIG. **1**); a lateral perspective view of the embodiment of the device shown in FIG. **1** in a post-deployment configuration (FIG. **2**); and a

lateral perspective view of the frame portion of the device shown in FIG. **2** in a post-deployment configuration (FIG. **3**). As can be seen, in this embodiment, the device **100** comprises a first side **102**, an opposing second side **104**, and a frame **106** between the first side **102** and the second side **104**.

[0057] In one embodiment, the first side **102** and the second side **104** comprise material selected from the group consisting of polypropylene, polytetrafluoroethylene (PTFE) graft material and silicone rubber. In a preferred embodiment, such as when the device **100** is being used to obliterate an inguinal hernia sac in a human, the first side **102** comprises polypropylene and the second side **104** comprises polytetrafluoroethylene. The first side **102** and the second side **104** can, however, comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure.

[0058] The frame **106** comprises a plurality of peripherally radiating members **108** comprising a first end **110** and a second end **112**. The first end **110** of each radiating member **108** is joined at a central connector **114**. The second end **112** of one or more than one of the radiating members **108** comprises a clip **116** to attach the radiating member **108** to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated, such as to the peritoneal surface at the entry site into the hernia sac of an inguinal hernia, thereby immobilizing the device **100** in position.

[0059] As can be seen with particular reference to FIG. **1**, when this embodiment is in a pre-deployment configuration, the second ends **112** of the radiating members **108** approximate, thereby rendering the device **100** into a smaller axial profile than in a post-deployment configuration suitable for deployment through a small opening. As can be seen with particular reference to FIG. **2**, in a preferred embodiment, when the device is deployed, the first side **102** and the second side **104** form a patch that is concave toward the first side **102** and that comprises a generally circular circumference, though other configurations are suitable for various uses of the device **100**, as will be understood by those with skill in the art with reference to this disclosure.

[0060] As can be seen with particular reference to FIG. **2** and FIG. **3**, after deployment, the second ends **112** of the radiating members **108** are separated by actuating a mechanism in the central connector **114**, thereby rendering the device **100** into a post-deployment configuration suitable for sealing the opening of the aberrant space or cavity. In one embodiment, the frame **106** comprises wire, such as a shaped metal alloy or is a shaped memory polymer, such as a suitable polystyrene material. In a preferred embodiment, the metal alloy is selected from the group consisting of a nitinol and a cobalt-chromium-nickel-molybdenum-iron alloy specified by ASTM F1058 and ISO 5832-7, stainless steel or a ferrous alloy containing cobalt, chromium, nickel, molybdenum, manganese, carbon, and beryllium, such as Elgiloy® (RMO, Denver, Colo. US). In a preferred embodiment, such as when the device **100** is used to obliterate an aberrant space or cavity within a human, the frame **106** comprises wire of a biocompatible material.

[0061] Referring now to FIG. **4**, FIG. **5** and FIG. **6**, there are shown, respectively, close-up, lateral perspective views of parts of one embodiment of a clip **116** suitable for incorporation into the embodiment shown in FIG. **1**, FIG. **2** and FIG. **3**. As will be understood by those with skill in the art with reference to this disclosure, other clips are also suitable for incorporation into the device **100**. In the embodiment shown in FIG. **4**, FIG. **5** and FIG. **6**, the clip **116** comprises a plurality of arms **118** comprising a first end **120** and a second end **122**. The first ends **120** of each arm **118** of each clip **116** are joined together, and are also joined to an attachment line **124**. In a preferred embodiment, the second end **122** of each arm **118** comprises one or more than one gripping tip, such as, for example, a sharp point or barb. Though shown with only two arms **118**, each clip **116** can comprise three or more arms, as will be understood by those with skill in the art with reference to this disclosure. Each clip **116** further comprises a tubular structure **126** surrounding the first end **120** and attached to the frame **106**. In one embodiment, each clip **116** comprises tantalum, titanium or another suitable metal; however, each clip **116** can comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure.

[0062] As can be seen with particular reference to FIG. **5**, in the pre-deployment position, the second ends **122** of each arm **118** are separated from each other and extend maximally outside the tubular structure **126**. As can be seen with particular reference to FIG. **6**, after deployment, axial force is applied to the attachment line **124**, toward the central connector **114** of the frame **106**, thereby translating the joined first ends **120** of the clip **116** axially toward the central connector **114**, and approximating the second ends **122** of the clip **116**. Any surface or structure adjacent to or within the aberrant space or cavity to be obliterated between the second ends **122** of the clip **116** at the time of deployment is then caught between the second ends **122**, thereby immobilizing the device **100** in position. In a preferred embodiment, the second side **104** comprises visually discernable markings corresponding to the placement of each clip **116**.

[0063] According to another embodiment of the present invention, there is provided a method for the obliteration of an aberrant space or cavity comprising an open end and a closed end. In a preferred embodiment, the aberrant space or cavity obliterated by the method is within a living organism, such as within a human. In another preferred embodiment, the aberrant space or cavity obliterated by the method is a hernia sac of an inguinal hernia. In one embodiment, the method comprises providing a device according to the present invention, and deploying the device to substantially seal the open end of the aberrant space or cavity. In another embodiment, the method comprises creating an opening in the closed end of the aberrant space or cavity, introducing a device through the opening in the closed end of the aberrant space or cavity, and deploying the device to substantially seal the open end of the aberrant space or cavity. In a preferred embodiment, the device introduced is a device according to the present invention.

[0064] By way of example, the method will now be disclosed in greater detail with specific reference to the obliteration of a hernia sac of an inguinal hernia. As will be understood by those with skill in the art with reference to this disclosure, however, equivalent steps can be used to obliterate any aberrant space or cavity suitable for obliteration by the present method, including an aberrant space or cavity other than the hernia sac of an inguinal hernia, other than within a living organism, and other than within a human.

[0065] As will be appreciated by one with skill in the art with reference to this disclosure, when the method of the present invention is used to obliterate the hernia sac of an inguinal hernia, the method preferably involves a percutaneous transcatheter approach, though a laparoscopic approach or open surgical approach can also be used. Specifically, in a

preferred embodiment, the method comprises deploying a device through an opening created in the closed end of the aberrant space or cavity using a percutaneous transcatheter approach. Compared with open surgical and laparoscopic approaches for the treatment of inguinal hernias currently performed, the percutaneous transcatheter approach of the present method reduces procedure times, decreases risks of infection, requires smaller incisions and fewer punctures, and reduces recuperation time. Further, the method reduces procedural costs due to the utilization of an interventional radiology suite for the repair instead of a more expensive operating room environment.

[0066] Referring now to FIG. **7**, there is shown a partial cross-sectional view of an aberrant space or cavity after having been obliterated by the device according to the present invention as shown in FIG. **1** and FIG. **2**. The steps disclosed are not intended to be limiting nor are they intended to indicate that each step depicted is essential to the method, but instead are exemplary steps only.

[0067] The method comprises, first selecting an aberrant space or cavity **150** that is suitable for obliteration by the method. The aberrant space or cavity **150** comprises an open end **152** and a closed end **154**. In one embodiment, the aberrant space or cavity **150** is within a living organism. In a preferred embodiment, the aberrant space or cavity **150** is within a human. In a particularly preferred embodiment, the aberrant space or cavity **150** is a hernia sac of an inguinal hernia within a human.

[0068] In one embodiment, selecting an aberrant space or cavity **150** that is suitable for obliteration by the method comprises selecting a patient having a disease or condition that includes the existence of an aberrant space or cavity **150**, such as, for example, the hernia sac of an inguinal hernia, and for which treatment of the disease or condition involves obliteration of the aberrant space or cavity **150**. In this embodiment, selecting the patient comprises diagnosing the existence of an aberrant space or cavity **150** using standard techniques, such as a technique selected from the group consisting of CT scan, herniography, history, MRI and physical examination.

[0069] The following steps are disclosed with respect to obliterating the hernia sac **150** of an inguinal hernia as an example. Next, anesthesia is induced, and the lower abdomen and inguinal areas prepped and draped in a sterile fashion, according to standard techniques. Then, an opening **158** is created in the closed end **154** of the hernia sac **150**. A device for obliterating the hernia sac **150** is deployed, thereby obliterating the hernia sac **150**. In a preferred embodiment, the device deployed is a device **100** for the obliteration of an aberrant space or cavity **150** according to the present invention. In another preferred embodiment, the device is introduced percutaneously. Introduction of the device can be accomplished in a number of ways depending on the embodiment of the device used, as will be understood by those with skill in the art with reference to this disclosure.

[0070] By way of example only, various introduction steps will now be disclosed in detail. A puncture incision is made in the skin of the lower abdomen **156** with a 20-22 gauge needle. In one embodiment, the peritoneal cavity is inflated with a suitable gas, such as, for example, carbon dioxide gas, which also distends the hernia sac **150**. Then, the closed end **154** of the distended hernia sac **150** is then entered by a second incision, such as a puncture incision, with an 18-gauge needle creating an opening **158** in the closed end **154**. A 1 mm diameter guidewire is advanced under suitable guidance, such as, for example, fluoroscopic guidance, through the opening **158** in the closed end **154** of the hernia sac **150**, through the hernia sac **150**, and through the open end **152** of the hernia sac **150** into the peritoneal cavity. Next, the needle is removed, and over the guidewire, a 12 F to 14 F (4.0 mm to 4.7 mm) introducer catheter with its central dilator is advanced through the opening **158** in the closed end **154** of the hernia sac **150**, through the hernia sac **150**, and through the open end **152** of the hernia sac **150** into the peritoneal cavity. The guidewire and central dilator are then removed.

[0071] Then, a device **100** according to the present invention in its pre-deployment configuration is advanced into the hernia sac **150**. In a preferred embodiment, the device **100** is advanced through the introducer catheter directly. Introducing the device **100** into the hernia sac **150**, whether through the introducer catheter or not, can comprise collapsing the device **100** by bringing the perimeter of the device **100** toward the center, or by another method as will be understood by those with skill in the art with reference to this disclosure. The device **100** is deployed at or near the open end **152** of the hernia sac **150** at the junction of the peritoneal cavity. As appropriate for the embodiment of the device **100**, the device **100** can be attached to a pusher rod to assist in proper placement of the device **100** during deployment. Referring again to FIG. **7**, when deployed, the clips **116** attach the frame **106**, and hence the device **100**, to the peritoneal surface adjacent to or within the hernia sac **150**, thereby immobilizing the device **100** and obliterating the cavity **150**.

[0072] Referring now to FIG. **8** through FIG. **18**, there are shown, respectively, a top perspective view of the first side of the patch portion of another embodiment of the device for the obliteration of an aberrant space or cavity in a post-deployment configuration (FIG. **8**); a bottom perspective view of the second side of the patch portion of the embodiment of the device shown in FIG. **8** in a post-deployment configuration (FIG. **9**); a lateral perspective view of the patch portion of the device shown in FIG. **8** and FIG. **9** in a post-deployment configuration (FIG. **10**); a lateral perspective view of a strut and clip of the patch portion of the device shown in FIG. **9** (FIG. **11**); a cross-sectional view of the strut shown in FIG. **11** (FIG. **12**); a close-up, partial, cutaway, perspective view of the second end of the strut shown in FIG. **11** shown in the pre-deployment configuration (FIG. **13**); a close-up, partial, cutaway, perspective view of the second end of the strut shown in FIG. **11** shown in the post-deployment configuration (FIG. **14**); a lateral perspective view of a stabilization wire used in the device (FIG. **15**); a lateral perspective view of the strut and clip of the patch portion of the device shown in FIG. **11** with the stabilization wire shown in FIG. **15** in position within the strut (FIG. **16**); a cross-sectional view of the mid section of the strut shown in FIG. **16** (FIG. **17**); and a lateral perspective view of a group of stabilization wires, as shown in FIG. **15**, joined together centrally by a fitting to a central pull wire (FIG. **18**). As can be seen, in this embodiment, the device **200** comprises a patch portion **202** comprising a first side **204**, an opposing second side **206**, a plurality of struts **208** arranged radially between the first side **204** and the second side **206**, and a clip **210** associated with each strut. Except as disclosed in this disclosure, the embodiment of the device **200** is constructed and functions similarly to the embodiment of the device **100** of the present invention.

[0073] In one embodiment, the first side **204**, the second side **206** or both the first side **204** and the second side **206**

comprise material selected from the group consisting of polypropylene, polypropylene mesh, polytetrafluoroethylene (PTFE) graft material and silicone rubber. In a preferred embodiment, such as when the device **200** is being used to obliterate an inguinal hernia sac in a human, the first side **204** comprises polypropylene mesh and the second side **206** comprises polytetrafluoroethylene. The first side **204** and the second side **206** can, however, comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure.

[0074] Each strut **208** comprises a first end **212** and a second end **214**. The patch portion **202** has a center and a circumference. The first end **212** of each strut **208** is oriented toward the center of the patch portion **202**, and the second end **214** is oriented toward the circumference of the patch portion **202**. Each strut **208** has a clip **210** associated with the second end **214** of the strut **208** to attach the patch portion **202** to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated, such as to the peritoneal surface at the entry site into the hernia sac of an inguinal hernia, thereby immobilizing the patch portion **202** of the device **200** in position.

[0075] In one embodiment, the device **200** comprises two or more than two struts **208**. In another embodiment, the device **200** comprises between 2 and 20 struts **208**. In another embodiment, the device **200** comprises between 5 and 8 struts **208**.

[0076] FIG. **8**, FIG. **9** and FIG. **10** show the device **200** in a post-deployment configuration. As can be seen with particular reference to FIG. **10**, in a preferred embodiment, when this embodiment is in a post-deployment configuration, the patch portion **202** is convex toward the first side **204** and comprises a generally circular circumference, though other configurations are suitable, as will be understood by those with skill in the art with reference to this disclosure.

[0077] In a preferred embodiment, the second side **206** comprises visually discernable markings **216**, such as for example colored dots, corresponding to the position of each clip **210**.

[0078] Referring now to FIG. **11** through FIG. **14**, each strut **208** is curved or bent to create the convex shape of the patch portion **202** in the post-deployment configuration. Each strut comprises material suitable for maintaining the desired shape of the patch portion **202**. In a preferred embodiment, such as when the device **200** is used to obliterate an aberrant space or cavity within a human, each strut **208** comprises polypropylene or another suitable biocompatible polymer.

[0079] As can be seen best in FIG. **12**, in one embodiment, each strut **208** comprises two lumens, a first lumen **218** and a second lumen **220**. The first lumen **218** is configured to contain a stabilization wire **222**. The second lumen **220** is configured to contain an attachment line **224**.

[0080] Referring now particularly to FIG. **13** and FIG. **14**, the clip **210** corresponds to the clip **116** disclosed in connection with the embodiment of the device **100**, and comprises a plurality of arm **226** comprising a first end **228** and a second end **230**. The first ends **228** of each arms **226** of each clip **210** are joined together, and are also connected to the attachment line **224**. In a preferred embodiment, the second end **230** of each arm **226** comprises one or more than one gripping tip, such as, for example, a sharp point or barb. Though shown with only two arms **226**, in one embodiment, each clip **210** comprises three or more arms, as will be understood by those with skill in the art with reference to this disclosure. In one embodiment, each clip **210** comprises tantalum, titanium or another suitable metal; however, each clip **210** can comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure.

[0081] As can be seen with particular reference to FIG. **13**, in the pre-deployment position, the second ends **230** of each arm **226** are separated from each other and extend maximally outside the second end **214** of the strut **208**. As can be seen with particular reference to FIG. **14**, after deployment, axial force is applied to the attachment line **224** toward the center of the patch portion **202**, thereby translating the joined first ends **212** of the clip **210** axially toward the center of the patch portion **202** within the strut **208**, and approximating the second ends **230** of the arms **226** of the clip **210** by crimping the clip **210** at the joined first ends **228**. Any surface or structure adjacent to or within the aberrant space or cavity to be obliterated between the second ends **230** of the clip **210** at the time of deployment is then caught between the second ends **230**, thereby immobilizing the device **200** in position. Each attachment line **224** is joined at the proximal end to form a collective attachment line allowing simultaneous closing of the second ends **230** of the arms **226** of multiple clips **210**.

[0082] Referring now to FIG. **15**, there is shown a lateral perspective view of a stabilization wire **222** used with the device **200**. The stabilization wire **222** assists in positioning and in deploying the device **200**. In one embodiment, the stabilization wire **222** comprises a superelastic shape memory material, such as a shaped metal alloy, or comprises a shaped memory polymer, such as a suitable polystyrene material. In a preferred embodiment, the metal alloy is selected from the group consisting of nitinol and Elgiloy®. In another preferred embodiment, the stabilization wire **222** has an outer diameter of between about 0.2 mm and 0.35 mm. In a preferred embodiment, there is provided one stabilization wire **222** for each strut **208**. The stabilization wire **222** comprises a proximal end **232** and a distal end **234**. As can be seen particularly in FIG. **18**, the proximal ends **232** of each stabilization wire **222** are joined to a central pull wire **236** by a small metal fitting **238**.

[0083] According to another embodiment of the present invention, there is provided a deployment system for deploying the device **200** for the obliteration of an aberrant space or cavity according to the present invention. Referring now to FIG. **19**, there is shown a partial, lateral perspective view of a deployment system **240** according to the present invention. As can be seen, the deployment system **240** comprises a device **200** according to the present invention. The deployment system **240** further comprises a deployment catheter **242** comprising a proximal end **244** and a distal end **246**. The deployment catheter **242** tapers from its proximal end **244** to its distal end **246**, such as for example being 8 F (2.7 mm) at its proximal end **244** and 4 F to 5 F (1.35 mm to 1.67 mm) at its distal end **246**. Preferably, the deployment catheter **242** is very stiff. The deployment catheter **242** is configured to advance over a guidewire **248**, such as for example a 1 mm guidewire, in monorail fashion, as will be understood by those with skill in the art with reference to this disclosure. The deployment system **240** further comprises one stabilization wire **222** within each of the plurality of struts **208**, where the stabilization wires **222** are joined to a central pull wire, such as for example by a small metal fitting **238**, within the deployment catheter **242**.

[0084] Referring now to FIG. **20**, FIG. **21** and FIG. **22**, there are shown partial, lateral perspective views of the stabiliza-

tion wires **222**, central pull wire **236** and metal fitting **238** as they are retracted into the proximal end **244** of the deployment catheter **242**. The stabilization wires **222** and deployment catheter **242** function to allow precise rotation and positioning of the device **200**, to maintain the shape and rigidity of the device **200** while the clips **210** are being crimped to engage the material around the opening of the aberrant space or cavity thereby obliterating the opening, and to allow the struts **208** to detach from the device **200**, thereby leaving the device **200** in position after sealing the opening.

[0085] Referring now to FIG. **23**, FIG. **24** and FIG. **25**, there are shown partial, lateral perspective views of the proximal end of the deployment system **240**, showing the device **200** being rotated for proper placement (FIG. **23**); showing the stabilization wires **222** being withdrawn from the struts **208** into the proximal end **244** of the deployment catheter **242** (FIG. **24**); and showing the deployment catheter **242** with the struts **208** inside being separated from the device **200** (FIG. **25**). The deployment catheter **242** also transmits the attachment line **224** (not shown in these Figures) for crimping the clips **210**.

[0086] According to another embodiment of the present invention, there is provided another method for the obliteration of an aberrant space or cavity comprising an open end and a closed end. In a preferred embodiment, the aberrant space or cavity obliterated by the method is within a living organism, such as within a human. In another preferred embodiment, the aberrant space or cavity obliterated by the method is a hernia sac of an inguinal hernia. In one embodiment, the method comprises providing a device according to the present invention, and deploying the device to substantially seal the open end of the aberrant space or cavity. In another embodiment, the method comprises creating an opening in the closed end of the aberrant space or cavity, introducing a device through the opening in the closed end of the aberrant space or cavity, and deploying the device to substantially seal the open end of the aberrant space or cavity. In a preferred embodiment, the device introduced is a device according to the present invention.

[0087] By way of example, the method will now be disclosed in greater detail with specific reference to the obliteration of a hernia sac of an inguinal hernia. As will be understood by those with skill in the art with reference to this disclosure, however, equivalent steps can be used to obliterate any aberrant space or cavity suitable for obliteration by the present method, including an aberrant space or cavity other than the hernia sac of an inguinal hernia, other than within a living organism, and other than within a human.

[0088] The method comprises, first selecting an aberrant space or cavity that is suitable for obliteration by the method. Referring now to FIG. **26**, there is shown a cross-sectional view of an aberrant space or cavity suitable for obliteration by a method for the obliteration of an aberrant space or cavity according to the present invention. As can be seen, the aberrant space or cavity **250** comprises an open end **252** and a closed end **254**. In one embodiment, the aberrant space or cavity is within a living organism. In a preferred embodiment, the aberrant space or cavity is within a human. In a particularly preferred embodiment, as shown in FIG. **26**, the aberrant space or cavity **250** is a hernia sac of an inguinal hernia within a human.

[0089] In one embodiment, selecting an aberrant space or cavity that is suitable for obliteration by the method comprises selecting a patient having a disease or condition that includes the existence of an aberrant space or cavity, such as, for example, the hernia sac of an inguinal hernia, and for which treatment of the disease or condition involves obliteration of the aberrant space or cavity. In this embodiment, selecting the patient comprises diagnosing the existence of an aberrant space or cavity using standard techniques, such as a technique selected from the group consisting of CT scan, herniography, history, MRI and physical examination.

[0090] The following steps for the present method are disclosed with respect to obliterating the hernia sac of an inguinal hernia as an example only of one type of aberrant space or cavity suitable for obliteration by the present method. After the patient having the inguinal hernia is selected, anesthesia is induced, and the lower abdomen **256** is prepped and draped in a sterile fashion according to standard techniques. Then, the intraperitoneal cavity **258** as well as the hernia sac **250** is distended with carbon dioxide gas according to standard techniques. Next, as can be seen in FIG. **27**, a trocar **260** capable of accommodating a device with an outer diameter of from 28 F to 30 F (9.3 mm to 10.0 mm) is inserted into the intraperitoneal cavity **258** adjacent the inguinal hernia.

[0091] Then, as shown in FIG. **28**, an adaptor sheath **262** having two proximal self-sealing valves **264** to prevent leakage of the carbon dioxide gas is provided. Next, the sheath **262** is introduced through the trocar **260** and a 5 mm laparoscope **266** is introduced through one of the valves **264** into the sheath **262** and, thus, into the intraperitoneal cavity **258**. Then, an Amplatz™ 90° wire snare **268** (Boston Scientific Corporation, Natick, Mass. US), or equivalent structure, within a 6 F to 8 F (2 mm to 2.7 mm) catheter **270** as shown in FIG. **29** is introduced into the second valve **264** of the trocar **260** into the sheath **262** and, thus, into the intraperitoneal cavity **258** as shown in FIG. **30**.

[0092] Next, a guidewire **272** of between about 0.45 mm and 0.9 mm and having a proximal end and a distal end is provided, and the guidewire is inserted through the skin over the hernia sac **250** and the proximal end of the guidewire **272** is advanced into the intraperitoneal cavity **258** as shown in FIG. **30**. Then, as shown in FIG. **31**, under direct vision provided by the laparoscope **266**, the wire snare **268** is used to capture the proximal end of the guidewire **272** and to pull the proximal end of the guidewire **272** through the trocar **260** and outside of the body to provide the operator with control over both the proximal end and the distal end of the guidewire **272**.

[0093] Next, the method comprises providing a delivery device. Referring now to FIG. **32**, there is shown a partial, lateral perspective view of a delivery device suitable for use in the present method. As can be seen, the delivery device **274** comprises a capsule **276** having a narrow proximal end **278** and an expanded distal end **280**. The delivery device **274** further comprises a pusher **282** at least partly within the proximal end **278** and extending outward from the proximal end **278** as shown. The delivery device **274** further comprises a rotating locking adaptor **284** at the proximal end **278** of the capsule **276** for creating a seal between the pusher **282** and the capsule **276**. By way of example only, the proximal end **278** of the capsule **276** is about 12 F to 14 F (4 mm to 4.7 mm), the distal end **280** of the capsule **276** is about 28 F to 30 F (9.3 mm to 10 mm), and the pusher **282** is about 10 F. Further as can be seen in FIG. **32**, the delivery device **274** contains a deployment system **240** comprising a device **200** according to the present invention in a pre-deployment configuration within the capsule.

[0094] Then, the delivery device **274** containing the deployment system **240** is advanced over the guidewire **272** through the trocar **260** using the delivery catheter **242** in monorail fashion as can be seen in FIG. **33**. Advancement of the delivery device **274** continues until the distal end **280** of the capsule **276** contacts the area surrounding the open end **252** (peritoneal surface) of the hernia sac **250** as can be seen in FIG. **34**.

[0095] Next, the deployment system **240** with the device **200** is released from the delivery device **274** by maintaining the pusher **282** in place and retracting the capsule **276** proximally. The patch portion **202** of the device **200** changes to a post-deployment configuration, and the delivery device **274** is withdrawn from the trocar **260** as can be seen in FIG. **35**.

[0096] Then, the laparoscope **266** is reinserted into the trocar **260** and, under direct vision provided by the laparoscope **266**, the patch portion **202** of the device **200** is rotated and otherwise positioned into its final position, such as for example to prevent the clips **210** from engaging neurovascular structures, using the deployment system **240** as shown in FIGS. **23-25** and in FIG. **36**. Next, as can be seen in FIG. **37**, the arms **226** of the clips **210** are crimped or otherwise activated, such as for example by retracting the attachment lines **224** (not shown) to engage the area surrounding the open end **252** (peritoneal surface) of the hernia sac **250**, thereby closing the open end **252** and effecting the obliteration of the aberrant space or cavity. Then, the deployment catheter **242**, the stabilization wires **222**, the laparoscope **266** and the trocar **260** are withdrawn, and the entry sites in the lower abdomen **256** are closed using standard techniques, as will be understood by those with skill in the art with reference to this disclosure.

[0097] Referring now to FIG. **38** through FIG. **42**, there are shown, respectively, a lateral perspective view of the second side of the patch portion of another embodiment of the device for the obliteration of an aberrant space or cavity in a post-deployment configuration (FIG. **38**); a top perspective view of the frame portion of the embodiment of the device shown in FIG. **38** in a post-deployment configuration (FIG. **39**); a bottom perspective view of the patch portion of the device shown in FIG. **38** and the frame shown in FIG. **39** in a post-deployment configuration, where the patch portion and frame portion are joined together (FIG. **40**); a partial lateral perspective view of the opposing surfaces of a hook and loop fastener with the two sides in the unattached configuration (FIG. **41**); and a partial lateral perspective view of the opposing surfaces of a hook and loop fastener as shown in FIG. **41** with the two sides in the attached configuration (FIG. **42**). As can be seen, in this embodiment, the device **300** comprises a patch portion **302** and a frame portion **304**. The patch portion **302** comprises a first side **306**, and an opposing second side **308**. Except as disclosed in this disclosure, the embodiment of the device **300** is constructed and functions in a manner corresponding to the embodiments of the device **100** and device **200** of the present invention, as will be understood by those with skill in the art with reference to this disclosure.

[0098] In one embodiment, the first side **306** and the second side **308** comprise material selected from the group consisting of polypropylene, polytetrafluoroethylene (PTFE) graft material and silicone rubber. In a preferred embodiment, such as when the device **300** is being used to obliterate an inguinal hernia sac in a human, the first side **306** comprises polypropylene and the second side **308** comprises polytetrafluoroethylene. The first side **306** and the second side **308** can, however, comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure.

[0099] In a preferred embodiment, the first side **306** of the device **300** comprises an expansile skeleton, corresponding to the frame **106** of the embodiment of the device **100** disclosed above, or comprises an inflatable structure or comprises an equivalent structure, where the expansile skeleton functions to permit the patch portion **302** of the device **300** to be put into a low profile, pre-deployment, configuration similar to the low profile, pre-deployment, configuration of the embodiments of the device **100** and the device **200**, as will be understood by those with skill in the art with reference to this disclosure.

[0100] The first side **306** of the patch portion **302** comprises a first surface **310** of two opposing surfaces of a hook and loop fastener, such as for example the hook and loop fastener known under the trademark VELCRO® (Velcro Industries, Curacao, Netherlands Antilles), though any equivalent fastener can be used, as will be understood by those with skill in the art with reference to this disclosure. As shown in FIG. **41** and in FIG. **42**, in one embodiment, the first surface **310** is the female surface of the hook and loop fastener; however, in another embodiment, not shown, the first surface **310** is the male surface of the hook and loop fastener.

[0101] Referring again to FIG. **39**, the device **300** further comprises a frame portion **304**. The frame portion **304** comprises a plurality of peripherally radiating members **312** comprising a first end **314** and a second end **316**. The first ends **314** of each radiating member **312** are joined together. In a preferred embodiment, as shown in FIG. **39**, each second end **112** of the peripherally radiating members **312** comprises a structure, such as a clip **318** or other equivalent structure to attach the radiating member **312**, and hence the frame portion **304**, to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated, such as to the peritoneal surface at the entry site into the hernia sac of an inguinal hernia, thereby immobilizing the device **300** in position. As will be understood by those with skill in the art with reference to this disclosure, the clip **318** or other equivalent structure corresponds to the clip **116** or the clip **210** as disclosed in this disclosure, as will be understood by those with skill in the art with reference to this disclosure.

[0102] Referring again to FIG. **39** and to FIG. **41** and **42**, the frame portion **304** further comprises a first side **320** and an opposing second side **322**. The second side **322** comprises a second surface **324** of two opposing surfaces of a hook and loop fastener, such as for example the hook and loop fastener known under the trademark VELCRO® (Velcro Industries, Curacao, Netherlands Antilles), though any equivalent fastener can be used, as will be understood by those with skill in the art with reference to this disclosure, where the second surface **324** is configured to mate with the first surface **310** of the first side **306** of the patch portion **302** as disclosed in this disclosure. As shown in FIG. **41** and in FIG. **42**, in one embodiment, the second surface **324** is the male surface of the hook and loop fastener; however, in another embodiment, not shown, the second surface **324** is the female surface of the hook and loop fastener.

[0103] Referring now to FIG. **40**, when contacted together, the first surface **310** on the first side **306** of the patch portion **302** joins to the second surface **324** on the second side **322** of the frame portion **304**, thereby attaching the patch portion **302** of the device **300** to the frame portion **304** of the device **300**.

[0104] According to another embodiment of the present invention, there is provided a method for the obliteration of an aberrant space or cavity comprising an open end and a closed end. In a preferred embodiment, the aberrant space or cavity obliterated by the method is within a living organism, such as within a human. In another preferred embodiment, the aberrant space or cavity obliterated by the method is a hernia sac of an inguinal hernia. In one embodiment, the method comprises providing a device according to the present invention, and deploying the device to substantially seal the open end of the aberrant space or cavity. In another embodiment, the method comprises creating an opening in the closed end of the aberrant space or cavity, introducing a device through the opening in the closed end of the aberrant space or cavity, and deploying the device to substantially seal the open end of the aberrant space or cavity. In a preferred embodiment, the device introduced is a device according to the present invention.

[0105] By way of example, the method will now be disclosed in greater detail with specific reference to the obliteration of a hernia sac of an inguinal hernia. As will be understood by those with skill in the art with reference to this disclosure, however, equivalent steps can be used to obliterate any aberrant space or cavity suitable for obliteration by the present method, including an aberrant space or cavity other than the hernia sac of an inguinal hernia, other than within a living organism, and other than within a human.

[0106] As will be appreciated by one with skill in the art with reference to this disclosure, the method of delivering and placing the device **300** can include an open procedure, a percutaneous transcatheter procedure, a laparoscopic procedure or a combination of the preceding procedures. Regardless of the procedure used, the method comprises, first selecting an aberrant space or cavity that is suitable for obliteration by the method. The aberrant space or cavity comprises an open end and a closed end. In one embodiment, the aberrant space or cavity is within a living organism. In a preferred embodiment, the aberrant space or cavity is within a human. In a particularly preferred embodiment, the aberrant space or cavity is a hernia sac of an inguinal hernia within a human, though any other suitable aberrant space or cavity can be obliterated.

[0107] In one embodiment, selecting an aberrant space or cavity that is suitable for obliteration by the method comprises selecting a patient having a disease or condition that includes the existence of an aberrant space or cavity, such as, for example, the hernia sac of an inguinal hernia, and for which treatment of the disease or condition involves obliteration of the aberrant space or cavity. In this embodiment, selecting the patient comprises diagnosing the existence of an aberrant space or cavity using standard techniques, such as a technique selected from the group consisting of CT scan, herniography, history, MRI and physical examination.

[0108] Then, the frame portion **304** of the device **300** is positioned at the open end of the aberrant space or cavity. Next, the frame portion **304** is attached to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated, such as to the peritoneal surface at the entry site into the hernia sac of an inguinal hernia, thereby immobilizing the frame portion **304** in position. Then, the patch portion **302** is introduced near the surface or structure adjacent to or within the aberrant space or cavity, and the patch portion **302** is converted from the pre-deployment configuration to the post-deployment configuration using techniques as will be understood by those with skill in the art with reference to this disclosure. Next, the patch portion **302** is positioned against the frame portion **304**, such that the first surface **310** on the first side **306** of the patch portion **302** contacts the second surface **324** on the second side **322** of the frame portion **304**, thereby attaching the patch portion **302** of the device **300** to the frame portion **304** of the device **300**, and thereby obliterating the cavity.

[0109] Referring now to FIG. **43** and FIG. **44**, there are shown, respectively, a top perspective view of the first side of the patch portion of another embodiment of the device for the obliteration of an aberrant space or cavity in a post-deployment configuration (FIG. **43**); and a lateral perspective view of the patch portion of the device shown in FIG. **43** in a post-deployment configuration (FIG. **44**). As can be seen, in this embodiment, the device **400** comprises a patch portion **402** comprising a first side **404** and an opposing second side **406**, and further comprising an outer edge. Except as disclosed in this disclosure, the embodiment of the device **400** is constructed and functions similarly to the embodiments of the device **100**, device **200** and device **300** of the present invention. Though shown as having a generally circular outer circumference, the patch portion **402** can be any shape suitable for its intended use, as will be understood by those with skill in the art with reference to this disclosure. Further, the patch portion **402** can be any size suitable for its intended use, as will be understood by those with skill in the art with reference to this disclosure. In one embodiment, the patch portion **402** has a maximum lateral extent of between 1 cm and 10 cm. In another embodiment, the patch portion **402** has a maximum lateral extent of greater than 5 cm. In another embodiment, the patch portion **402** has a maximum lateral extent of greater than 10 cm.

[0110] In one embodiment, the first side **404** and the second side **406** comprise material selected from the group consisting of polypropylene, polytetrafluoroethylene (PTFE) graft material and silicone rubber. In a preferred embodiment, as shown, such as when the device **400** is being used to obliterate an inguinal hernia sac in a human, the first side **404** comprises polypropylene mesh and the second side **406** comprises polytetrafluoroethylene (PTFE). The first side **404** and the second side **406** can, however, comprise any suitable material, as will be understood by those with skill in the art with reference to this disclosure.

[0111] The patch portion **402** of the device **400** further comprises an inflation area or inflation channel **408**. When inflated, the inflation area or inflation channel **408** gives shape to the patch portion **402** of the device **400** in a post-deployment configuration, thereby corresponding in function to the frame **106** of the device **100**, the struts **208** of the device **200**, and the peripherally radiating members **312** of the device **300**.

[0112] As can be seen in FIG. **43**, in one embodiment, the inflation area or inflation channel **408** is a circumferential conduit arrayed just central to the outer edge **410** of the patch portion **402** of the device **400**. In a preferred embodiment, the inflation area or inflation channel **408** comprises a single, centrally orientated inflation arm **412**, as shown in FIG. **43**. The inflation area or inflation channel **408** can, however, be any shape or area, or series of multiple shapes or areas suitable for use with the device **400**, as will be understood by those with skill in the art with reference to this disclosure.

[0113] The patch portion **402** of the device **400** further comprises an adhesive delivery channel **414**. When the device is in the post-deployment configuration, adhesive is intro-

duced into the adhesive delivery channel **414**, thereby attaching the patch portion **402** of the device **400** to the area surrounding the open end of the aberrant space or cavity and obliterating the aberrant space or cavity. Therefore, the adhesive delivery channel **414** corresponds in function to the clips **116** of the device **100**, and the clips **210** of the device **200**, and the clips **318** of the device **300** (as well as the hook and loop fastener system of the device **300**).

[0114] As can be seen in FIG. **43**, in a one embodiment, the adhesive delivery channel **414** is a circumferential conduit arrayed just central to the inflation area or inflation channel **408** of the device **400**. In a preferred embodiment, the adhesive delivery channel **414** comprises a single, centrally orientated adhesive delivery arm **416**, as shown in FIG. **43**. The adhesive delivery channel **414** can, however, be any shape or area, or series of multiple shapes or areas suitable for use with the device **400**, as will be understood by those with skill in the art with reference to this disclosure. The adhesive delivery channel **414** comprises a series of perforations to allow adhesive to exit from the adhesive delivery channel **414**.

[0115] The patch portion **402** of the device **400** further comprises one or more than one valve **418** for introducing inflation material into the inflation area or inflation channel **408** and for introducing adhesive into the adhesive delivery channel **414**. In a preferred embodiment, the one or more than one valve is a single valve **418**, as shown in FIG. **43**. In a preferred embodiment, the one or more than one valve **418** is self-sealing and is detachable. The valve **418** can be placed anywhere on the patch portion **402** that is suitable for its intended use. In a preferred embodiment, the inflation area or inflation channel **408** comprises a single, centrally orientated inflation arm **412**, and the adhesive delivery channel **414** comprises a single, centrally orientated adhesive delivery arm **416**, and the one or more than one valve **418** is positioned in the center of the patch portion **402** in continuity with the centrally orientated inflation arm **412** and the centrally orientated adhesive delivery arm **416**, as shown in FIG. **43**.

[0116] In a preferred embodiment, the patch portion **402** of the device **400** further comprises a peripheral flange **420**, oriented peripherally to the inflation area or inflation channel **408**. The first side **404** and second side **406** are tightly joined together at the flange **420**, and do not separate when the inflation area or inflation channel **408** is inflated in the post-deployment configuration. When present, the flange **420** serves to allow the device **400** to be fixed into position through the flange **420**, such as by suturing or clipping the flange **420** to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated, such as to the peritoneal surface at the entry site into the hernia sac of an inguinal hernia, thereby immobilizing the device **400** in position, as will be understood by those with skill in the art with reference to this disclosure.

[0117] Referring now to FIG. **45**, there is shown a lateral perspective view of the patch portion and optional suture harness of the device shown in FIG. **43** in a post-deployment configuration. As can be seen, in one embodiment, the device **400** further comprises a suture harness **422**. The suture harness **422** comprises a web of sutures **424** attached to the first side **404** of the patch portion **402** of the device **400**. In a preferred embodiment, the device **400** comprises a peripheral flange **420**, and the web of sutures **424** attach to the flange **420**. In a preferred embodiment, the web of sutures **424** are gathered or joined together to form a central suture or central sutures **426**. In a particularly preferred embodiment, the central suture or central sutures **426** is a single central suture **426** as shown in FIG. **45**. The suture harness **422** can be used to fix or to assist in fixing into position the device **400** by, for example, securing the central suture **426** into the subcutaneous tissues superficial to an inguinal hernia, or in a corresponding manner when the device **400** is used to obliterate an aberrant space or cavity other than a hernia sac of an inguinal hernia, as will be understood by those with skill in the art with reference to this disclosure.

[0118] According to another embodiment of the present invention, there is provided another method for the obliteration of an aberrant space or cavity comprising an open end and a closed end. The method comprises providing a device **400** according to the present invention. Except as disclosed in this disclosure, the method corresponds to the method for the obliteration of an aberrant space or cavity comprising an open end and a closed end as disclosed in connection with the device **200**, above.

[0119] In summary, the method comprises, first selecting an aberrant space or cavity that is suitable for obliteration by the method. The following steps for the present method are disclosed with respect to obliterating the hernia sac of an inguinal hernia as an example only of one type of aberrant space or cavity suitable for obliteration by the present method. Further, the method steps are disclosed partly with reference to corresponding steps for other embodiments of methods according to the present invention, as disclosed in connection with this disclosure, and as will be understood by those with skill in the art with reference to this disclosure. After the patient having the inguinal hernia is selected, the inguinal hernia sac is distended, and a trocar is inserted into the intraperitoneal cavity as shown in FIG. **27**.

[0120] Then, a guidewire is introduced through the closed end of the hernia sac and drawn through the trocar to provide the operator with control over both the proximal end and the distal end of the guidewire as shown using the apparatuses and steps in FIGS. **28** through **31**. Next, a delivery device corresponding to the delivery device **274** as shown in FIG. **32** is provided containing the device **400** in connection with a deployment system corresponding to the deployment system **240** as shown in FIG. **19**. Then, the delivery device containing the deployment system is advanced over the guidewire through the trocar using the delivery catheter part of the deployment system in monorail fashion, and the device **400** is deployed adjacent the open end of the hernia sac as shown in FIG. **33**, FIG. **34** and FIG. **35**.

[0121] Referring now to FIG. **46**, there is shown a cross-sectional view of one step in the present method for the obliteration of an aberrant space or cavity according to the present invention. As can be seen, deployment of the device **400** results in the first side **404** of the patch portion **402** and the suture harness **422** of the device **400** facing the open end **500** of the inguinal hernia sac **502**. Further, both the distal portion **428** of the deployment catheter **430** and the central suture **426** extend through the hernia sac **502** and out of the skin **504** over the hernia sac **502**.

[0122] The method now comprises fixing the patch portion **402** of the device **400** to the open end **500** of the hernia sac **502** under guidance of a laparoscope **506**. Referring now to FIG. **47**, FIG. **48** and FIG. **49**, there are shown a partial, close-up lateral perspective view of the distal end of the deployment catheter as shown in FIG. **46** (FIG. **47**); a partial, close-up lateral perspective view of the distal end of the deployment catheter as shown in FIG. **47** with the distal portion of the

deployment catheter removed (FIG. **48**); and a partial, close-up lateral perspective view of the distal end of the deployment catheter as shown in FIG. **48** with luer lock hubs attached to the inflation material delivery conduit and to the adhesive delivery conduit (FIG. **49**). As can be seen, in one embodiment, the deployment catheter **430** comprises a locking mechanism **432** that allows an operator to separate the distal portion **428** of the deployment catheter **430** from the proximal portion **434** of the deployment catheter **430**, thereby exposing an inflation material delivery conduit **436**, an adhesive delivery conduit **438** and a pusher rod **440**. In one embodiment, the locking mechanism **432** comprises an indentation **442** on the distal portion **428** of the deployment catheter **430** that mates with a raised protrusion **444** on the proximal portion **434** of the deployment catheter **430** as shown in FIG. **47**. In this embodiment, the distal portion **428** of the deployment catheter **430** is separated from the proximal portion **434** by rotating and then axially retracting the distal portion **428** relative to the proximal portion **434**. The locking mechanism **432** can, however, be any suitable locking mechanism as will be understood by those with skill in the art with reference to this disclosure. In one embodiment, the deployment catheter comprises a locking mechanism, and the method comprises separating the distal portion of the deployment catheter from the proximal portion, thereby exposing an inflation material delivery conduit, an adhesive delivery conduit and a pusher rod. In this embodiment, the method further comprises attaching luer lock hubs **446** to the inflation material delivery conduit, an adhesive delivery conduit and a pusher rod as seen in FIG. **49**.

[0123] Next, the method comprises inflating the inflation area or inflation channel of the patch portion of the device to impart structural rigidity to the patch portion. Then, under direct vision provided by the laparoscope, the patch portion of the device is rotated and otherwise positioned into its final position using the deployment catheter in combination with the central suture and pusher rod. Next, adhesive is introduced through the adhesive delivery conduit and the adhesive is allowed to discharge from the series of perforations in the adhesive delivery channel, depositing adhesive between the patch portion of the device and the peritoneal surface adjacent to the open end of the inguinal hernia sac, sealing the patch portion of the device to the peritoneal surface, and thereby, obliterating the inguinal hernia sac. When used in the human body, the adhesive is biocompatible. In one embodiment, the adhesive is n-butyl cyanoacrylate (NBCA) tissue adhesive.

[0124] Referring now to FIG. **50** and FIG. **51**, there are shown sequential, partial, close-up lateral perspective views of the patch portion of the device in the post-deployment configuration being separated from the proximal portion of the deployment catheter, the inflation material delivery conduit, the adhesive delivery conduit and the pusher rod according to the embodiment of the method shown in FIG. **46**. The method then comprises confirming the position of the patch portion of the device using the laparoscope. Next, as can be seen in FIG. **50** and FIG. **51**, the patch portion **402** of the device **400** in the post-deployment configuration is separated from the proximal portion **434** of the deployment catheter **430**, the inflation material delivery conduit **436**, the adhesive delivery conduit **438** and the pusher rod **440**. First, the proximal portion **434** is retracted through the skin **504** over the hernia sac **502**. Next, the inflation material delivery conduit **436** and the adhesive delivery conduit **438** are detached from the valve or valves **418** using standard techniques, as will be understood by those with skill in the art with reference to this disclosure. Then, the pusher rod **440** is detached from the patch portion **402** of the device **400**. Detachment of the pusher rod **440** can be accomplished by exposing a laterally expanding clip **448** attached to loop **450** on the patch portion **402** of the device **400**, where exposing the clip **448** occurs when the proximal portion **434** of the deployment catheter **430** is retracted, thereby allowing the clip **448** to expand laterally and detach from the loop **450**. Any suitable technique for detaching the pusher rod **440** from the patch portion **402** of the device **400** can, however, be used as will be understood by those with skill in the art with reference to this disclosure. In one embodiment, the device comprises a suture harness with a central suture, and the method further comprises attaching the central suture to the subcutaneous tissue of the skin over the hernia sac.

[0125] Finally, the laparoscope and the trocar are withdrawn, and the entry sites in the lower abdomen are closed using standard techniques, as will be understood by those with skill in the art with reference to this disclosure.

[0126] Although the present invention has been discussed in considerable detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the scope of the appended claims should not be limited to the description of preferred embodiments contained in this disclosure. All references cited herein are incorporated by reference to their entirety.

What is claimed is:

1. A device for the obliteration of an aberrant space or cavity comprising:

a) a patch portion comprising a first side and an opposing second side;

b) a plurality of struts arranged radially between the first side and the second side, where each strut comprises a first end and a second end; and

c) a clip associated with the second end of each strut;

where the patch portion has a center and a circumference;

where the first end of each strut is oriented toward the center of the patch portion, and the second end is oriented toward the circumference of the patch portion;

where each clip is configured to attach the patch portion to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated; and

where each strut comprises two lumens, a first lumen configured to contain a stabilization wire, and a second lumen configured to contain an attachment line.

2. The device of claim **1**, where the device comprises between 2 and 20 struts.

3. The device of claim **1**, where the patch portion is convex toward the first side and comprises a generally circular circumference.

4. The device of claim **1**, where the second side comprises visually discernable markings corresponding to the position of each clip.

5. The device of claim **1**, where each strut is curved or bent to create the convex shape of the patch portion.

6. The device of claim **1**, where each clip comprises a plurality of arms comprising a first end and a second end, where the first ends of each arm of each clip are joined together, and are also connected to an attachment line.

7. The device of claim **6**, where the second end of each arm comprises one or more than one gripping tip.

8. The device of claim **6**, where each attachment line is joined at the proximal end to form a collective attachment line allowing simultaneous closing of the second ends of the arms of multiple clips.

9. A deployment system for deploying a device according to claim **1**, comprising:

a) a device according to claim **1**;

b) a deployment catheter comprising a proximal end and a distal end, and configured to advance over a guidewire; and

c) one stabilization wire within each of the plurality of struts, where the stabilization wires are joined to a central pull wire within the deployment catheter.

10. A device for the obliteration of an aberrant space or cavity, the device comprising:

a) a patch portion comprising a first side and an opposing second side; and

b) a frame portion comprising a first side and an opposing second side;

where the first side of the patch portion comprises a first surface of two opposing surfaces of a hook and loop fastener;

where the second side of the frame portion further comprises a second surface of two opposing surfaces of a hook and loop fastener configured to mate with the first surface of the first side of the patch portion;

where the frame portion further comprises a plurality of peripherally radiating members, each of the peripherally radiating members comprising a first end and a second end;

where the first ends of each radiating member are joined together; and

where each of the second ends of the peripherally radiating members comprises a structure to attach the radiating member, and hence the frame portion, to a surface or structure adjacent to or within the aberrant space or cavity to be obliterated.

11. A device for the obliteration of an aberrant space or cavity comprising:

a) a patch portion comprising a first side, an opposing second side, and an outer edge;

b) an inflation area or inflation channel, which when inflated, gives shape to the patch portion in a post-deployment configuration;

c) an adhesive delivery channel comprising a series of perforations to allow adhesive to exit from the adhesive delivery channel; and

d) one or more than one valve for introducing inflation material into the inflation area or inflation channel and for introducing adhesive into the adhesive delivery channel.

12. The device of claim **11**, where the inflation area or inflation channel is a circumferential conduit arrayed just central to the outer edge.

13. The device of claim **12**, where the inflation area or inflation channel comprises a single, centrally orientated inflation arm.

14. The device of claim **13**, where the inflation area or inflation channel comprises a single, centrally orientated inflation arm, and the adhesive delivery channel comprises a single, centrally orientated adhesive delivery arm, and the one or more than one valve is positioned in the center of the patch portion in continuity with the centrally orientated inflation arm and the centrally orientated adhesive delivery arm.

15. The device of claim **14**, where the patch portion further comprises a peripheral flange, oriented peripherally to the inflation area or inflation channel to allow the device to be fixed into position through the flange.

16. The device of claim **1**, where the device further comprises a suture harness attached to the first side of the patch portion.

17. The device of claim **1**, where the patch portion further comprises a peripheral flange, oriented peripherally to the inflation area or inflation channel to allow the device to be fixed into position through the flange;

where the device further comprises a suture harness attached to the first side of the patch portion; and

where the suture harness is attached to the flange.

18. The device of claim **1** or claim **10** or claim **11**, where the first side, the second side or both the first side and the second side of the patch portion comprise material selected from the group consisting of polypropylene, polypropylene mesh, polytetrafluoroethylene (PTFE) graft material and silicone rubber.

19. A method for the obliteration of an aberrant space or cavity comprising an open end and a closed end, the method comprising:

a) selecting an aberrant space or cavity that is suitable for obliteration by the method;

b) providing a device according to claim **1** or claim **10** or claim **11**; and

c) deploying the device to substantially seal the open end of the aberrant space or cavity.

20. The method of claim **19**, where the aberrant space or cavity obliterated by the method is within a living organism.

21. The method of claim **19**, where the aberrant space or cavity obliterated by the method is within a human.

22. The method of claim **19**, where the aberrant space or cavity obliterated by the method is a hernia sac of an inguinal hernia.

23. The method of claim **19**, where the method further comprises creating an opening in the closed end of the aberrant space or cavity and introducing the device through the opening in the closed end of the aberrant space or cavity.

24. The method of claim **19**, where the aberrant space or cavity is the hernia sac of an inguinal hernia, where the hernia sac is covered by skin, and where deploying the device comprises:

a) inducing anesthesia;

b) distending the hernia sac with carbon dioxide gas; and

c) inserting a trocar into the intraperitoneal cavity adjacent the inguinal hernia.

25. The method of claim **24**, where the method further comprises:

a) providing an adaptor sheath having two proximal self-sealing valves;

b) introducing the sheath through a trocar;

c) introducing a laparoscope through the sheath;

d) introducing a wire snare into the intraperitoneal cavity through the sheath;

e) providing a guidewire having a proximal end and a distal end, and inserting the proximal end of the guidewire through the skin over the hernia sac;

f) advancing the proximal end of the guidewire into the intraperitoneal cavity;

g) capturing the proximal end of the guidewire with the wire snare;

h) pulling the proximal end of the guidewire through the trocar;

i) providing a delivery device comprising a capsule having a proximal end and a distal end and a pusher, and containing a deployment system comprising the device in a pre-deployment configuration within the capsule;

j) advancing the delivery device containing the deployment system over the guidewire through the trocar using the delivery catheter in monorail fashion until the distal end of the capsule contacts the area surrounding the hernia sac;

k) releasing the deployment system with the device from the delivery device by maintaining the pusher in place and retracting the capsule proximally;

l) changing the patch portion of the device to a post-deployment configuration;

m) withdrawing the delivery device from the trocar; and

n) positioning the patch portion of the device, thereby effecting the obliteration of the aberrant space or cavity.

26. A method for the obliteration of an aberrant space or cavity comprising an open end and a closed end, the method comprising:

a) selecting an aberrant space or cavity that is suitable for obliteration by the method;

b) providing a device according to claim **11**;

c) deploying the device to substantially seal the open end of the aberrant space or cavity;

d) inflating the inflation area or inflation channel of the patch portion of the device to impart structural rigidity to the patch portion; and

e) introducing adhesive through the adhesive delivery conduit and allowing the adhesive to discharge from the series of perforations in the adhesive delivery channel.

* * * * *

专利名称(译)	用于腔体闭塞的方法和装置		
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摘要(译)

用于消除异常空间或腔的装置。一种用于消除异常空间或空腔的方法，包括提供根据本发明的装置。