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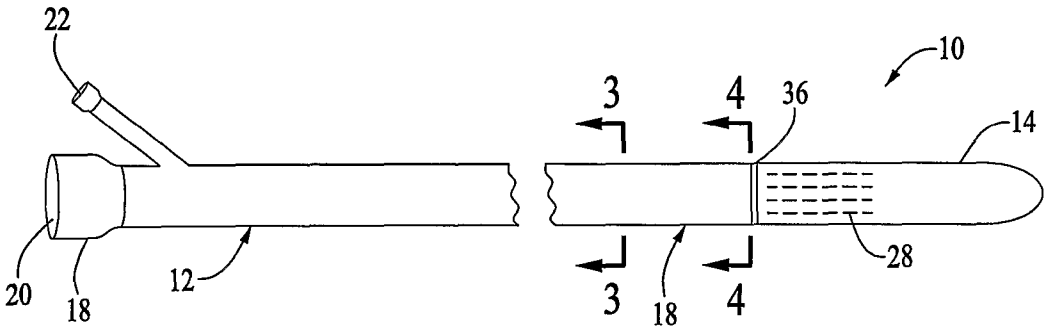

(57) Abstract: A device (10) that can be used to obliterate a cavity comprising a proximal segment (12) comprising a proximal end, a distal segment (14) comprising an inner balloon layer (24) surrounded by an outer balloon layer (26), and an intermediate segment (16) between the proximal segment (12) and distal segment (14); a connector (18), on the proximal end of the proximal segment (12), comprising a balloon layer inflation and deflation port (20) and comprising an adhesive delivery port (22); an inflation and deflation lumen (30) connecting the inflation and deflation port (20) with the inner balloon layer (24); and an adhesive delivery lumen (22) connecting the adhesive delivery port (22) with the outer balloon layer (26); where the outer balloon layer (26) comprises a plurality of perforations (28). A method of obliterating a cavity, such as an inguinal hernia sac.

WO 2005/051172 A2

METHOD AND DEVICE FOR CAVITY OBLITERATION

CROSS-REFERENCE TO RELATED APPLICATIONS

The present Application claims the benefit of United States Provisional Patent Application 60/524,366, titled "Method and Device for Cavity Obliteration," filed November 20, 2003, the contents of which are incorporated in this disclosure by reference in their entirety.

BACKGROUND

There are a variety of diseases and conditions in humans and in animals which result in the creation of abnormal cavities which cause real or potential morbidity *in vivo*. For example, patients with advanced emphysema typically have chronic bullous formations within the superior lung tissue that can render the patient symptomatic due to pressure from the formation. Other examples of abnormal cavities include enteric or urinary fistulas, large varicosities, and arteriovenous fistulas. Similarly, iatrogenic cavities are created by large surgical incisions used in major open abdominal and spinal surgeries. Closure of such large surgical incisions requires repair generally performed in multiple layers, sometimes using metal wires to secure the closure. Large surgical incision closures pose the risk of wound dehiscence, as well as abdominal wall hernias, hematomas, abscesses, lymphoceles, and seromas.

One of the most common abnormal cavities created by a disease or condition in humans which requires medical intervention is an inguinal hernia, either direct or indirect. Inguinal hernias are treated in a variety of ways, for example, such as by utilizing an external truss. Large inguinal hernias or inguinal hernias containing or potentially containing small bowel generally require surgical obliteration. Generally, surgical obliteration for inguinal hernias involves an open procedure comprising incising the integument and abdominal wall overlying the hernia sac, opening the hernia sac, and obliterating the hernia sac using sutures, with or without placing a mesh to reinforce the abdominal wall and prevent recurrences.

More recently, endoscopic procedures for the repair of inguinal hernias have been

developed which are less invasive than open procedures, however, both open procedures and endoscopic procedures have a significant recurrence rate estimated at between 1 and 10 percent depending on the study. Further, open procedures in particular have a significant recovery time associated with the repair. Additionally, both open procedures and endoscopic procedures are relatively expensive.

Therefore, it would be useful to have a new method for the obliteration of abnormal cavities *in vivo* caused by diseases or conditions, where the cavities cause real or potential morbidity. Preferably, the new method would also be less traumatic and less expensive than present method. Further, the new method would be rapid, and would be useful in patients with significant underlying diseases which place them at risk for more invasive surgical procedures. Additionally, the new method would not be associated with long recoveries.

SUMMARY

According to one embodiment of the present invention, there is provided a device that can be used to obliterate a cavity comprising a) a proximal segment comprising a proximal end, a distal segment comprising an inner balloon layer surrounded by an outer balloon layer, and an intermediate segment between the proximal segment and distal segment; b) a connector, on the proximal end of the proximal segment, comprising a balloon layer inflation and deflation port and comprising an adhesive delivery port; c) an inflation and deflation lumen connecting the inflation and deflation port with the inner balloon layer; and d) an adhesive delivery lumen connecting the adhesive delivery port with the outer balloon layer; where the outer balloon layer comprises a plurality of perforations. In one embodiment, the outer balloon layer comprises a proximal portion adjacent the intermediate segment, and a distal portion; where all of the perforations in the outer balloon layer are in the proximal portion of the outer balloon layer. In another embodiment, the device further comprises a self-sealing valve connected to the inflation and deflation lumen. In another embodiment, the device further comprises a separation area between the distal segment and intermediate segment configured to separate the distal segment from the intermediate segment. In another embodiment, the inflation and deflation port and the

adhesive delivery port are combined into a single port. In another embodiment, the device further comprises a fine mesh layer completely surrounding the outer balloon layer. In another embodiment, the outer balloon layer is replaced with one or more than one microcatheter attached to the external surface of the inner balloon layer; and the one or more than one microcatheter comprises a plurality of perforations.

According to another embodiment of the present invention, there is provided a method for obliterating a cavity comprising a wall. The method comprises a) selecting a patient with a cavity requiring obliteration; b) providing a device for obliteration of the cavity, the device comprising a proximal segment and a distal segment, and comprising an inner balloon layer with one or more than one layer or structure external to the inner balloon layer; c) inserting the device into the cavity until the distal segment of the device lies within the cavity; d) inflating the inner balloon layer until all layers or structures of the device external to the inner balloon layer contact the wall of the cavity; e) introducing an adhesive through the one or more than one layer or structure external to the inner balloon layer thereby binding the device to the wall of the cavity; and f) deflating the inner balloon layer, thereby obliterating the cavity. In one embodiment, the method further comprises detaching the distal segment of the device, thereby leaving the distal segment of the device within the obliterated cavity and surrounded by the obliterated cavity. In another embodiment, the cavity is selected from the group consisting of a chronic bullous formation, an enteric fistula, a urinary fistula, a varicosity, an arteriovenous fistula, an inguinal hernia sac and the stomach. In another embodiment, the device provided is a device according to the present invention.

According to another embodiment of the present invention, there is provided a method for obliterating a hernia sac of an inguinal hernia in a patient. The method comprises a) selecting a patient with an inguinal hernia with a hernia sac; b) accessing the peritoneal cavity of the patient through the integument and abdominal wall of the patient; c) introducing a guidewire and introducing an anchor comprising a proximal portion attached to a distal portion into the peritoneal cavity until the distal portion extends into hernia sac; d) retracting the proximal portion of the anchor proximally approximating the

wall of the hernia sac with the integument and abdominal wall; e) advancing a peel-away sheath with a central dilator into the hernia sac; f) removing the central dilator and guidewire; g) inserting a device for obliterating a cavity through the peel-away sheath; h) removing the peel-away sheath from the hernia sac; and i) obliterating the hernia sac using the device. In one embodiment, one or more than one step of the method is performed using an imaging technique. In another embodiment, the imaging technique is selected from the group consisting of thin cut computerized tomography, fluoroscopy, rapid magnetic resonance imaging, digital rotational angiography with three-dimensional reconstruction, ultrasound and a combination of the preceding. In another embodiment, the method further comprises anesthetizing the patient. In another embodiment, the method further comprises introducing a biocompatible gas into the peritoneal cavity after accessing the peritoneal cavity, thereby causing the hernia sac to distend. In a preferred embodiment, the device provided is a device according to the present invention. In another embodiment, the method further comprises detaching the distal segment of the device at the separation area from the proximal segment and intermediate segment of the device. In another embodiment, the method further comprises providing an introducing catheter comprising a lumen with a sealing wire within the lumen, and retracting the sealing wire causing the end to loop tightly around the distal segment of the device, thereby sealing off the proximal end of the inflation and deflation lumen. In another embodiment, the method further comprises closing the integument and abdominal wall. In another embodiment, the device comprises a proximal segment connected to a distal segment; the distal segment comprises a plurality of axially arranged wire-like structures forming a basket; and the method comprises collapsing the distal segment down to a low profile during insertion of the device.

According to another embodiment, of the present invention, there is provided a device that can be used to obliterate a cavity. The device comprises a) a proximal segment; and b) a distal segment connected to the proximal segment. The distal segment comprises an inflatable balloon comprising a plurality of perforations. In one embodiment, the proximal segment further comprises a self-sealing valve. In another embodiment, the device further comprises a delivery system and detachment system. In a preferred

embodiment, the delivery system and detachment system comprise an adhesive delivery and aspiration catheter.

According to another embodiment of the present invention, there is provided a method for obliterating a cavity comprising a wall. The method comprises a) selecting a patient with a cavity requiring obliteration; b) providing a device for obliteration of the cavity according to the present invention; c) inserting the device into the cavity; d) inflating the balloon by introducing adhesive, or adhesive combined with a biocompatible diluting liquid, into the balloon until the inflated balloon contacts the wall of the cavity; e) allowing the adhesive to exit the balloon through the perforations, thereby adhering the balloon to the wall of the cavity; f) deflating the balloon by aspirating adhesive, or adhesive combined with the biocompatible diluting liquid from the balloon, thereby obliterating the cavity. In one embodiment, the device comprises a delivery system and detachment system, and the method further comprises detaching the device from the delivery system and detachment system after deflating the balloon. In a preferred embodiment, the delivery system and detachment system comprises an introducing catheter comprising a lumen with a sealing wire within the lumen, and the method further comprises retracting the sealing wire causing the end to loop tightly around the proximal segment of the device, thereby sealing off the balloon. In another embodiment, the cavity is selected from the group consisting of a chronic bullous formation, an enteric fistula, a urinary fistula, a varicosity, an arteriovenous fistula, an inguinal hernia sac and the stomach.

FIGURES

These and other features, aspects and advantages of the present invention will become better understood from the following description, appended claims, and accompanying figures where:

Figure 1 is a partial lateral perspective view of one embodiment of a device according to the present invention;

Figure 2 is an enlarged, cutaway, lateral perspective view of the distal end of the device shown in Figure 1;

Figure 3 is an enlarged, cross-sectional, perspective view of the device shown in

Figure 1 taken along the line 3-3;

Figure 4 is an enlarged, cross-sectional, perspective view of the device shown in Figure 1 taken along the line 4-4;

Figure 5 is a partial, lateral prospective view of the distal segment of another embodiment of the device according to the present invention;

Figure 6 is a partial, lateral prospective view of the distal segment of another embodiment of the device according to the present invention;

Figure 7 through Figure 11 are cross-sectional, perspective views of some of the steps of one embodiment of the method according to the present invention for obliterating a cavity;

Figure 12 through Figure 19 are cross-sectional, perspective views of some of the steps of one embodiment of a method according to the present invention for obliterating the cavity of an inguinal hernia;

Figure 20 is an anchor useful in a method according to the present invention;

Figure 21 and Figure 22 are lateral perspective views of the distal segment of an alternate embodiment of a device useful in the obliteration of cavities caused by a disease or condition which causes real or potential morbidity, shown in the expanded and collapsed configuration;

Figure 23 is a lateral perspective view of another embodiment of the device according to the present invention;

Figure 24 is a cross-sectional, perspective view of the device shown in Figure 23, taken along the line 24-24; and

Figure 25 is a lateral, cutaway perspective view of the device shown in Figure 23.

DESCRIPTION

According to one embodiment of the present invention, there is provided a device that can be used to obliterate a cavity caused by a disease or condition, where the cavity causes real or potential morbidity. According to another embodiment of the present invention, there is provided a method for obliterating a cavity caused by a disease or condition, where the cavity causes real or potential morbidity. In one embodiment, the

method comprises providing a device according to the present invention. The method of the present invention is relatively less traumatic and relatively less expensive than open procedures, and is rapid and useful in patients with significant underlying diseases which place them at risk for more invasive surgical procedures, and is not associated with long recoveries. The device and method will now be disclosed in greater detail.

As used herein, the term "comprise" and variations of the term, such as "comprises" and "comprising," are not intended to exclude other additives, components, integers or steps.

According to one embodiment of the present invention, there is provided a device that can be used to obliterate a cavity caused by a disease or condition, where the cavity causes real or potential morbidity. Referring now to Figure 1 to Figure 4 there are shown, respectively, a partial lateral perspective view of one embodiment of the device according to the present invention (Figure 1); an enlarged, cutaway, lateral perspective view of the distal end of the device shown in Figure 1 (Figure 2); an enlarged, cross-sectional, perspective view of the device shown in Figure 1 taken along the line 3-3 (Figure 3); and an enlarged, cross-sectional, perspective view of the device shown in Figure 1 taken along the line 4-4 (Figure 4). As can be seen, the device 10 generally comprises a proximal segment 12, a distal segment 14, and an intermediate segment 16 between the proximal segment 12 and distal segment 14. Preferably, the proximal end of the proximal segment 12 comprises at least one connector 18 comprising a balloon layer inflation and deflation port 20, and comprises an adhesive delivery port 22. In one embodiment, as shown in Figure 1, the inflation and deflation port 20 is separate from the adhesive delivery port 22. Alternately, however, the inflation and deflation port 20 and the adhesive delivery port 22 can be combined into a single port, not shown, as will be understood by those with skill in the art with reference to this disclosure.

In one embodiment, as shown in Figure 1 and Figure 2, the distal segment 14 of the device 10 comprises an inner balloon layer 24 surrounded by an outer balloon layer 26. The outer balloon layer 26 surrounding the inner balloon layer 24 comprises a plurality of perforations 28. In a preferred embodiment, all of the perforations 28 in the outer balloon

layer 26 are in the proximal portion of the outer balloon layer 26 adjacent the distal end of the intermediate segment 16, though other arrangements of the perforations 28 can be used, as will be understood by those with skill in the art with reference to this disclosure.

The device 10 further comprises at least two lumens. One lumen, an inflation and deflation lumen 30, connects the inflation and deflation port 20 in the proximal segment 12 with the inner balloon layer 24 in the distal segment 14 through a self-sealing valve 32. Another lumen, an adhesive delivery lumen 34, connects the adhesive delivery port 22 in the proximal segment 12 with the outer balloon layer 26 in the distal segment 14. In one embodiment, as shown in Figure 2, the device 10 further comprises a separation area 36 between the distal segment 14 and the intermediate segment 16 configured to separate the distal segment 14 from the intermediate segment 16, when the device 10 is separated along the separation area.

The distal segment 14 at least, and preferably, the entire device 10, comprises biocompatible material. The device is made according to techniques known to those with skill in the art, as will be understood by those with skill in the art with reference to this disclosure.

Referring now to Figure 5, there is shown a partial, lateral prospective view of the distal segment of another embodiment of the device according to the present invention. As can be seen, in this embodiment, the device 38 further comprises a fine mesh layer 40 completely surrounding the outer balloon layer 42. The fine mesh layer 40 can be any suitable biocompatible material. In a preferred embodiment, the mesh comprises one or more substance selected from the group consisting of polypropylene, polyethylene, polytetrafluoroethylene and polyglycolic acid. Any suitable biocompatible substance can be used, however, as will be understood by those with skill in the art with reference to this disclosure.

Referring now to Figure 6, there is shown a partial, lateral prospective view of the distal segment of another embodiment of the device according to the present invention. As can be seen, in this embodiment, the device 44 comprises one or more than one microcatheter 46 attached to the external surface of the inner balloon layer 48 of the distal

segment 50 in place of the outer balloon layer 26 of the devices 10 and 38 shown in Figure 1 through Figure 4. Preferably, each microcatheter 46 is in communication with the adhesive delivery port, not shown, through a single adhesive delivery lumen in the intermediate segment 52. As will be understood by those with skill in the art with reference to this disclosure, however, a plurality of microcatheters could also be connected to the adhesive delivery port by a plurality of adhesive delivery lumens. Further, preferably, each of the one or more than one microcatheter 46 comprises a plurality of perforations 54 to the perforations 28 in the outer balloon layer 26 in the embodiment of the device 10 shown in Figure 1 and Figure 2. The one or more than one microcatheter 10 can extend from the proximal end of the distal segment 50 to the distal end of the distal segment 50, or can extend only partway toward the distal end of the distal segment 50, as shown in Figure 6. Preferably, however, each microcatheter preferably has a plurality of perforations 54 only in the proximal portion of the microcatheter 46 at the distal segment 50. In a preferred embodiment, the device 44 comprises between three and six microcatheters 46. In another preferred embodiment, each microcatheter 46 has an inner diameter less than about 2 French.

According to another embodiment of the present invention, there is provided a method for obliterating a cavity caused by a disease or condition, where the cavity causes real or potential morbidity. The method comprises, first, selecting a patient with a cavity requiring obliteration. In one embodiment, the cavity is selected from the group consisting of a chronic bullous formation, an enteric fistula, a urinary fistula, a varicosity and an arteriovenous fistula, an inguinal hernia sac and the stomach, though a large variety of cavities are susceptible to obliteration by the present method, as will be understood by those with skill in the art with reference to this disclosure. In a preferred embodiment, the condition is severe obesity and the cavity is formed by the gastric mucosa, where the method is used to decrease the potential volume of the stomach as part of a treatment for severe obesity.

Referring now to Figure 7 through Figure 11, there are shown cross-sectional, perspective views of some additional steps of one embodiment of a method according to the

present invention for obliterating such a cavity. It should be understood, however, that each step shown is not necessarily required for every embodiment of the method of the present invention, nor is the order of the steps shown intended to be limiting.

As can be seen, after selecting the patient, a device for obliteration of the cavity is provided. In a preferred embodiment, the device is a device according to one embodiment of the present invention, such as the device 10 shown in the Figure 1 through Figure 4, though other devices, such as another device according to the present invention can be used. Next, the device 10 is inserted into the cavity 56 until the distal segment 14 of the device 10 lies within the cavity 56. The inner balloon layer 24 is then inflated causing both the inner balloon layer 24 and outer balloon layer 26, or any layer or structures external to the inner balloon layer 24, to contact the inner surface 58 of the wall 60 of the cavity 56. Then, an adhesive is introduced through the adhesive delivery lumen external to the inner balloon layer 24, such as into the potential space between the inner balloon layer 24 and the outer balloon layer 26, or other layer or structures external to the inner balloon layer, causing adhesive to extrude through the perforations 28 in the outer balloon layer 26 or corresponding structures, and spread between the device 10 and the inner surface 58 of the wall 60 of the cavity 56, thereby binding the outer balloon layer 26 to the inner surface 58 of the wall 60 of the cavity 56. Next, the inner balloon layer 24 is deflated through the inflation and deflation lumen, thereby contracting the previously expanded wall 60 of the cavity 56 until the cavity 56 surrounds the deflated distal segment 14 of the device 10, thereby obliterating the cavity 60. Then, the distal segment 14 of the device 10 is detached at the separation area 36 leaving the distal segment 14 of the device 10 within the obliterated cavity 60 and surrounded by the obliterated cavity 60, while the proximal segment 12 and intermediate segment 16 of the device 10 are removed.

By way of example only, the method will now be disclosed with respect to obliterating the cavity of an inguinal hernia in a patient, that is, a hernia sac. However, corresponding steps can be used to obliterate other cavities, as will be understood by those with skill in the art with reference to this disclosure. Referring now to Figure 12 through Figure 19, there is shown cross-sectional, perspective views of some of the steps of one

embodiment of a method according to the present invention for obliterating the cavity of an inguinal hernia. It should be understood, however, that each step shown is not necessarily required for every embodiment of the method of the present invention, nor is the order of the steps shown intended to be limiting.

The method comprises, first, selecting a patient with an inguinal hernia with a hernia sac 62 suitable for obliteration according to the present method. After selecting the patient, the remaining steps of the method are performed using an imaging technique as required, such as a technique selected from the group consisting of thin cut computerized tomography, fluoroscopy, rapid magnetic resonance imaging, digital rotational angiography with three-dimensional reconstruction, ultrasound, and another suitable technique, and a combination of the preceding. The patient is anesthetized as required, such as by I.V. sedation and local skin anesthesia. Next, the peritoneal cavity 64 is accessed through a small opening made through the integument and abdominal wall 66. In a preferred embodiment, the opening is made using a small gauge needle, such as a 21 to 25 gauge needle. Further, preferably, the opening is made in the periumbilical region. In a preferred embodiment, once the peritoneal cavity 64 is accessed, a biocompatible gas, such as a carbon dioxide, is introduced through the opening into the peritoneal cavity 64 causing the peritoneal cavity 64 and hernia sac 62 to distend, as shown in Figure 12, according to techniques well known to those with skill in the art. Additionally, in a preferred embodiment, the patient's pelvis is elevated relative to the patient's abdomen to encourage the biocompatible gas to enter the hernia sac 62 through the proximal communication 68 between the hernia sac 62 and the peritoneal cavity 64.

Next, an appropriate site for creating an opening into the hernia sac 62 is located using an appropriate imaging technique. Then, an opening is made through the integument and abdominal wall 66 and hernia sac wall 70 into the hernia sac 62. In a preferred embodiment, the opening is made using a needle 72, such as an 18 or 21 gauge needle, as shown.

Next, in a preferred embodiment, an anchor 74 is introduced through the needle 72. Referring now to Figure 20, there is shown an anchor 74 useful in the present method. As

can be seen, the anchor 74 comprises a proximal portion 76 attached to a distal portion 78. The proximal portion 76 comprises an elongated thread-like structure, such as for example a biocompatible suture material such as VICRYL®. The distal portion 78 comprises a relatively stiff elongated structure connected to the proximal portion 76 at the approximate center of the long axis of the distal portion 78. The distal portion 78 can comprise any suitable biocompatible material, as will be understood by those with skill in the art with reference to this disclosure. In a preferred embodiment, the distal portion 78 comprises polyglycolic acid. In another preferred embodiment, the distal portion 78 comprises guidewire material comprising a length between about 8 mm to about 10 mm.

As shown in Figure 14, the distal portion 78 of the anchor 74 and a guidewire 80 are advanced through the lumen of the needle 72 until the distal portion 78 extends completely through the distal end of the needle 72 and into hernia sac 62. The needle 72 is then removed from the hernia sac 62 and overlying structures leaving the anchor 74 and guidewire 80 in place.

Next, the proximal portion 76 of the anchor 74, if used, is retracted proximally approximating the wall of the hernia sac 62 with the integument and abdominal wall 66. Then, a peel-away sheath 82 with a central dilator 84, such as a 9-12 French peel-away sheath, is inserted over the guidewire 80, and the distal end of the peel-away sheath 82 and dilator 84 are advanced into the hernia sac 62. Then, the dilator 84 and guidewire 80 are removed.

Next, a device for obliterating a cavity, such as a device 10 according to the present invention, is inserted through the peel-away sheath 82 until the distal segment 14 of the device 10 is completely within the hernia sac 62. Then, the peel-away sheath 82 is removed from the hernia sac 62 completely.

Next, the inner balloon layer is inflated through the inflation and deflation lumen using a suitable inflation material, until the surface of the distal segment substantially contacts the wall of the hernia sac 62. The inflation material can be, for example, air, saline, or a gas such as carbon dioxide. Proximal traction on the anchor, if used, is used to assist in this maneuver. After inflation, correct positioning of the device is verified using

an imaging technique.

Next, an adhesive is then delivered through the adhesive delivery port of the device 10 into the space between the outer surface of the inner balloon layer 24 and the inner surface of the hernia sac wall 70. Any suitable biocompatible adhesive can be used, such as for example, a cyanoacrylate such as N-butyl cyanoacrylate (NBCA), or DERMABOUND® (Johnson & Johnson Corp., New Brunswick, NJ US). Preferably, the adhesive requires an ionic environment to become activated and cured, so that it will not cure within the balloon, but only when in the ionic environment of the cavity. The adhesive is left to cure until adhesion has been achieved between the distal segment 14 of the device 10 and the hernia sac wall 70.

Then, the inner balloon 24 of the distal segment 14 of the device is deflated by withdrawing the inflation material from the inflation and deflation port. This deflation causes the hernia sac wall 70 to implode, thereby obliterating the cavity of the hernia sac 62.

Next, the distal segment 14 of the device 10 is detached at the separation area 36 from the proximal segment 12 and intermediate segment 16 of the device 10. Finally, the opening through the integument and abdominal wall 66 into the hernia sac 62 is closed in a routine manner as will be understood by those with skill in the art with reference to this disclosure, such as by sutures, staples, and routine post-procedure care would be instituted. If necessary, post-procedure imaging can be performed to confirm obliteration of the cavity.

The method of the present invention can be performed using any device according to the present invention as is suitable for the cavity. Additionally, other devices could also be used if appropriate. For example, referring now to Figure 21 and Figure 22, there is shown a lateral perspective view of the distal segment of an alternate embodiment of a device 86 useful in the obliteration of cavities caused by real or potential morbidity. As can be seen, the device 86 comprises a proximal segment 88 and a distal segment 90. The distal segment 88 of the device 86 comprises a plurality of axially arranged wire-like structures 92 forming a basket, such as is used for percutaneous retrieval of urinary and

biliary calculi, and for intravascular foreign body retrieval. During insertion, the distal segment 88 is collapsible down to a low profile as shown in Figure 22. Once deployed within the target cavity, the distal segment 88 of the device 86 is expanded to approximate the cavity wall, and an adhesive is introduced through thin sleeves that allow the adhesive to express out along the length of the basket wires. This causes adherence of the wires to the cavity wall, and obliteration of the cavity upon collapsing the distal segment 88.

According to another embodiment of the present invention, the device according to the present invention includes a removable guidewire in the inner balloon layer to assist in locating the device within the cavity to be obliterated, such as for example, within a long varicose vein.

According to another embodiment of the present invention, the method for obliterating a cavity according to the present invention comprises providing an introducing catheter comprising a lumen with a sealing wire within the lumen. After the cavity is obliterated using a device according to the present invention, the sealing wire is retracted causing the end to loop tightly around the distal segment of the device, thereby sealing off the proximal end of the inflation and deflation lumen. Then, the sealing wire is cut and the introduction catheter is removed.

According to another embodiment of the present invention, there is provided a device that can be used to obliterate a cavity caused by a disease or condition, where the cavity causes real or potential morbidity. Referring now to Figure 23 to Figure 25, there are shown, respectively, a lateral perspective view of one embodiment of the device according to the present invention (Figure 23); a cross-sectional, perspective view of the device shown in Figure 23, taken along the line 24-24 (Figure 24); and a lateral, cutaway perspective view of the device shown in Figure 23 (Figure 25). As can be seen, the device 100 comprises a proximal segment 102 and a distal segment 104. In one embodiment, as shown in Figure 23, the proximal segment 102 comprises a self-sealing valve 106. The distal segment comprises an inflatable balloon 108. The balloon 108 comprises a plurality of perforations 110. In a preferred embodiment, the perforations 110 are distributed throughout the balloon 108 as shown, though other arrangements of the perforations 110

can be used, as will be understood by those with skill in the art with reference to this disclosure. In a preferred embodiment, the balloon is folded into pleats 112 in the uninflated state, as shown in Figure 23 and Figure 24, to permit placement of the device 100 through narrow openings. The device 100 can further comprise a delivery system and detachment system, such as the adhesive delivery and aspiration catheter 114 shown in Figure 25.

According to another embodiment of the present invention, there is provided a method for obliterating a cavity caused by a disease or condition, where the cavity causes real or potential morbidity. The method comprises, first, selecting a patient with a cavity requiring obliteration, as previously disclosed in this disclosure. Next, a device for obliteration of the cavity is provided, such as the device 100. Then, the device 100 is placed on an adhesive delivery and aspiration catheter 114, as shown in Figure 23 and Figure 25, inserted into the cavity until the device 100 lies within the cavity. Next, the balloon 104 is inflated as shown in Figure 25 by introducing adhesive, or adhesive combined with a biocompatible diluting liquid such as a dextrose solution, through the catheter 114 into the balloon 108 until the inflated balloon 108 generally contacts the wall of the cavity. Adhesive, as disclosed in this disclosure, is then allowed to exit the balloon 108 through the perforations 110, thereby adhering the balloon 108 to the wall of the cavity. The adhesive remaining in the balloon is then aspirated through the catheter 114 causing the balloon 108 to deflate, contracting the wall of the cavity and, thereby, obliterating the cavity. Then, the catheter 114 is removed leaving the device 100 within the cavity. In another embodiment, the device 100 is detached from the catheter 114 using a sealing wire as disclosed in this disclosure. In this embodiment, the delivery system and detachment system comprises an introducing catheter comprising a lumen with a sealing wire within the lumen, and the method comprises retracting the sealing wire causing the end to loop tightly around the proximal segment of the device, thereby sealing off the balloon. Other detachment systems can also be used, as will be understood by those with skill in the art with reference to this disclosure.

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.

WHAT IS CLAIMED IS:

1. A device that can be used to obliterate a cavity comprising:

a) a proximal segment comprising a proximal end, a distal segment comprising an inner balloon layer surrounded by an outer balloon layer, and an intermediate segment between the proximal segment and distal segment;

b) a connector, on the proximal end of the proximal segment, comprising a balloon layer inflation and deflation port and comprising an adhesive delivery port;

c) an inflation and deflation lumen connecting the inflation and deflation port with the inner balloon layer; and

d) an adhesive delivery lumen connecting the adhesive delivery port with the outer balloon layer;

where the outer balloon layer comprises a plurality of perforations.

2. The device of claim 1, where the outer balloon layer comprises a proximal portion adjacent the intermediate segment, and a distal portion;

where all of the perforations in the outer balloon layer are in the proximal portion of the outer balloon layer.

3. The device of claim 1, further comprising a self-sealing valve connected to the inflation and deflation lumen.

4. The device of claim 1, further comprising a separation area between the distal segment and intermediate segment configured to separate the distal segment from the intermediate segment.

5. The device of claim 1, where the inflation and deflation port and the adhesive delivery port are combined into a single port.

6. The device of claim 1, further comprising a fine mesh layer completely surrounding the outer balloon layer.

7. The device of claim 1, where the outer balloon layer is replaced with one or more than one microcatheter attached to the external surface of the inner balloon layer; and

where the one or more than one microcatheter comprises a plurality of perforations.

8. A method for obliterating a cavity comprising a wall, the method comprising:

a) selecting a patient with a cavity requiring obliteration;

b) providing a device for obliteration of the cavity, the device comprising a proximal segment and a distal segment, and comprising an inner balloon layer with one or more than one layer or structure external to the inner balloon layer;

c) inserting the device into the cavity until the distal segment of the device lies within the cavity;

d) inflating the inner balloon layer until all layers or structures of the device external to the inner balloon layer contact the wall of the cavity;

e) introducing an adhesive through the one or more than one layer or structure external to the inner balloon layer thereby binding the device to the wall of the cavity; and

f) deflating the inner balloon layer, thereby obliterating the cavity.

9. The method of claim 8, further comprising detaching the distal segment of the device, thereby leaving the distal segment of the device within the obliterated cavity and surrounded by the obliterated cavity.

10. The method of claim 8, where the cavity is selected from the group consisting of a chronic bullous formation, an enteric fistula, a urinary fistula, a varicosity, an arteriovenous fistula, an inguinal hernia sac and the stomach.

11. The method of claim 8, where the device provided is a device according to any of claims 1-7.

12. A method for obliterating a hernia sac of an inguinal hernia in a patient, the method comprising;

a) selecting a patient with an inguinal hernia with a hernia sac;

b) accessing the peritoneal cavity of the patient through the integument and abdominal wall of the patient;

c) introducing a guidewire and introducing an anchor comprising a proximal portion attached to a distal portion into the peritoneal cavity until the distal portion extends into hernia sac;

d) retracting the proximal portion of the anchor proximally approximating the wall of the hernia sac with the integument and abdominal wall;

e) advancing a peel-away sheath with a central dilator into the hernia sac;

f) removing the central dilator and guidewire;

g) inserting a device for obliterating a cavity through the peel-away sheath;

h) removing the peel-away sheath from the hernia sac; and

i) obliterating the hernia sac using the device.

13. The method of claim 12, where one or more than one step of the method is performed using an imaging technique.

14. The method of claim 13, where the imaging technique is selected from the group consisting of thin cut computerized tomography, fluoroscopy, rapid magnetic resonance imaging, digital rotational angiography with three-dimensional reconstruction, ultrasound and a combination of the preceding.

15. The method of claim 12, further comprising anesthetizing the patient.

16. The method of claim 12, further comprising introducing a biocompatible gas into the peritoneal cavity after accessing the peritoneal cavity, thereby causing the hernia sac to distend.

17. The method of claim 12, where the device provided is a device according to any of claims 1-7.

18. The method of claim 17, further comprising detaching the distal segment of the device at the separation area from the proximal segment and intermediate segment of the device.

19. The method of claim 17, further comprising providing an introducing catheter comprising a lumen with a sealing wire within the lumen, and retracting the sealing wire causing the end to loop tightly around the distal segment of the device, thereby sealing off the proximal end of the inflation and deflation lumen.

20. The method of claim 12, further comprising closing the integument and abdominal wall.

21. The method of claim 12, where the device comprises a proximal segment connected to a distal segment;

where the distal segment comprises a plurality of axially arranged wire-like

structures forming a basket; and

where the method comprises collapsing the distal segment down to a low profile during insertion of the device.

22. A device that can be used to obliterate a cavity comprising:

a) a proximal segment; and

b) a distal segment connected to the proximal segment;

where the distal segment comprises an inflatable balloon comprising a plurality of perforations.

23. The device of claim 22, where the proximal segment further comprises a self-sealing valve.

24. The device of claim 22, further comprising a delivery system and detachment system.

25. The device of claim 24, where the delivery system and detachment system comprise an adhesive delivery and aspiration catheter.

26. A method for obliterating a cavity comprising a wall, the method comprising:

a) selecting a patient with a cavity requiring obliteration;

b) providing a device for obliteration of the cavity according to claim 22

c) inserting the device into the cavity;

d) inflating the balloon by introducing adhesive, or adhesive combined with a biocompatible diluting liquid, into the balloon until the inflated balloon contacts the wall of the cavity;

e) allowing the adhesive to exit the balloon through the perforations, thereby adhering the balloon to the wall of the cavity; and

f) deflating the balloon by aspirating adhesive, or adhesive combined with the biocompatible diluting liquid from the balloon, thereby obliterating the cavity.

27. The method of claim 26, where the device comprises a delivery system and detachment system, and where the method further comprises detaching the device from the delivery system and detachment system after deflating the balloon.

28. The method of claim 27, where the delivery system and detachment system

comprises an introducing catheter comprising a lumen with a sealing wire within the lumen, and the method further comprises retracting the sealing wire causing the end to loop tightly around the proximal segment of the device, thereby sealing off the balloon.

29. The method of claim 26, where the cavity is selected from the group consisting of a chronic bullous formation, an enteric fistula, a urinary fistula, a varicosity, an arteriovenous fistula, an inguinal hernia sac and the stomach.

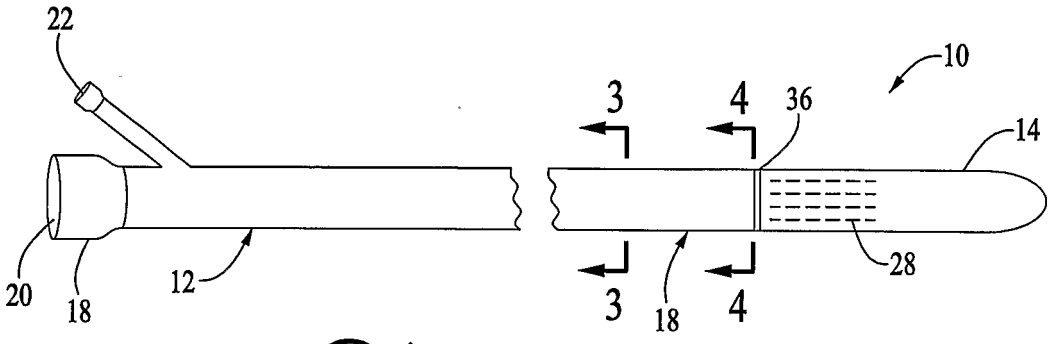

FIG. 1

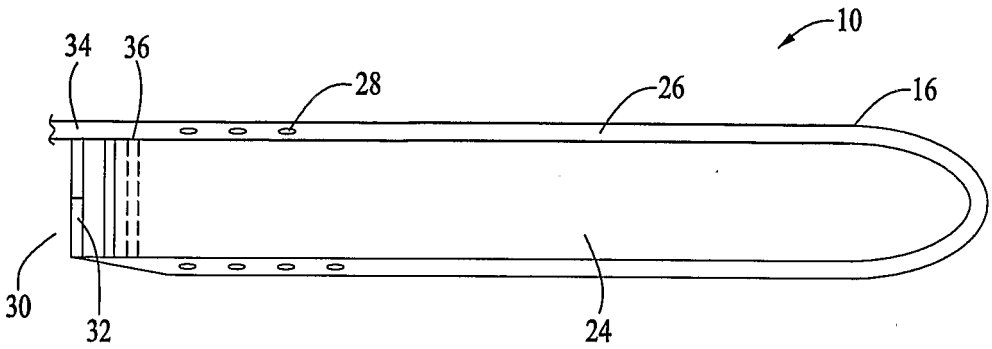

FIG. 2

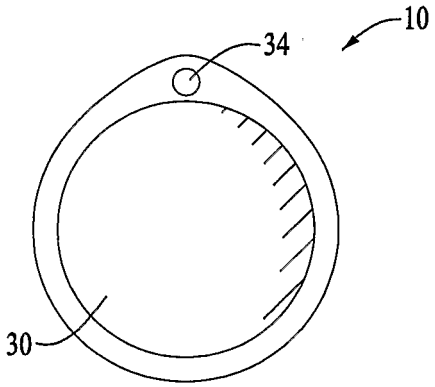

FIG. 3

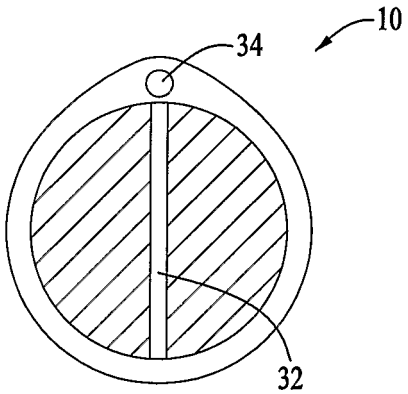

FIG. 4

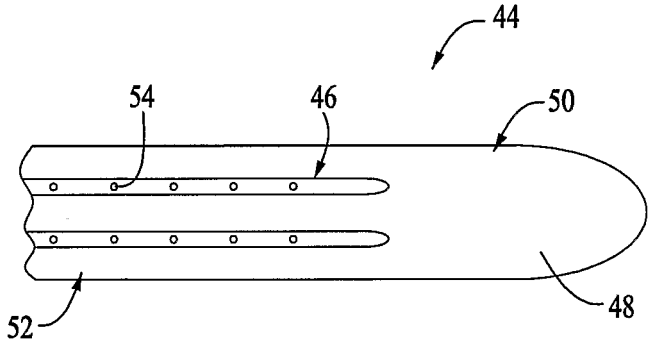

FIG. 6

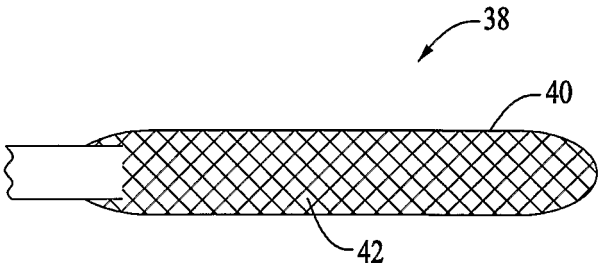

FIG. 5

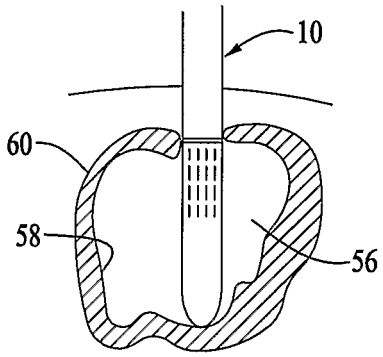

FIG. 7

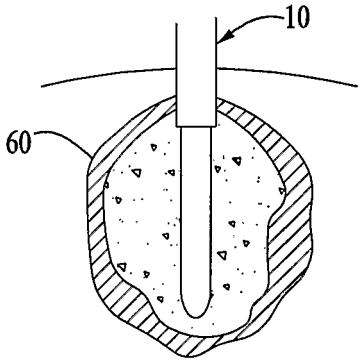

FIG. 8

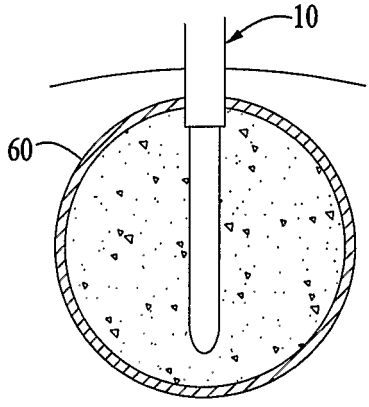

FIG. 9

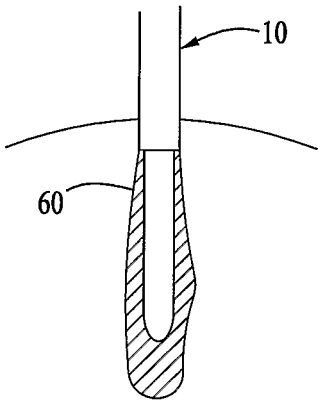

FIG. 10

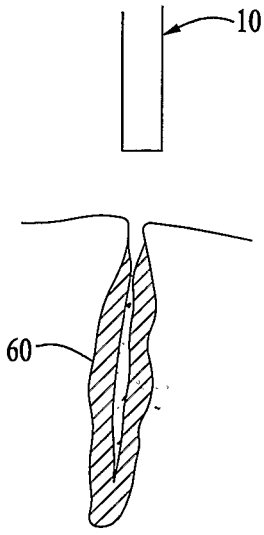

FIG. 11

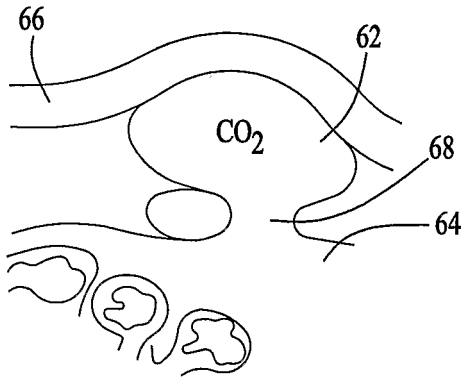

FIG. 12

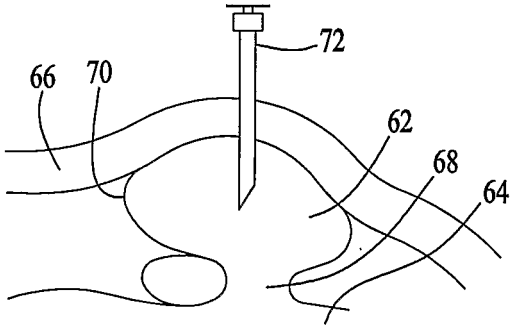

FIG. 13

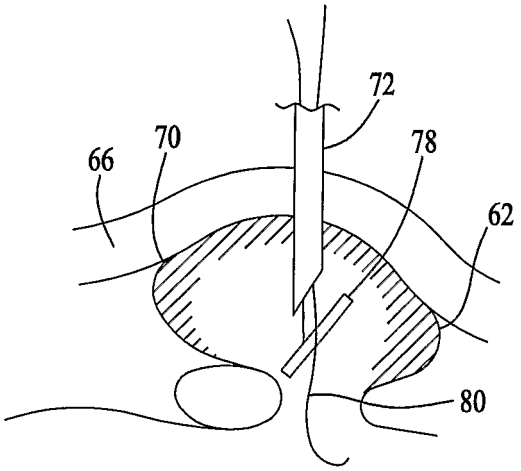

FIG. 14

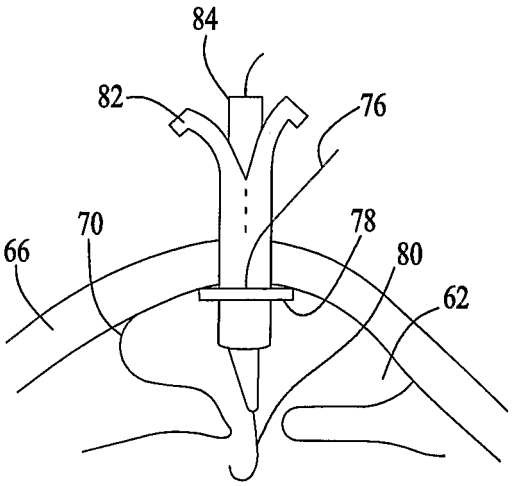

FIG. 15

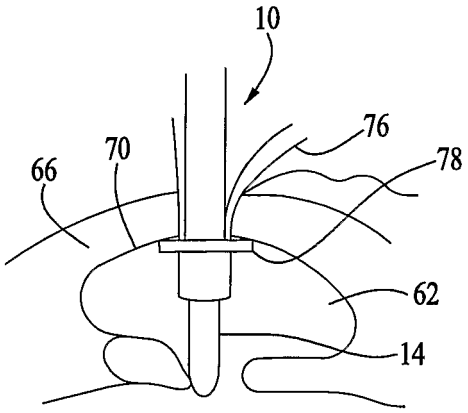

FIG. 16

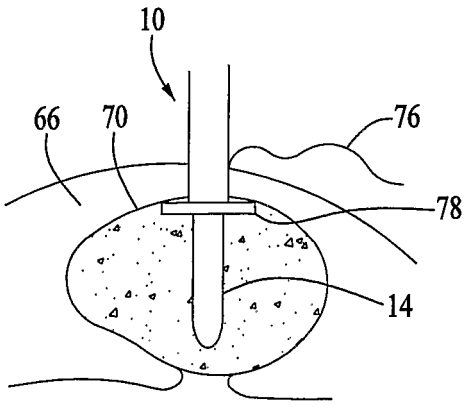

FIG. 17

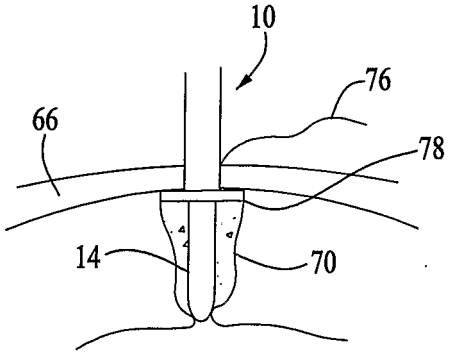

FIG. 18

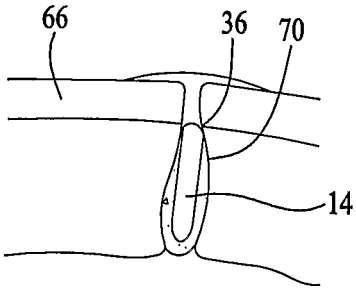

FIG. 19

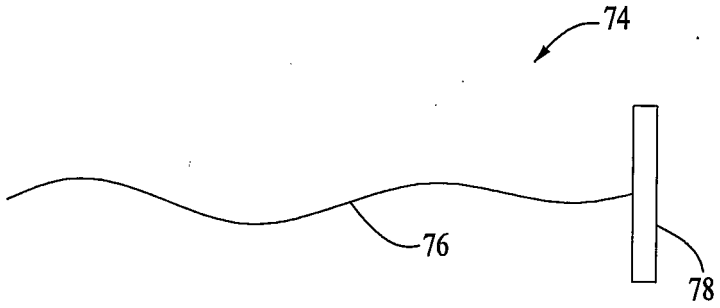

FIG. 20

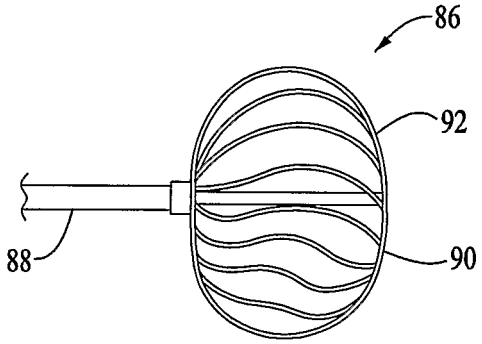

FIG. 21

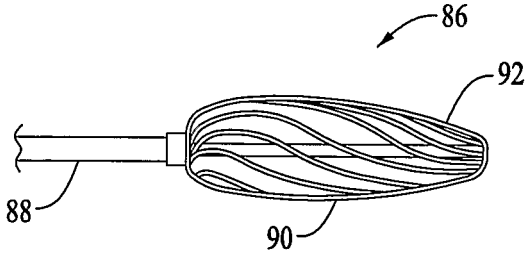

FIG. 22

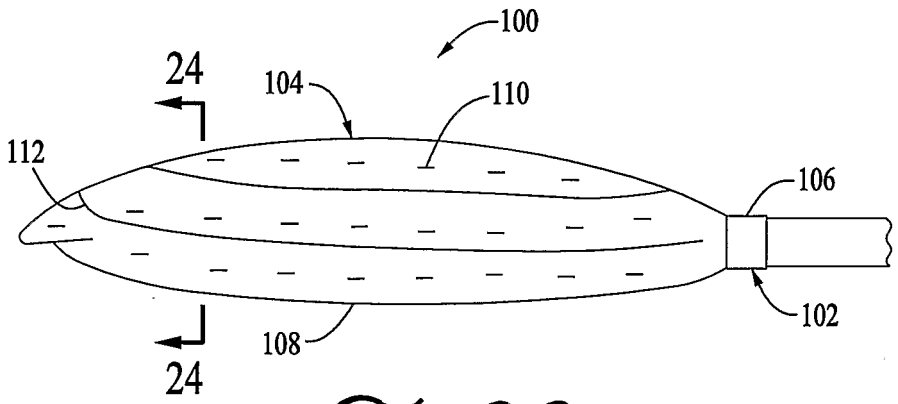

FIG. 23

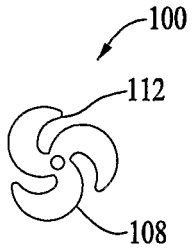

FIG. 24

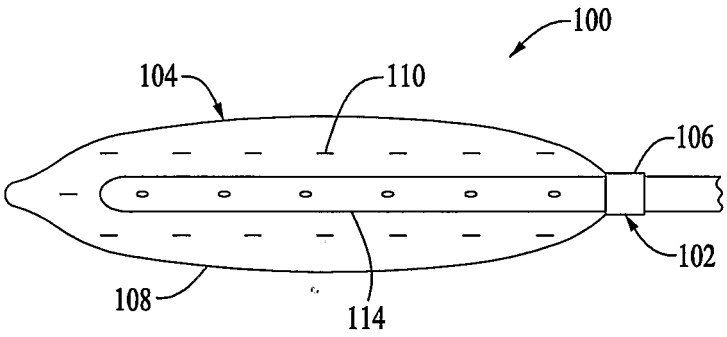

FIG. 25

专利名称(译)	用于腔体闭塞的方法和装置		
公开(公告)号	EP1691879A2	公开(公告)日	2006-08-23
申请号	EP2004811751	申请日	2004-11-19
[标]申请(专利权)人(译)	导管交换		
申请(专利权)人(译)	导管交流，INC.		
当前申请(专利权)人(译)	导管交流，INC.		
[标]发明人	DEUT HARVEY L		
发明人	DEUTSCH, HARVEY L.		
IPC分类号	A61M29/00 A61B A61B17/00 A61B17/08 A61B17/22 A61B17/34		
CPC分类号	A61B17/00491 A61B17/08 A61B17/085 A61B17/221 A61B2017/081 A61B2017/22082 A61B2017/3486 A61M2025/1013 A61M2025/105 A61M2025/1054		
代理机构(译)	GARAVELLI，PAOLO		
优先权	60/524366 2003-11-20 US		
其他公开文献	EP1691879A4 EP1691879B1		
外部链接	Espacenet		

摘要(译)

一种可用于消除腔的装置（10），包括近端区段（12），近端区段（12）包括近端，远端区段（14）包括由外部球囊层（26）围绕的内部球囊层（24），以及近端段（12）和远端段（14）之间的中间段（16）;连接器（18），位于近端段（12）的近端上，包括球囊层膨胀和收缩端口（20）并包括粘合剂输送端口（22）;膨胀和收缩管腔（30）连接膨胀和收缩口（20）与内部球囊层（24）;连接粘合剂输送口（22）和外部球囊层（26）的粘合剂输送管腔（22）;其中外球囊层（26）包括多个穿孔（28）。一种消除腔的方法，例如腹股沟疝囊。