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(54) METHOD AND DEVICE FOR CAVITY OBLITERATION

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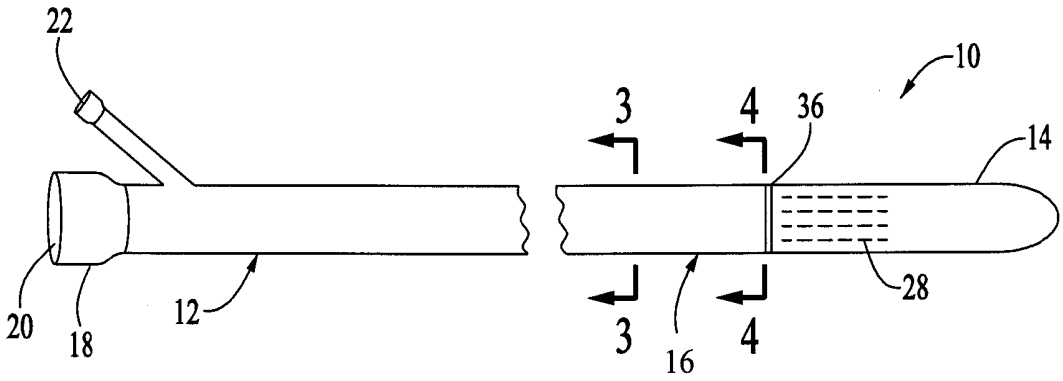
(52) **U.S. Cl.** **606/194**

(57) **ABSTRACT**

A device that can be used to obliterate a cavity comprising a proximal segment comprising a proximal end; a distal segment comprising a plurality of microcatheters attached to the external surface of the inner balloon layer, each microcatheter comprising a plurality of perforations; an intermediate segment between the proximal segment and the distal segment; a connector on the proximal end of the proximal segment, the connector comprising a balloon layer inflation and deflation port and further comprising an adhesive delivery port; an inflation and deflation lumen connecting the inflation and deflation port with the inner balloon layer; an adhesive delivery lumen connecting the adhesive delivery port with the plurality of microcatheters; a self-sealing valve connected to the inflation and deflation lumen; and a separation area between the distal segment and the intermediate segment configured to separate the distal segment from the intermediate segment.



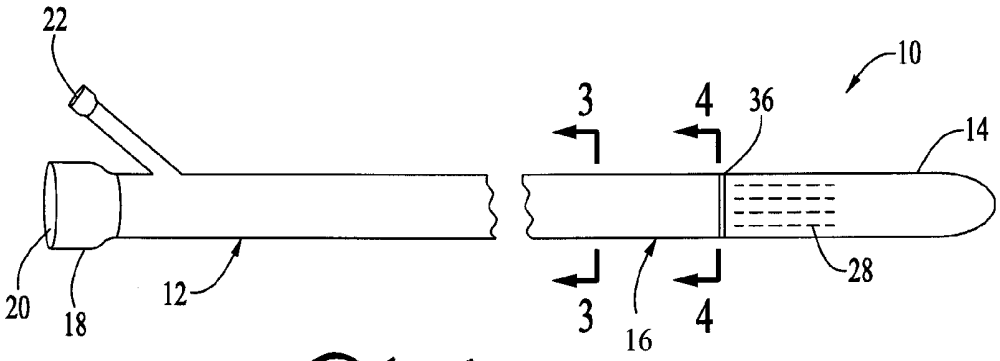


FIG. 1

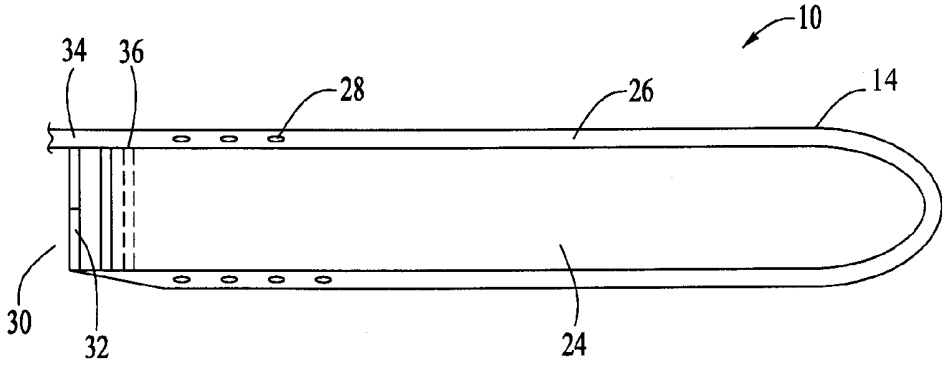


FIG. 2

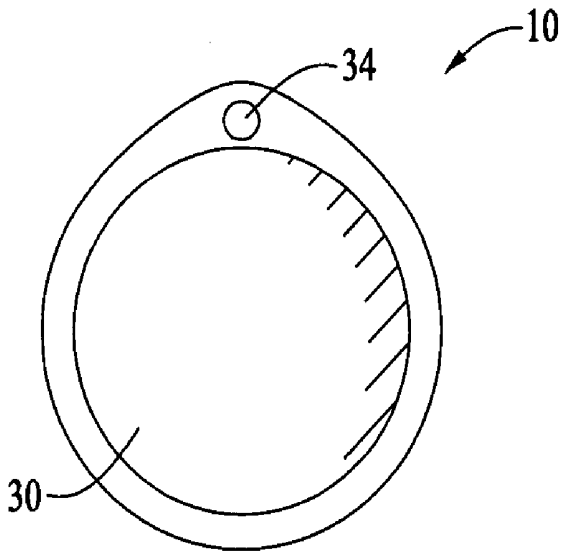


FIG. 3

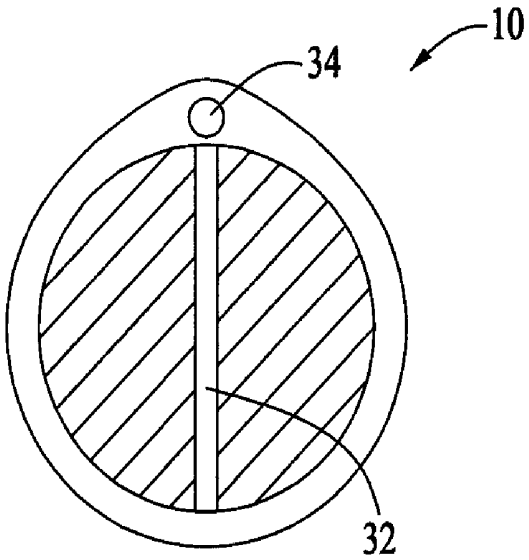


FIG. 4

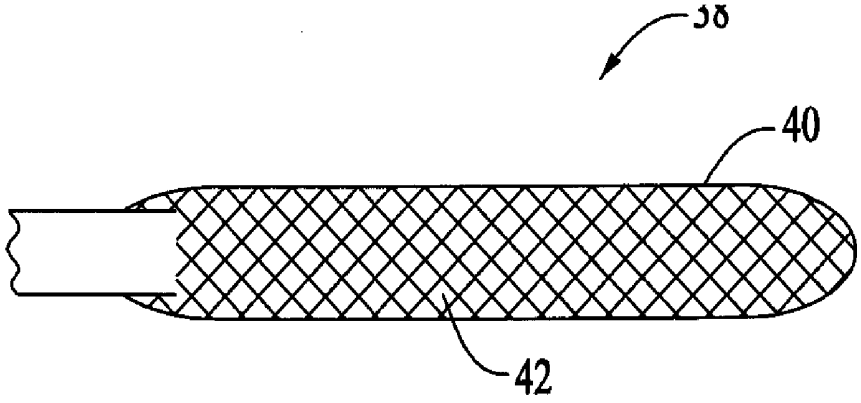


FIG. 5

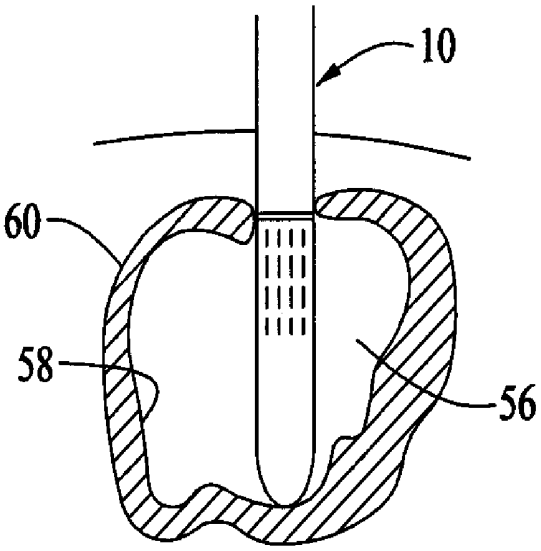


FIG. 7

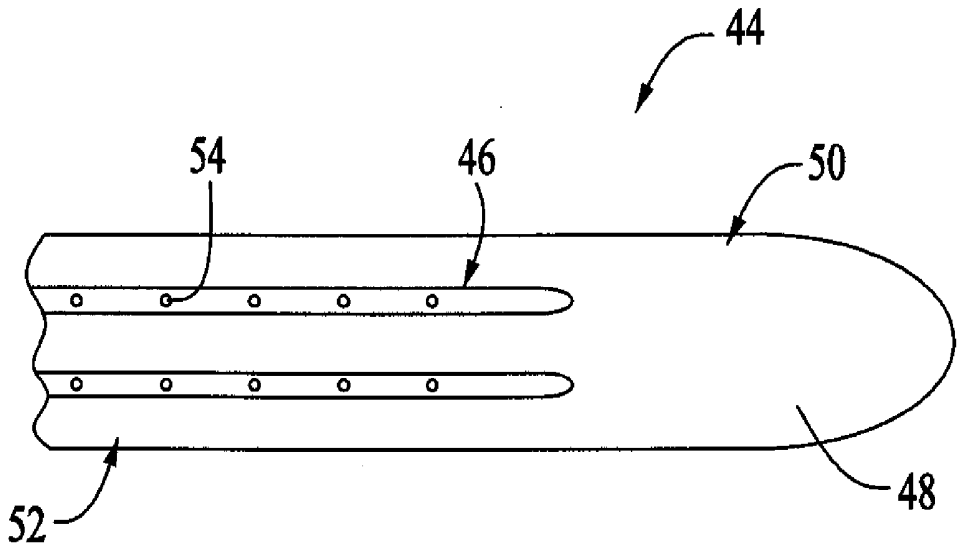


FIG. 6

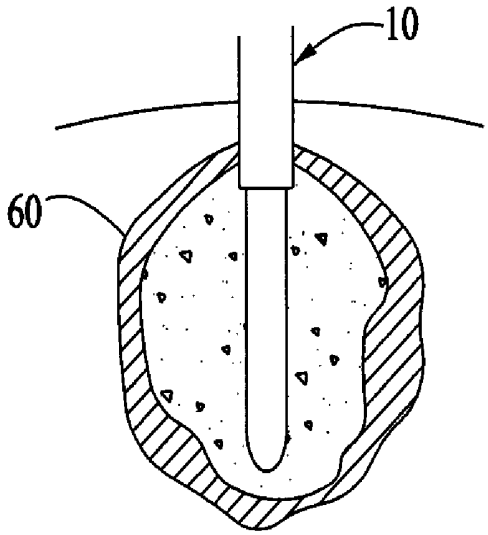


FIG. 8

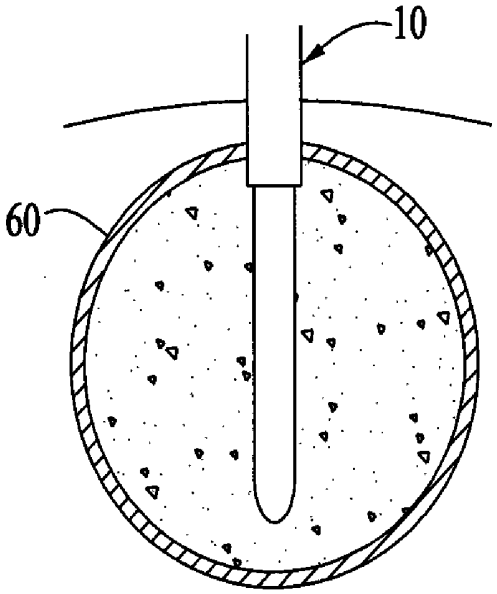


FIG. 9

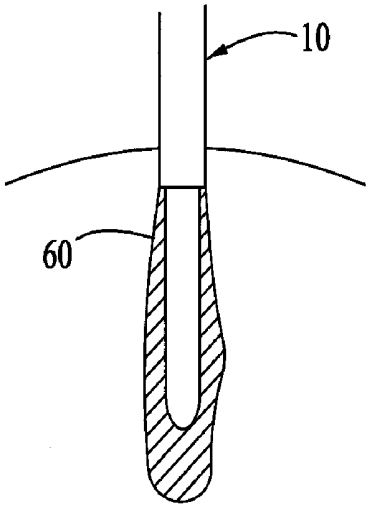


FIG. 10

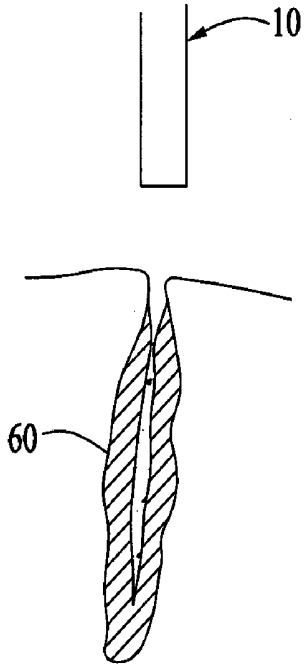


FIG. 11

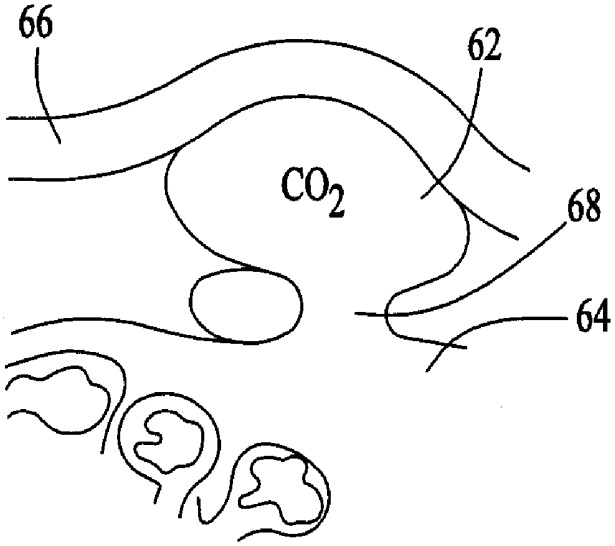


FIG. 12

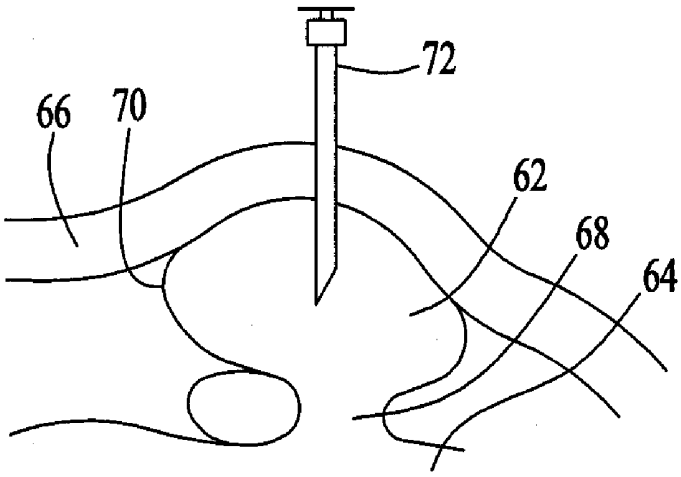


FIG. 13

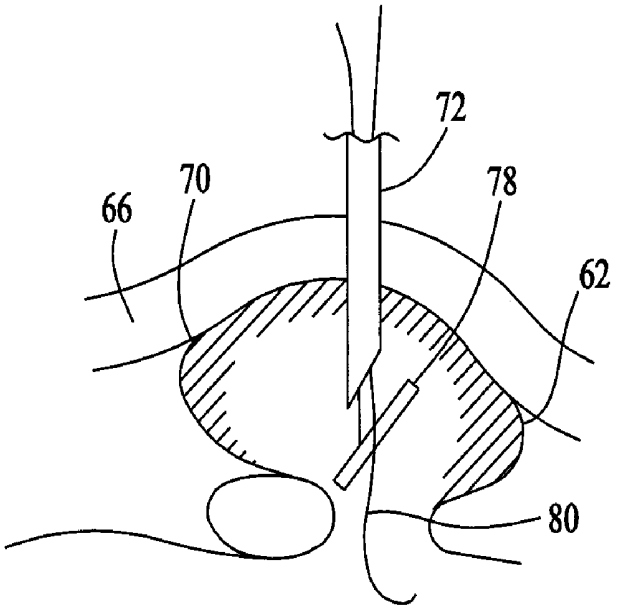


FIG. 14

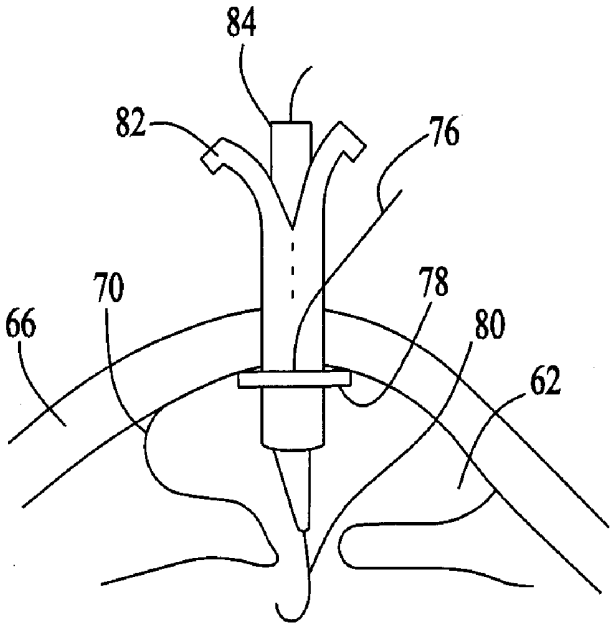


FIG. 15

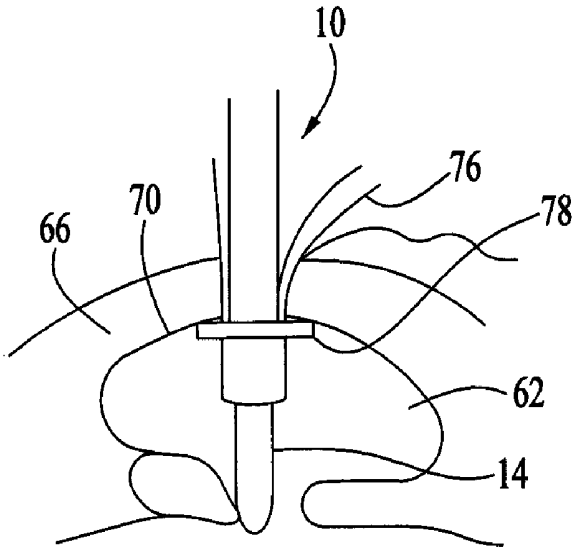


FIG. 16

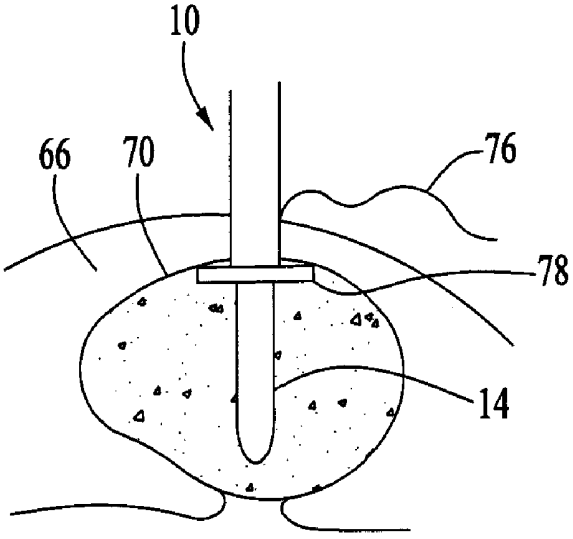


FIG. 17

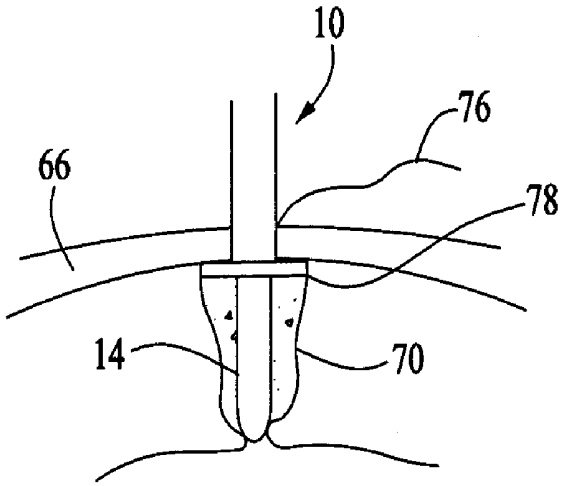


FIG. 18

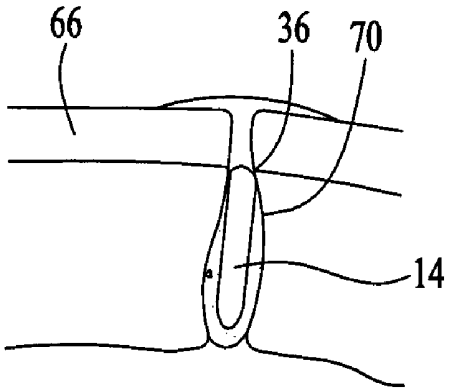


FIG. 19

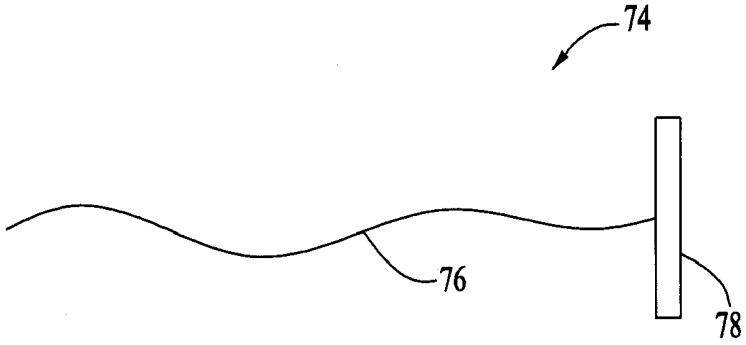


FIG. 20

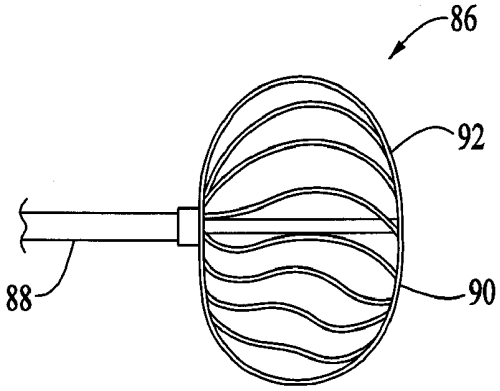


FIG. 21

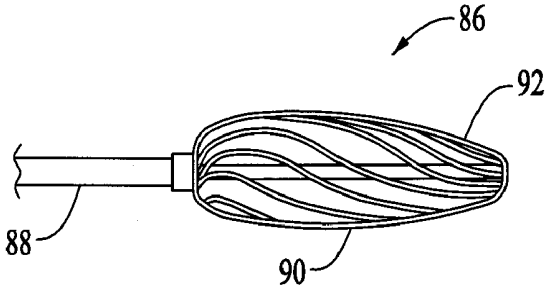


FIG. 22

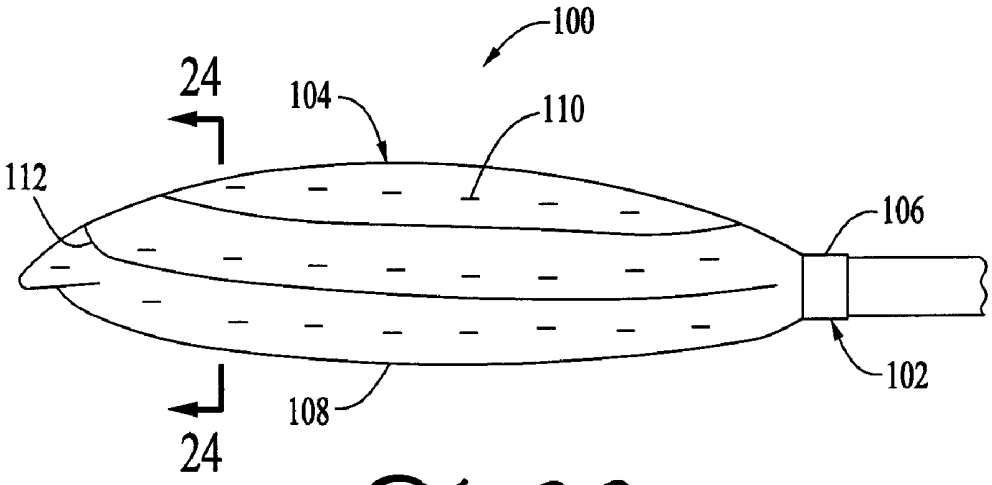


FIG. 23

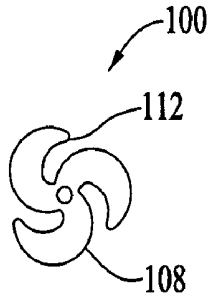


FIG. 24

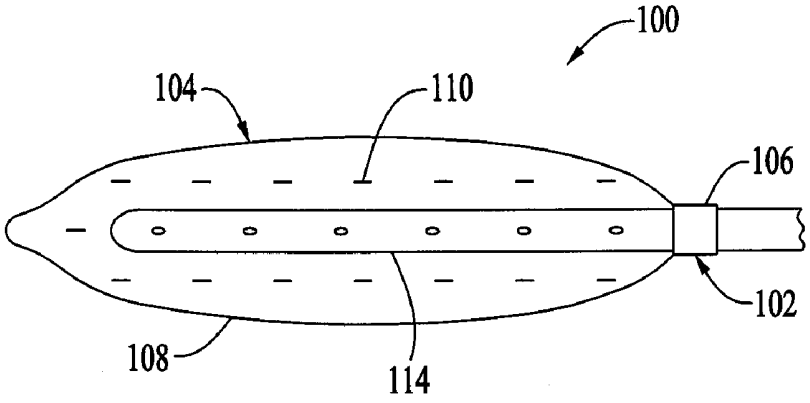


FIG. 25

METHOD AND DEVICE FOR CAVITY OBLITERATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present Application is a divisional of U.S. patent application Ser. No. 10/993,940 titled "Method and Device for Cavity Obliteration," filed Nov. 19, 2004, which claims the benefit of U.S. Provisional Patent Application No. 60/524,366 titled "Method and Device for Cavity Obliteration," filed Nov. 20, 2003, the contents of which are incorporated in this disclosure by reference in their entirety.

BACKGROUND

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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

[0006] According to one embodiment of the present invention, there is provided a device that can be used to obliterate a cavity, the device comprising a) a proximal segment comprising a proximal end; b) a distal segment comprising an inner balloon layer having an external surface and surrounded by a plurality of microcatheters attached to the external surface of the inner balloon layer, each microcatheter comprising a plurality of perforations; c) an intermediate segment between the proximal segment and distal segment; d) a connector on the proximal end of the proximal segment, the connector comprising a balloon layer inflation and deflation port and further comprising an adhesive delivery port; e) an inflation and deflation lumen connecting the inflation and deflation port with the inner balloon layer; f) an adhesive delivery lumen connecting the adhesive delivery port with the plurality of microcatheters; g) a self-sealing valve connected to the inflation and deflation lumen; and h) a separation area between the distal segment and the intermediate segment configured to separate the distal segment from the intermediate segment. In one embodiment, the inflation and deflation port and the adhesive delivery port are combined into a single port.

[0007] 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 according to the present invention; c) inserting the device into the cavity until the distal segment of the device lies within the cavity; d) inflating the inner balloon layer; e) introducing an adhesive through the plurality of microcatheters 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 and the stomach. In a preferred embodiment, the cavity is a hernia sac of an inguinal hernia in a patient. In one embodiment, the method further comprises a) selecting the patient with the inguinal hernia; 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 segment 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 another embodiment, one or more than one step of the method is performed using an imaging technique. In a preferred 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 one 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 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.

FIGURES

[0008] 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:

[0009] FIG. **1** is a partial lateral perspective view of one embodiment of a device according to the present invention;

[0010] FIG. **2** is an enlarged, cutaway, lateral perspective view of the distal end of the device shown in FIG. **1**;

[0011] FIG. **3** is an enlarged, cross-sectional, perspective view of the device shown in FIG. **1** taken along the line **3-3**;

[0012] FIG. **4** is an enlarged, cross-sectional, perspective view of the device shown in FIG. **1** taken along the line **4-4**;

[0013] FIG. **5** is a partial, lateral prospective view of the distal segment of another embodiment of the device according to the present invention;

[0014] FIG. **6** is a partial, lateral prospective view of the distal segment of another embodiment of the device according to the present invention;

[0015] FIG. **7** through FIG. **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;

[0016] FIG. **12** through FIG. **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;

[0017] FIG. **20** is an anchor useful in a method according to the present invention;

[0018] FIG. **21** and FIG. **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;

[0019] FIG. **23** is a lateral perspective view of another embodiment of the device according to the present invention;

[0020] FIG. **24** is a cross-sectional, perspective view of the device shown in FIG. **23**, taken along the line **24-24**; and

[0021] FIG. **25** is a lateral, cutaway perspective view of the device shown in FIG. **23**.

DESCRIPTION

[0022] 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.

[0023] 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.

[0024] 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 FIG. **1** to FIG. **4** there are shown, respectively, a partial lateral perspective view of one embodiment of the device according to the present invention (FIG. **1**); an enlarged, cutaway, lateral perspective view of the distal end of the device shown in FIG. **1** (FIG. **2**); an enlarged, cross-sectional, perspective view of the device shown in FIG. **1** taken along the line **3-3** (FIG. **3**); and an enlarged, cross-sectional, perspective view of the device shown in FIG. **1** taken along the line **4-4** (FIG. **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 FIG. **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.

[0025] In one embodiment, as shown in FIG. **1** and FIG. **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.

[0026] 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 deliv-

ery port **22** in the proximal segment **12** with the outer balloon layer **26** in the distal segment **14**. In one embodiment, as shown in FIG. **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.

[**0027**] 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.

[**0028**] Referring now to FIG. **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.

[**0029**] Referring now to FIG. **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 FIG. **1** through FIG. **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 FIG. **1** and FIG. **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 FIG. **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.

[**0030**] 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.

[**0031**] Referring now to FIG. **7** through FIG. **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.

[**0032**] 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 FIG. **1** through FIG. **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.

[**0033**] 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 FIG. **12** through FIG. **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.

[**0034**] 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 FIG. **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**.

[**0035**] 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.

[**0036**] Next, in a preferred embodiment, an anchor **74** is introduced through the needle **72**. Referring now to FIG. **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.

[**0037**] As shown in FIG. **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.

[**0038**] 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.

[**0039**] 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.

[**0040**] 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.

[**0041**] 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, N.J. 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**.

[**0042**] 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**.

[**0043**] 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.

[**0044**] 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 FIG. **21** and FIG. **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 FIG. **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**.

[**0045**] 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.

[**0046**] 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.

[**0047**] 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 FIG. **23** to FIG. **25**, there are shown, respectively, a lateral perspective view of one embodiment of the device according to the present invention (FIG. **23**); a cross-sectional, perspective view of the device shown in FIG. **23**, taken along the line **24-24** (FIG. **24**); and a lateral, cutaway perspective view of the device shown in FIG. **23** (FIG. **25**). As can be seen, the device **100** comprises a proximal segment **102** and a distal segment **104**. In one embodiment, as shown in FIG. **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 FIG. **23** and FIG. **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 FIG. **25**.

[**0048**] 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 FIG. **23** and FIG. **25**, inserted into the cavity until the device **100** lies within the cavity. Next, the balloon **104** is inflated as shown in FIG. **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.

[**0049**] 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;

b) a distal segment comprising an inner balloon layer having an external surface and surrounded by a plurality of microcatheters attached to the external surface of the inner balloon layer, each microcatheter comprising a plurality of perforations;

c) an intermediate segment between the proximal segment and distal segment;

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

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

f) an adhesive delivery lumen connecting the adhesive delivery port with the plurality of microcatheters;

g) a self-sealing valve connected to the inflation and deflation lumen; and

h) a separation area between the distal segment and the intermediate segment configured to separate the distal segment from the intermediate segment.

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

3. 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 according to claim 1;

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

d) inflating the inner balloon layer;

e) introducing an adhesive through the plurality of microcatheters thereby binding the device to the wall of the cavity; and

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

4. The method of claim 3, 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.

5. The method of claim 3, 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 and the stomach.

6. The method of claims **3**, where the cavity is a hernia sac of an inguinal hernia in a patient.

7. The method of claim 6, where the method further comprises:

a) selecting the patient with the inguinal hernia;

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 segment 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.

8. The method of claim 7, where one or more than one step of the method is performed using an imaging technique.

9. The method of claim 8, 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.

10. The method of claim 7, further comprising anesthetizing the patient.

11. The method of claim 7, further comprising introducing a biocompatible gas into the peritoneal cavity after accessing the peritoneal cavity, thereby causing the hernia sac to distend.

12. The method of claim 7, further comprising detaching the distal segment of the device at the separation area from the proximal segment and intermediate segment of the device.

13. The method of claim 7, 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.

14. The method of claim 7, further comprising closing the integument and abdominal wall.

* * * * *

专利名称(译)	用于腔体闭塞的方法和装置		
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[标]申请(专利权)人(译)	导管交换		
申请(专利权)人(译)	导管交流，INC.		
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摘要(译)

一种可用于消除腔的装置，包括近端段，所述近端段包括近端;远端段包括连接到内部球囊层的外表面的多个微导管，每个微导管包括多个穿孔;近端节段和远端节段之间的中间节段;在近端段的近端上的连接器，连接器包括球囊层充气和放气端口，并且还包括粘合剂输送端口;连通膨胀和收缩口与内气囊层的膨胀和收缩管腔;连接粘合剂输送口和多个微导管的粘合剂输送管腔;自动密封阀，连接到膨胀和收缩腔;以及远端段和中间段之间的分离区域，其被配置为将远端段与中间段分开。