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(71) Applicant: SAFESAC MEDICAL LTD. [IL/IL]; 11 Ruth
Street, 3440416 Haifa (IL).

(72) Inventors: BAR-YOSEPH, Gill; 11 Ruth Street, 34404
Haifa (IL). BLEICHER, David; 24 Hazohar Street,
6233912 Tel-Aviv (IL).

(74) Agent: FRIEDMAN, Mark; Moshe Aviv tower 54th
Floor, 7 Jabotinski St., 5252007 Ramat-Gan (IL).

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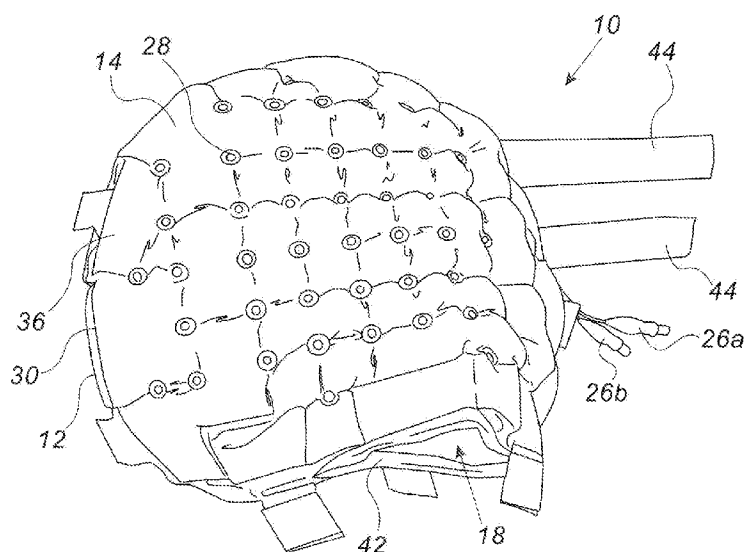


Fig. 1A

(57) Abstract: A tissue containment device (10) for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue includes a bag (12) formed by one or more walls (14) defining a containment compartment (16) and an opening (18) for accessing the containment compartment. Each wall (14) is formed from at least two layers including an inner layer (20) facing the containment compartment and an outer layer (22) facing outwards from bag (12). The layers define between them one or more inflatable volumes (24). Layers (20) and (22) are interconnected at spaced-apart connection regions (28) that are arranged such that, when a fluid is introduced into the inflatable volumes (24), regions of the at least two layers between the connection regions form wall cavity regions surrounding an internal volume of the containment compartment.



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Tissue Containment Device for Use in Surgical Procedures

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to surgical devices and, in particular, it concerns a tissue containment device for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue, and corresponding systems and methods.

During the performance of various gynecological procedures, such as myomectomy and hysterectomy, via an access opening which is smaller than the size of the uterus to be removed, a tissue reduction (or morcellation) process is required in order to reduce dimensions of the tissue to facilitate removal. Such processes raise concerns regarding the potential dissemination of tissue that is suspected of including cancerous cells, with an associated risk of seeding cancer growth at other locations within the body.

In an attempt to mitigate this risk, it has been proposed to introduce the tissue into an intra-body containment bag within which the tissue reduction process is performed. There remains however a significant risk of perforation of the bag by the various tools used during the procedure. Such perforation may go undetected, and may still allow leakage of cancerous cells into the abdominal cavity.

SUMMARY OF THE INVENTION

The present invention is a tissue containment device for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue, and corresponding systems and methods employing the device.

According to the teachings of an embodiment of the present invention there is provided, a tissue containment device for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue, the device comprising: (a) a bag comprising one or more walls, defining a containment compartment and an opening for accessing the containment compartment, wherein the one or more walls are formed from at least two layers defining at least one inflatable volume therebetween; and (b) at least one inflation port in fluid connection with the at least one inflatable volume for introducing and removing a fluid to and from the at least one inflatable volume, wherein the at least two layers are interconnected at spaced-apart connection regions, the spaced-apart connection regions being configured such that, when a fluid is introduced to the at least one inflatable volume, regions of the at least two layers between the connection regions form wall cavity regions substantially surrounding an internal volume of the containment compartment.

According to a further feature of an embodiment of the present invention, the wall cavity regions extend over at least 85% of an inward facing surface of the at least one wall facing the internal volume as projected to a centroid of the internal volume.

5 According to a further feature of an embodiment of the present invention, the wall cavity regions form a plurality of adjacent bulges in proximity to each other such that an instrument having a width of at least 8 mm cannot reach the connection regions without first contacting the bulges.

10 According to a further feature of an embodiment of the present invention, the at least two layers are implemented as initially flat sheets of material that are selectively interconnected at the connection regions.

According to a further feature of an embodiment of the present invention, an outer layer of the at least two layers is implemented as a layer having an increased resistance to flexing compared to an inner layer of the at least two layers.

15 According to a further feature of an embodiment of the present invention, an outer layer of the at least two layers differs from an inner layer of the at least two layers in at least one property selected from the group consisting of: shear strength, burst limit and puncture resistance.

20 According to a further feature of an embodiment of the present invention, the at least two layers are implemented as three layers of material, and wherein spaced apart connection regions between a first of the layers and a second of the layers are interspaced between spaced apart connection regions between the second of the layers and a third of the layers.

According to a further feature of an embodiment of the present invention, an inward-facing layer of the at least two layers is implemented with preformed inflatable pockets between the connection regions.

25 According to a further feature of an embodiment of the present invention, the bag assumes a compact state in which a first region of the at least one wall is adjacent to a second region of the at least one wall, and wherein the spaced-apart connection regions define elongated inflatable deployment cavities extending within the first and second regions such that, on inflation of the at least one inflatable volume, the inflatable deployment cavities press against
30 each other so as to tend to force apart the first and second regions, thereby opening up the internal volume of the containment compartment.

According to a further feature of an embodiment of the present invention, the at least one wall is configured to form at least two of the inflatable volumes, the at least two inflatable volumes being independently inflatable.

According to a further feature of an embodiment of the present invention, the spaced-apart connection regions are deployed so as to define elongated inflatable boundary cavities extending so as to circumscribe a majority of the opening such that, on inflation of the at least one inflatable volume, the inflatable boundary cavities tend to open the opening.

5 According to a further feature of an embodiment of the present invention, the spaced-apart connection regions are deployed such that, on inflation of the at least one inflatable volume, at least part of the at least one wall presents an array of inflated bulges in facing relation to the containment volume, and further comprising printed markings disposed within a central region of a plurality of the bulges.

10 According to a further feature of an embodiment of the present invention, the at least one wall comprises two walls interconnected at a peripheral seal such that the bag is formed from at least four of the layers in overlying relation.

 According to a further feature of an embodiment of the present invention, the bag further comprises at least one loop element deployed on an external surface of the bag, the loop element
15 being located to facilitate rolling of the bag by insertion of an instrument through the at least one loop element and rotation of the instrument.

 According to a further feature of an embodiment of the present invention, there is also provided a pressure indicator in fluid interconnection with the inflatable volume, the pressure indicator being configured to generate a visible and/or audible indication when a pressure within
20 the inflatable volume decreases or falls below a reference pressure value.

 According to a further feature of an embodiment of the present invention, the bag further comprises at least one instrument insertion branch implemented as a flexible access tube communicating with the containment compartment and allowing instrument access via an incision in a direction angularly spaced from the opening of the bag.

25 According to a further feature of an embodiment of the present invention, the instrument insertion branch is formed by an extension of at least one of the layers from each of two regions of the at least one wall, the extensions being interconnected to form a collapsible tube.

 According to a further feature of an embodiment of the present invention, the at least two layers are manufactured from a thermoplastic material.

30 There is also provided according to the teachings of an embodiment of the present invention, a system for implementing a surgical procedure to remove tissue from a body, the system comprising: (a) the aforementioned device; and (b) a heat sealing device configured for performing a heat sealing process on the instrument insertion branch so as to prevent leakage of

cells from the instrument insertion branch on introduction of the instrument insertion branch into the body.

There is also provided according to the teachings of an embodiment of the present invention, a system for implementing a surgical procedure to remove tissue from a body, the system comprising: (a) the aforementioned device; (b) a source of pressurized fluid for connection to the at least one inflation port; and (c) a tissue reducing device for insertion through the opening for reducing a dimension of tissue located within the containment compartment.

According to a further feature of an embodiment of the present invention, there is also provided a pressure monitoring system comprising: (a) a pressure sensor deployed for sensing a pressure within the at least one inflatable volume; and (b) logic circuitry in communication with the pressure sensor and configured to monitor variations in the pressure within the at least one inflatable volume to determine whether the variations are indicative of a malfunction condition of the bag.

According to a further feature of an embodiment of the present invention, the logic circuitry is further configured to generate an audible and/or visible indication on identification of a malfunction condition of the bag.

According to a further feature of an embodiment of the present invention, the logic circuitry is further configured to determine if a layer of the bag has been breached and, in response to such breaching, to generate an output for initiating a corrective action, the corrective action including increasing a pressure supplied to the inflatable volume.

According to a further feature of an embodiment of the present invention, the bag further comprises an access sleeve sealingly connected to the opening and defining a sealed access channel for performing a tissue reduction process on tissue within the containment compartment.

According to a further feature of an embodiment of the present invention, there is also provided an abdominal cavity insufflation port and an associated flow channel configured for providing insufflation pressure to an abdominal cavity external to the access sleeve.

According to a further feature of an embodiment of the present invention, a pressure monitoring system comprising: (a) a first pressure sensor deployed for sensing a pressure within the at least one inflatable volume; (b) a second pressure sensor configured for deployment to sense abdominal cavity pressure exterior to the bag; and (c) logic circuitry in communication with the first and second pressure sensors, and configured to monitor variations in the pressure within the at least one inflatable volume relative to the pressure exterior to the bag, and to determine whether the variations are indicative of a malfunction condition of the bag.

According to a further feature of an embodiment of the present invention, the logic circuitry is further configured to generate an audible and/or visible indication on identification of a malfunction condition of the bag.

5 According to a further feature of an embodiment of the present invention, the logic circuitry is further configured to determine if a layer of the bag has been breached and, in response to such breaching, to generate an output for initiating a corrective action, the corrective action including increasing a pressure supplied to the abdominal cavity volume exterior to the bag.

10 According to a further feature of an embodiment of the present invention, there is also provided a third pressure sensor deployed for sensing a pressure within the containment compartment, the logic circuitry further being in communication with the third pressure sensor.

There is also provided according to the teachings of an embodiment of the present invention, a method for surgical removal of tissue from a body, the method comprising the steps of: (a) introducing the device of claim 24 into the body through an incision or body orifice in a compact, uninflated state; (b) inflating the inflatable volume with a fluid so as to deploy the bag within the body; (c) inserting into the bag the tissue to be removed from the body; (d) extending the access sleeve out through the incision or body orifice; (e) performing via the access sleeve reduction and removal of the tissue; (f) deflating the inflatable volume while maintaining part of the access sleeve extending out through the incision or body orifice; and (g) removing the device via the incision or body orifice.

20 According to a further feature of an embodiment of the present invention, insertion of the device is performed via a laparoscopic incision.

According to a further feature of an embodiment of the present invention, the inflation is performed using saline solution.

25 According to a further feature of an embodiment of the present invention, the bag further comprises at least one instrument insertion branch implemented as a flexible access tube communicating with the containment compartment, the method further comprising extending the at least one instrument insertion branch out through an incision or body orifice.

30 According to a further feature of an embodiment of the present invention, an instrument is inserted through the at least one instrument insertion branch.

According to a further feature of an embodiment of the present invention, the at least one instrument insertion branch is heat sealed prior to reintroduction of the instrument insertion branch into the body.

According to a further feature of an embodiment of the present invention, the device is formed with at least one loop element, the method further comprising inserting at least one instrument through the at least one loop element, and rolling at least part of the device around the instrument.

5 According to a further feature of an embodiment of the present invention, a pressure is sensed within the at least one inflatable volume and variations in the pressure are monitored to determine whether variations in the pressure are indicative of a malfunction condition of the bag.

 According to a further feature of an embodiment of the present invention, an abdominal cavity exterior to the bag is insufflated and a pressure within the abdominal cavity exterior to the
10 bag is sensed.

 According to a further feature of an embodiment of the present invention, the containment compartment of the bag is inflated and a pressure within the containment compartment of the bag is sensed.

 According to a further feature of an embodiment of the present invention, it is determined
15 whether a layer of the bag has been breached and, in response to such breaching, a corrective action is initiated, the corrective action including introducing a fluid into the inflatable volume and/or into the abdominal cavity exterior to the bag.

BRIEF DESCRIPTION OF THE DRAWINGS

 The invention is herein described, by way of example only, with reference to the
20 accompanying drawings, wherein:

 FIGS. 1A and 1B are isometric views of a tissue containment device, constructed and operative according to an embodiment of the present invention, for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue, the device being shown in an inflated state;

25 FIGS. 2A and 2B are schematic partial cross-sectional views taken through a wall of the device of FIG. 1A illustrating two versions of a wall structure;

 FIG. 3 is a schematic view similar to FIG. 2B illustrating a projection from a centroid of a volume within a containment compartment of the device towards the wall;

 FIGS. 4A and 4B are schematic partial cross-sectional views taken through a wall of the
30 device of FIG. 1A illustrating a further two variant implementations of a wall structure;

 FIG. 5 is a schematic partial isometric view illustrating a tool projecting into the containment compartment of the device of FIG. 1A;

 FIG. 6A is a further isometric view of the device of FIG. 1A;

FIGS. 6B and 6C are more detailed views of the regions of FIG. 6A designated by corresponding dashed ellipses;

FIGS. 7A and 7B are isometric views of the device of FIG. 1A after extending of a sealed access sleeve, the device being shown in uninflated and inflated states, respectively;

5 FIG. 8 is a schematic view of a variant implementation of the device of FIG. 1A showing interdigitated inflatable volumes;

FIGS. 9A and 9B are schematic illustrations of a duckbill check valve for use with the devices of the present invention, the check valve being shown in a closed state and an open state, respectively;

10 FIG. 9C is a schematic illustration of the valve of FIG. 9A connected to a pressure monitor;

FIGS. 10A and 10B are schematic views of two stages during a gynecological procedure performed using the device of FIG. 1A;

15 FIGS. 11 and 12 are two schematic illustrations showing different modes of anchoring of the access sleeve at an abdominal incision, without and with use of a trocar, respectively;

FIGS. 13A and 13B are schematic representations of arrangements for applying pressure and monitoring pressure in the cases of FIGS. 11 and 12, respectively;

FIG. 13C illustrates schematically a further option for insufflation of the abdominal cavity via a separate incision;

20 FIG. 14 illustrates schematically performance of a manual tissue reduction procedure via an abdominal incision employing a device according to the teachings of the present invention;

FIG. 15 illustrates schematically performance of a manual tissue reduction procedure performed vaginally employing a device according to the teachings of the present invention;

25 FIG. 16 illustrates schematically an instrument insertion branch of the device of FIG. 1A anchored within an abdominal incision employing a trocar;

FIG. 17 is a schematic isometric view illustrating deployment of a gripping tool via an instrument insertion branch to access the containment compartment of the device of FIG. 1A;

FIG. 18 illustrates schematically a branch sealing operation employing a sealing tool to seal an instrument insertion branch;

30 FIGS. 19A and 19B are schematic illustrations showing two stages in a procedure for compacting the device of FIG. 1A; and

FIG. 20 is a flow diagram illustrating an aspect of operation of a system including the device of FIG. 1A according to a further aspect of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is a tissue containment device for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue, and corresponding systems and methods employing the device.

5 The principles and operation of devices, systems and methods according to the present invention may be better understood with reference to the drawings and the accompanying description.

10 Referring now to the drawings, FIGS. 1-20 illustrate the structure and operation of a tissue containment device, generally designated 10, constructed and operative according to the teachings of an embodiment of the present invention, for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue. In general terms, device 10 has a bag 12 formed by one or more walls 14 defining a containment compartment 16 and an opening 18 for accessing the containment compartment. Each wall 14 is formed from at least two layers including an inner layer 20 facing the containment compartment and an outer layer 22 facing
15 outwards from bag 12. The layers define between them one or more inflatable volumes 24 in fluid connection with a corresponding one or more inflation ports 26a, 26b for introducing and removing a fluid to and from the at least one inflatable volume.

20 It is a particular feature of certain preferred implementations of the present invention that the at least two layers 20 and 22 are interconnected at spaced-apart connection regions 28 that are arranged such that, when a fluid is introduced into the inflatable volumes 24, regions of the at least two layers between the connection regions form wall cavity regions substantially surrounding an internal volume of the containment compartment.

25 It will be appreciated that the provision of inflated wall cavity regions substantially surrounding the internal volume of the containment compartment provides profound advantages regarding the potential risks of disseminating tissue that is suspected to include cancerous cells during a tissue removal procedure. Specifically, by providing a cavity wall structure in which at least two layers are separated by a fluid-filled cavity, the risks of leakage from the bag are greatly reduced, since any minor puncture will typically penetrate one layer without reaching the second layer. Furthermore, the presence of a fluid-filled volumes maintained at a pressure
30 elevated above atmospheric pressure surrounding the internal volume facilitates immediate detection of any puncture event through detection of loss of pressure. These and other features of preferred embodiments of the present will be described further below.

The present invention is applicable to a wide range of laparoscopic and open surgery procedures, whether performed through one or more external incision and/or via a body orifice.

Examples include, but are not limited to, various gynecological procedures, such as myomectomy and hysterectomy.

Where reference is made to “tissue reduction”, this refers to a process through which at least one dimension of a piece of tissue is reduced in order to facilitate removal of the tissue from the body. Tissue reduction thus defined includes a wide range of techniques, including power morcellation and various sectioning processes, for example, manual morcellation during which a piece of tissue may be converted into an elongated rope of tissue, or into a number of separate pieces. A tissue reduction tool may employ one or more blades, or may use RF or other energy applicators to convert the form of the tissue.

Where reference is made herein in the description to inflation using a fluid, the term is used generically to refer to options of inflation by gas or by liquid. Gases suitable for inflation of device 10 include all biocompatible gases such as those that are typically used for insufflation of the abdominal cavity during laparoscopic procedures, including but not limited to carbon dioxide, nitrous oxide and helium. Liquids suitable for inflation of device 10 include all biocompatible liquids, including but not limited to isotonic saline solution, optionally with a marker or dye to facilitate visual detection of any puncture, or optionally a liquid used to enhance transparency of walls 14.

The term “wall cavity region” is used herein in the description and claims to refer to any regions of wall in which two layers of the wall are separated by fluid-filled cavity, thereby requiring penetration of two spaced-apart layers before a leakage path through the wall would result.

As mentioned, it is a particular feature of one aspect of the present invention that the wall cavity regions formed by inflatable volumes 24 when inflated substantially surround an internal volume of the containment compartment. In this context, “substantially surround” is used to refer to an arrangement in which the inflatable volumes are sufficiently closely packed and have sufficiently small spaces between them that any puncturing of an inner layer of the bag by a tissue reduction tool, such as a power morcellator, or by any other instrument used during the procedure is likely to result in breaching of one of the inflatable volumes, and will thus cause pressure loss to the inflatable volume. “Surrounding” in this context refers to the walls of the bag 12 which define the containment compartment, but excludes the area of opening 18. There are a number of different structural features and options which may contribute to this property, as will be described below.

Firstly, the spaced apart connection regions 28 are preferably laid out in a pattern in which each connection region is relatively small or narrow. In most cases, the connection regions

have at least one dimension which is less than 8 mm, preferably no more than 5 mm, and typically in the range of 2-3 mm. The same dimensional limitations are preferably also true for any continuous seal lines separating between inflatable volumes (discussed further below) that are in facing relation to the containment compartment. (Seal lines at which two regions of wall meet and turn outwards from the bag, such as those at an outer seam 30 of the illustrated embodiment, may be larger than the above dimensions, since the width of the seam is not exposed to the containment compartment.) The connection regions 28 and any seal lines passing across the inward-facing surfaces of the walls preferably have a total area of not more than 20% of the internal surface area of the bag prior to inflation, and more preferably not more than 10%.

In certain cases, particularly where the spaced apart connection regions 28 are implemented primarily as a pattern of isolated "dot" regions, the total area of these regions is typically about 5% or less.

Inaccessibility of the connection regions 28 for accidental perforation is preferably further enhanced by the geometrical form assumed by inflatable volumes 24 when inflated. Firstly, the inflatable volumes of certain embodiments form inward bulges of inner layer 20. Because of these inward bulges, the inflated regions are typically encountered first by any instrument which is inadvertently advanced towards the wall. Furthermore, the adjacent peripheral edges of the bulges typically form a crevice at connection regions 28, which may in some cases have an acute angle of convergence, as illustrated in FIGS. 2A and 2B. This crevice configuration further reduces the probability of an instrument causing puncture in the region of connection without impinging on the inflatable volumes, since such selective puncture would only be likely to occur in the event of an instrument of particular dimensions which approaches the crevice within a particular range of angles of approach, and with a specific instrument orientation that presents a sufficiently narrow profile.

The proximity of the adjacent bulges adjacent to each region of connection is preferably sufficiently small that an instrument having a width of at least 8 mm, and most preferably even 5 mm, or even 3 mm, cannot reach the connection regions without first contacting the bulges.

Another way to express the property that the wall cavity regions formed by inflatable volumes 24 when inflated substantially surround an internal volume of the containment compartment is by considering a projection of the wall surface towards a centroid of the internal volume of the containment compartment. This is illustrated in the partial view of FIG. 3, where dashed lines extend between the centroid of the internal volume of the inflated bag and the wall. According to this definition, the wall cavity regions preferably extend over at least 85%, more preferably at least 90%, and in certain cases at least 95% or even at least 97%, of the inward

facing surface of the walls facing the internal volume as projected towards a centroid of the internal volume. In alternative terms, this may be considered the proportion of the solid angle subtended at the centroid by the wall cavity regions compared to that of the wall as a whole, not including the opening.

5 The wall structure of bag 12 may be implemented in many ways, and generate many variant structures which exhibit properties as described above. According to one particularly preferred subset of implementations, the layers 20, 22 of the walls are formed primarily as layers of biocompatible thermoplastic material which are selectively welded together by some combination of heat and pressure to form connection regions 28. In one example, the structure
10 can be formed from two bags, which may themselves be seamless, placed one inside the other and then interconnected at an arrangement of spaced apart connection regions 28, thereby forming a bag that is essentially a single-wall structure with a layered wall structure. A similar approach can be taken to a three-layer wall structure, as discussed below.

15 In an alternative subset of implementations, separate regions of the wall or walls are connected to each other, also typically by a welding process, to form a seam of bag 12. This may be achieved by taking a two-layer wall and folding it over to double on itself followed by a heat/pressure welding process, or by stacking two separate layered walls and performing a heat/pressure welding process. In certain cases, the bag typically exhibits a flat pouch-like form when uninflated, which opens into a three dimensional open pouch on inflation. It should be
20 noted that the above examples, while considered particularly advantageous, are not limiting, and many other ways of forming an appropriate layered-wall bag structure also fall within the scope of the present invention.

25 Examples of possible structures of the layered wall, shown in an inflated state, are illustrated schematically in FIGS. 2A, 2B, 4A and 4B. In the case of FIG. 2A, two similar layers 20, 22, typically initially in the form of flat sheets, are interconnected at connection regions 28, thereby defining inflatable volumes 24 which, when inflated form wall cavities between the layers extending between the connection regions. In this case, the two layers typically bulge
30 outwards from the local midline of the wall roughly symmetrically to the inside and outside of the bag, although the inward bulges are typically closer to each other due to an overall concave profile of the bag wall.

 In some cases, it may be preferred to generate asymmetric wall cavity regions where the external layer 22 is relatively smoother than the internal layer 20, thereby minimizing the risk of applying localized pressure on adjacent organs within the abdominal cavity. An example of such a structure is shown in FIG. 2B. This structure may be achieved by defining a preferential

direction of inflation of the cavities, by pre-shaping layer 20 to have pre-formed inflatable cavities and/or by forming outer layer 22 with increased resistance to flexing compared to inner layer 20. An increased resistance to flexing may be generated by using an increased thickness layer and/or by use of different materials, or reinforced materials, for the different layers. Pre-shaping of a layer with pre-formed inflatable cavities can be achieved by various polymer production techniques, such as flow-forming or suction-forming, all as is known in the art.

It will be noted that the ability to form the bag wall from a number of layers having different properties can be used to advantage in other ways. For example, in some cases, it may be advantageous to provide outer layer 22 and inner layer 20 with different properties for at least one of the properties: shear strength, burst limit and puncture resistance. For example, in order to facilitate compact insertion and removal of the device, it may be preferable to combine one layer which provides the requisite physical properties for burst limit, puncture resistance etc. while the remaining layer or layers are formed from relatively thinner material which are more easily compacted by rolling or the like when deflated.

In certain cases, it may be advantageous to employ more than two layers in the wall of the device. In one example, illustrated in FIG. 4A, a wall structure similar to that of FIG. 2A is supplemented by an additional external bag 32, which is not necessarily bonded to the main bag. In this case, the external bag provides an additional degree of leak protection, and also tends to help distribute any external contact pressure exerted by the bag.

A further particularly preferred exemplary implementation is illustrated schematically in FIG. 4B. In this case, the inner and outer layers 20 and 22 are supplemented by an intermediate layer 34. Spaced apart connection regions 28a between inner layer 20 and intermediate layer 34 are interspaced between spaced apart connection regions 28b between intermediate layer 34 and outer layer 22. The result of this structure is that the connection regions are staggered and that each connection region occurs at a location that a wall cavity region is provided between the other layers, thereby providing continuous cavity-wall protection that cannot be accidentally breached without puncturing an inflatable volume of the structure. The inflatable volumes on both sides of the intermediate layer 34 may be two independent inflatable volumes, or may be interconnected at some location in the bag, either by an aperture or apertures formed through the intermediate layer or by terminating the intermediate layer just short of a boundary of the wall.

Manufacture of a wall structure such as that of FIG. 4B can be achieved using techniques known in the art. For example, inserts, such as insulating strips or other forming elements, may be inserted between a first layer and a second layer prior to welding the two layers together along lines, or dots or dashes spaced along lines, between the inserts. A third layer is then

superimposed over that structure and the second and third layers are bonded along lines, dots or dashes overlying the inserts. The inserts are then withdrawn.

In all of the implementations described herein, the pattern of connection regions **28** is not necessarily uniform over the area of the walls, and may advantageously be implemented with patterns that enhance various properties of the deployed inflated bag and/or the sequence in which it deploys. By way of one example, in implementations of the invention which have a defined crease line (which may be a seam) along which the bag is folded or otherwise closed against itself when deflated, the configuration of connection regions between the layers may advantageously define elongated inflatable deployment cavities **36** extending along at least part of the crease line within two facing portions of the wall. As a result, on inflation of the bag walls, the inflatable deployment cavities **36** press against each other so as to tend to open up the internal volume of the containment compartment.

Similarly, the spaced-apart connection regions **28** may advantageously be deployed so as to define elongated inflatable boundary cavities **38** which extend so as to circumscribe a majority of opening **18** such that, on inflation of the bag **12**, inflatable boundary cavities **38** tend to open up opening **18**, thereby facilitating introduction of tissue into the bag.

Additionally, or alternatively, inflatable deployment cavities **36** and inflatable boundary cavities **38** may be arranged to form a framework running in one or more directions through bag **12** so as to enhance deployment of bag **12** into a desired form. Typically, the regions between these enlarged cavities have more closely spaced connection regions **28**, thereby defining a "quilt" like effect, i.e., an array of smaller cavities forming a corresponding array of inflated bulges in facing relation to the containment volume, thereby maintaining flexibility of the wall while still ensuring the various advantages described herein of the cavity wall structure.

Printed markings, such as ruler markings or crossed grid vertices, are preferably applied to at least some of the above bulges. The printed markings are preferably applied within a central region of each bulge, i.e., within a middle third in each dimension between the adjacent connection regions, so that after inflation the printed markings are on the region of the bulge facing generally inwards into the containment volume. These marking preferably provide a visual frame of reference for the size of tissue pieces viewed by endoscopy within the bag. Despite the isolated positioning of each marking on a separate bulge, the marking when viewed together provide a visual effect of a grid, without the confusion that would be caused by continuous lines following the contours of the inflated wall through the crevices adjacent to the regions of interconnection.

The various implementations of bag 12 described herein may be implemented with one shared inflatable volume which allows inflation of the entire device via a single connector, or may be implemented as two or more independently inflatable volumes. The provision of two or more independently inflatable volumes may be valuable in certain cases as providing structural support to the deployed bag even in the event that one of the inflatable volumes is punctured, and further allows flexibility in cases where it may be desired to deploy the device in a specific sequence, or to inflate different parts of the device to different pressures.

The presence of multiple independent inflatable volumes may result from a wall structure such as that illustrated in FIG. 4B, from a bag structure in which two separate walls are interconnected around a peripheral seal line, or by various other arrangements of the interconnection regions that are designed to define distinct inflatable volumes. One further example is illustrated schematically in FIG. 8, where in addition to a pattern of dot-like interconnection regions, an arrangement of seal-line interconnections are configured to define an interdigitated arrangement of inflatable volumes 24a, 24b that are selectively and independently inflatable via corresponding inflation channels 40.

According to certain preferred implementations of the present invention, each inflation channel of device 10 is provided with a check valve so that, once inflated, the inflatable volumes remain pressurized without constant connection to a source of pressure. Any type of check valve may be used, including but not limited to a duckbill valve 41 such as is illustrated in a closed and open state, respectively, in FIGS. 9A and 9B. Advantageously, the check valve(s) may be integrated with connection ports 26a, 26b. In certain cases, where it is desired to perform quantitative monitoring of pressure variations within the inflatable volume(s) during a procedure, tubing 43 to support connection of a pressure sensor may be connected to the check valve, or a pressure sensor may be integrated with the check valve, as illustrated schematically in FIG. 9C. Where a qualitative indication of maintaining inflation pressure is considered sufficient, the pressure sensor may be replaced by a pressure indicator, such as a mechanical pressure sensor device which with an indicator rotor which reveals different colors according to the current pressure, or a coiled-finger indicator in which a finger-like branch tube is biased to a coiled state by an elongated leaf spring, and is extended by pressure within the branch tube while pressure is maintained above a given threshold target pressure. The pressure indicator is deployed in fluid interconnection with the inflatable volume, and generates a visible and/or audible indication when a pressure within the inflatable volume decreases or falls below a reference pressure value, which may be a fixed pressure value, or may be a reference value defined by the pressure in

another volume, such as in the abdominal cavity outside the bag. Optionally, such a sensor may be provided with a battery used to generate the visible or audible indication.

A primary application of device **10** is for providing an isolated intra-body containment volume from which tissue can be removed in a bitwise or otherwise reduced-dimension manner with enhanced protection from seeding of diseased tissue or cells within the body. In order to provide a sealed access channel for removing tissue, bag **12** preferably includes an access sleeve **42** sealingly connected to opening **18**. Access sleeve **42** is typically introduced in a rolled or concentrically folded configuration so as to be collapsed against opening **18**, and is extended, typically by pulling on a deployment thread **47**, after the tissue to be removed has been inserted into the containment volume. Access sleeve **42** is then deployed through an incision or body orifice to form a sealed working channel from the containment volume to outside the body for performing a tissue reduction process on the tissue.

In certain implementations of the present invention, access sleeve **42** is implemented from a layer of material without inflatable internal structure. Particularly in cases where a manual tissue reduction process is performed at an access incision as illustrated in FIG. 14, or at a body orifice as illustrated in FIG. 15, there is an increased risk of perforation of the access sleeve, and it may therefore be preferable to implement an inflatable cavity wall structure within access sleeve **42**. In these latter cases, the access sleeve **42** is preferably implemented with one or more independently inflatable volume that can be inflated after introduction of the tissue into bag **12** and optionally also after correct positioning of the sleeve through the access incision or body orifice.

For a fully laparoscopic tissue reduction, it is typically desired to insert one or more instruments into containment compartment **16** within bag **12**. The instruments typically include a tissue reduction tool **100**, such as a power morcellator, one or more gripping tools **102** for manipulating the tissue, and an endoscope **104** for visualization. In order to facilitate introduction of these instruments, bag **12** is preferably provided with one or more instrument insertion branches **44**, each implemented as a flexible access tube communicating with containment compartment **16**, to allow instrument access via a minor incision in a direction angularly spaced from opening **18** of bag **12**. The entry of an instrument **102** into the containment compartment via branch **44** is illustrated in FIG. 5. An overall surgical procedure employing a main access sleeve **42** and instruments inserted via two branches **44** is shown in FIGS. 10A and 10B.

Specifically, in use, after severing of the tissue to be removed, for example, uterus **110**, from all connections to other tissue, the tissue is introduced via opening **18** into containment

volume 16 of device 10, which has been introduced via an incision or body orifice. This process is shown in FIG. 10A. Access sleeve 42 is then extended by drawing deployment thread 47, and is withdrawn from an incision in the abdominal wall after removal of the corresponding insertion trocar. Where instrument insertion branches 44 are to be used, they are retrieved through
5 corresponding incisions, also after removal of any trocar. Optionally, access sleeve 42 may then be secured by reinsertion of the trocar within access sleeve 42, as illustrated in FIG. 12. Alternatively, access sleeve 42 may be secured by stretching it around a ring template 46, as illustrated in FIG. 11. Instrument insertion branches 44 may also be used with or without insertion of a trocar within the branch sleeves, where FIG. 16 illustrates the option of reinserting
10 the trocar 106 into the branch sleeve 44. The resulting tool deployment, ready for tissue reduction and removal, is illustrated in FIG. 10B.

As mentioned previously, instrument insertion branches 44 are advantageously used to provide access for instruments during the procedure, as illustrated in FIGS. 5, 10B and 17. After completion of a tissue reduction process and removal of the tissue via access sleeve 42,
15 instrument insertion branches 44 are preferably sealed before being reintroduced into the body, for removal together with the rest of device 10, typically via the primary incision (or body orifice). The sealing of branches 44 helps to insure that any contaminated tissue or cells present within containment volume 16 do not leak out into the abdominal cavity when the branches are reintroduced into the body.

When implemented using thermoplastic materials, according to certain particularly preferred implementations of the invention, branches 44 can advantageously be sealed prior to reintroduction into the body by use of a sealing tool 48 (FIG. 18) to apply heat and/or pressure so as to form one or more welded seal line across the branch 44. In a particularly preferred
25 implementation, the extremity of the branch is turned in on itself so that only uncontaminated external surfaces are exposed, and these surfaces are then welded together using the sealing tool 48. Sealing tools commercially available for domestic applications, such as for sealing plastic storage bags, have been found to be highly effective for this purpose, rendering the branch tubes watertight, and thus certainly impervious to any potential biological contaminants (such as cancerous cells) within the containment volume.

30 Optionally, instrument insertion branch 44 is formed by an extension of at least one of the layers from each of two regions of wall 14 interconnected so as to form a collapsible tube. The collapsible tube configuration lends itself particularly well to the aforementioned sealing functionality.

It will be noted that device **10** may also be used to advantage in manual tissue reduction procedures, where the tissue to be removed is manipulated to be directly accessible via an access incision, and is reduced by using tissue reduction tools **100**, such as scalpels, at or near the incision. FIG. 14 illustrates such a procedure performed via an abdominal incision, while FIG. 15 illustrates a similar procedure performed vaginally. In these cases, when it is not intended to introduce any additional implements into bag **12**, an implementation of device **10** which does not include branches **44** may be used.

During the procedure, while device **10** is deployed, it may be desired to perform insufflation of the abdominal cavity in addition to inflation of the device wall. Where trocars are used within access sleeve **42** and/or instrument insertion branches **44**, the normal inflation ports of the trocars are typically located within the sleeves/branches, and so are not in fluid flow connection with the abdominal cavity for insufflation thereof. A number of different options may be used for performing abdominal cavity insufflation, as illustrated schematically in FIGS. 13A-13C. In an implementation such as in FIG. 11 where device **10** is used without reinsertion of a trocar and access sleeve **42** is secured by stretching it around a ring template **46**, an insufflation pressure supply tube **50** may be integrated with, or otherwise associated with, ring template **46**, as shown schematically in FIG. 13A, for connection to a source of insufflation pressure. Where a trocar is used, such as is illustrated in FIG. 12, insufflation pressure may be provided via an insufflation pressure supply tube **50** integrated with, or otherwise associated with, an external surface of access sleeve **42**, or via an insufflation port formed in a dedicated collar **45** surrounding the anchoring region of the trocar external to sleeve **42**. The options of FIGS. 13A and 13B can equally be implemented at secondary incisions where instrument access branches **44** are deployed. A further option is to provide insufflation pressure via an additional incision that is not being used for instrument insertion. In this case, the incision should be sealed by a plug element **52** with an insufflation port **54** (FIG. 13C), but should not have any element projecting significantly into the abdominal cavity in order to avoid presenting a puncture hazard for bag **12**.

In certain implementations, particularly where access to sleeve **42** is provided via a trocar, it may be desired to additionally provide insufflation pressure to the containment compartment volume and/or to measure a current pressure within the containment compartment. Fluid connection to the interior of bag **12** may be achieved either via a connection tube (not shown) associated with an internal surface of access sleeve **42** or via a suitably configured trocar insufflation port.

Certain particularly preferred implementations of a system employing device 10 include various pressure sensors and associated logic circuitry for monitoring fluid pressure within the inflatable volumes of device 10, and optionally also within the abdominal cavity and/or within the containment compartment, and for determining and acting on various malfunction indications. Structurally, the system preferably includes a pressure sensor P_1 associated with each independently inflatable volume of device 10, and preferably also a sensor P_2 for sensing pressure within the abdominal cavity external to the bag and P_3 for pressure within the containment compartment, if maintained at pressure (FIGS. 13A and 13B). The various pressure sensors are preferably connected to logic circuitry 56 configured for implementing various monitoring algorithms described below with reference to FIG. 20. Logic circuitry 56 may be implemented as custom hardware using digital or analogue circuitry, or may be implemented using a general-purpose processing system configured by suitable software, or any combination thereof, as will be clear to a person having ordinary skill in the art. The logic circuitry may additionally control valves and/or regulators 58 for directly controlling supply of pressurized fluid to one or more of the pressurized volumes, and/or may have a user interface 59 for providing audible and/or visual outputs indicative of various malfunction conditions, or conditions likely to lead to malfunction.

Referring to FIG. 20, the pressure control flow chart illustrates initial steps of supplying inflation pressure to the inflatable volume(s) of device 10 (step 60), as well as insufflation of the abdominal cavity (step 62) and/or containment compartment (step 64) as relevant. The pressure of each inflated volume is then monitored at step 66 to identify various malfunction, or pre-malfunction, indications.

If the pressure within the inflatable volume, or one of the inflatable volumes, of device 10 increases, this indicates that an object is pressing against a wall of the bag, which may be a tool within the bag at risk of causing puncture. In such a case, logic circuitry preferably actuates a suitable indication (e.g., an audible buzzer or verbal message, or a visual flashing light and/or information display) at step 68.

During normal operation, the internal inflatable volume(s) of device 10 are typically maintained at a higher pressure than a pressure of the abdominal cavity. If the pressures of the inflatable volume(s) and the abdominal cavity become equalized, the system identifies that an external layer of the bag wall has been punctured (step 70). As a variant of this case, if the pressure is also equalized to the inside of the bag (in a case where the containment compartment pressure is monitored), this indicates puncturing of all layers (step 72). In either of these cases, a corresponding audio and/or visual indication is preferably generated and, in cases where

automated pressure regulation is available, pressure is preferably increased in the abdominal cavity in order to create a pressure gradient inwards through the puncture (step 74), thereby tending to inhibit leakage of tissue or fluids from the containment compartment outwards. The walls of the bag, once deployed, will support a small pressure differential from outside to inside the bag. Where the bag includes more than one independently inflatable volume, a non-punctured inflatable volume may provide sufficient structural support to withstand a relatively larger external pressure, thereby allowing for enhanced pressure-differential anti-leak protection.

Finally, in a case in which the inflatable volume pressure becomes equalized with the containment compartment pressure, or with atmospheric pressure, this is identified as an indication of puncturing of an internal layer of the bag wall (step 76). In this case, in addition to a corresponding audio and/or visual indication, where automatic inflation control is available, the logic circuitry will typically supply additional inflation pressure to the inflatable volume (step 78) in an attempt to maintain at least partial inflation pressure within the bag wall despite the leak.

It should be noted that the above functionality is considered to be applicable broadly in the context of otherwise conventional tissue containment bags which lack the cavity wall structure of bag 12 of the present invention. Thus, in a conventional tissue containment bag, for example, which is supported by a collapsible or inflatable frame, the device may be used under conditions of a small pressure differential between the abdominal cavity pressure outside the bag and a volume within the bag. Optionally, the volume within the bag may be open to the atmosphere and unmonitored. Alternatively, the internal volume may also be insufflated and the pressure monitored, but maintained at a slightly different level, preferably lower, than the abdominal cavity pressure outside the bag. In the event of a sudden loss of abdominal cavity pressure, or equalization of the pressure inside and out, logic circuitry identifies a malfunction (puncture) condition, and preferably notifies the medical practitioner. Additionally, or alternatively, the logic circuitry may actuate a source of insufflation pressure and/or a system of valves connected to such a source, in order to try to maintain a pressure differential from outside the bag to within the bag, thereby tending to inhibit leakage of biological matter from the bag.

While the above options of quantitative measurement of pressure in multiple volumes provide advantageous functionality, such as that already described, it should be noted that the device of the present invention may also be used to advantage employing pressure monitoring for only the internal inflatable volumes of device 10, or even without any distinct arrangement for pressure monitoring, for example, relying on manual determination by a practitioner as to whether the internal pressure has been maintained or not by pressing manually on an exposed

region of the inflatable structure. In certain preferred implementations, a visual indication is provided to the practitioner, such as by an inflatable element which changes size or shape according to whether the pressure is within a target range or falls below (or in some cases above) the target range, or a mechanical pressure sensor which provides a visual and/or audible output indicative of whether the pressure falls within the target range.

On completion of the tissue reduction and removal process, pressure is preferably released from the inflatable volume(s) of device 10, such as by neutralizing or removing the check valves, as is known in the art. Optionally, active suction can be used to ensure that the thickness of the device walls is reduced as much as possible. The device is then preferably compacted to facilitate removal from the body. According to one particularly preferred approach, illustrated in FIGS. 19A and 19B, for compacting the device for removal, bag 12 is provided with at least one loop element 80, deployed on an external surface of the device. Loop element 80 is located and configured to facilitate rolling of the bag by insertion of an instrument through the loop element and rotation of the instrument. The term "loop" is used here to refer to any structure which forms a closed loop around a shaft of an instrument, and may be either a localized loop or an extended structure which is effectively a tube or sleeve. In the example illustrated here, the loop element 80 is implemented as an elongated sleeve passing along an external surface of access sleeve 42. When the practitioner is ready to remove the device, she inserts a gripper tool 102 through the sleeve of loop element 80 and then grips part of the bag, preferably via a projecting tab 82, as shown in FIG. 19A. Subsequent rotation of the gripper tool about its direction of elongation results in rolling of the bag around the tool, as shown in FIG. 19B. Once fully rolled, the gripper tool can be removed together with the rolled device via the primary incision.

To the extent that the appended claims have been drafted without multiple dependencies, this has been done only to accommodate formal requirements in jurisdictions which do not allow such multiple dependencies. It should be noted that all possible combinations of features which would be implied by rendering the claims multiply dependent are explicitly envisaged and should be considered part of the invention.

It will be appreciated that the above descriptions are intended only to serve as examples, and that many other embodiments are possible within the scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A tissue containment device for isolating tissue from surrounding tissue during a surgical procedure to remove the tissue, the device comprising:

- (a) a bag comprising one or more walls, defining a containment compartment and an opening for accessing said containment compartment, wherein said one or more walls are formed from at least two layers defining at least one inflatable volume therebetween; and
- (b) at least one inflation port in fluid connection with said at least one inflatable volume for introducing and removing a fluid to and from said at least one inflatable volume,

wherein said at least two layers are interconnected at spaced-apart connection regions, said spaced-apart connection regions being configured such that, when a fluid is introduced to said at least one inflatable volume, regions of said at least two layers between said connection regions form wall cavity regions substantially surrounding an internal volume of said containment compartment.

2. The device of claim 1, wherein said wall cavity regions extend over at least 85% of an inward facing surface of said at least one wall facing said internal volume as projected to a centroid of said internal volume.

3. The device of claim 1, wherein said wall cavity regions form a plurality of adjacent bulges in proximity to each other such that an instrument having a width of at least 8 mm cannot reach said connection regions without first contacting said bulges.

4. The device of claim 1, wherein said at least two layers are implemented as initially flat sheets of material that are selectively interconnected at said connection regions.

5. The device of claim 1, wherein an outer layer of said at least two layers is implemented as a layer having an increased resistance to flexing compared to an inner layer of said at least two layers.

6. The device of claim 1, wherein an outer layer of said at least two layers differs from an inner layer of said at least two layers in at least one property selected from the group consisting of: shear strength, burst limit and puncture resistance.

7. The device of claim 1, wherein said at least two layers are implemented as three layers of material, and wherein spaced apart connection regions between a first of said layers and a second of said layers are interspaced between spaced apart connection regions between said second of said layers and a third of said layers.

8. The device of claim 1, wherein an inward-facing layer of said at least two layers is implemented with preformed inflatable pockets between said connection regions.

9. The device of claim 1, wherein said bag assumes a compact state in which a first region of said at least one wall is adjacent to a second region of said at least one wall, and wherein said spaced-apart connection regions define elongated inflatable deployment cavities extending within said first and second regions such that, on inflation of said at least one inflatable volume, said inflatable deployment cavities press against each other so as to tend to force apart said first and second regions, thereby opening up said internal volume of said containment compartment.

10. The device of claim 1, wherein said at least one wall is configured to form at least two of said inflatable volumes, said at least two inflatable volumes being independently inflatable.

11. The device of claim 1, wherein said spaced-apart connection regions are deployed so as to define elongated inflatable boundary cavities extending so as to circumscribe a majority of said opening such that, on inflation of said at least one inflatable volume, said inflatable boundary cavities tend to open said opening.

12. The device of claim 1, wherein said spaced-apart connection regions are deployed such that, on inflation of said at least one inflatable volume, at least part of said at least one wall presents an array of inflated bulges in facing relation to said containment volume, and further comprising printed markings disposed within a central region of a plurality of said bulges.

13. The device of claim 1, wherein said at least one wall comprises two walls interconnected at a peripheral seal such that said bag is formed from at least four of said layers in overlying relation.

14. The device of claim 1, wherein said bag further comprises at least one loop element deployed on an external surface of the bag, said loop element being located to facilitate rolling of said bag by insertion of an instrument through said at least one loop element and rotation of the instrument.

15. The device of claim 1, further comprising a pressure indicator in fluid interconnection with said inflatable volume, said pressure indicator being configured to generate a visible and/or audible indication when a pressure within said inflatable volume decreases or falls below a reference pressure value.

16. The device of claim 1, wherein said bag further comprises at least one instrument insertion branch implemented as a flexible access tube communicating with said containment compartment and allowing instrument access via an incision in a direction angularly spaced from said opening of said bag.

17. The device of claim 16, wherein said instrument insertion branch is formed by an extension of at least one of said layers from each of two regions of said at least one wall, said extensions being interconnected to form a collapsible tube.

18. The device of claim 1, wherein said at least two layers are manufactured from a thermoplastic material.

19. A system for implementing a surgical procedure to remove tissue from a body, the system comprising:

- (a) the device of claim 16; and
- (b) a heat sealing device configured for performing a heat sealing process on said instrument insertion branch so as to prevent leakage of cells from said instrument insertion branch on introduction of the instrument insertion branch into the body.

20. A system for implementing a surgical procedure to remove tissue from a body, the system comprising:

- (a) the device of claim 1;
- (b) a source of pressurized fluid for connection to said at least one inflation port; and
- (c) a tissue reducing device for insertion through said opening for reducing a dimension of tissue located within said containment compartment.

21. The system of claim 20, further comprising a pressure monitoring system comprising:

- (a) a pressure sensor deployed for sensing a pressure within said at least one inflatable volume; and
- (b) logic circuitry in communication with said pressure sensor and configured to monitor variations in the pressure within said at least one inflatable volume to determine whether the variations are indicative of a malfunction condition of said bag.

22. The system of claim 21, wherein said logic circuitry is further configured to generate an audible and/or visible indication on identification of a malfunction condition of said bag.

23. The system of claim 21, wherein said logic circuitry is further configured to determine if a layer of said bag has been breached and, in response to such breaching, to generate an output for initiating a corrective action, said corrective action including increasing a pressure supplied to said inflatable volume.

24. The system of claim 20, wherein said bag further comprises an access sleeve sealingly connected to said opening and defining a sealed access channel for performing a tissue reduction process on tissue within said containment compartment.

25. The system of claim 24, further comprising an abdominal cavity insufflation port and an associated flow channel configured for providing insufflation pressure to an abdominal cavity external to said access sleeve.

26. The system of claim 25, further comprising a pressure monitoring system comprising:

- (a) a first pressure sensor deployed for sensing a pressure within said at least one inflatable volume;
- (b) a second pressure sensor configured for deployment to sense abdominal cavity pressure exterior to said bag; and

- (c) logic circuitry in communication with said first and second pressure sensors, and configured to monitor variations in the pressure within said at least one inflatable volume relative to the pressure exterior to said bag, and to determine whether the variations are indicative of a malfunction condition of said bag.

27. The system of claim 26, wherein said logic circuitry is further configured to generate an audible and/or visible indication on identification of a malfunction condition of said bag.

28. The system of claim 26, wherein said logic circuitry is further configured to determine if a layer of said bag has been breached and, in response to such breaching, to generate an output for initiating a corrective action, said corrective action including increasing a pressure supplied to the abdominal cavity volume exterior to said bag.

29. The system of claim 26, further comprising a third pressure sensor deployed for sensing a pressure within said containment compartment, said logic circuitry further being in communication with said third pressure sensor.

30. A method for surgical removal of tissue from a body, the method comprising the steps of:

- (a) introducing the device of claim 24 into the body through an incision or body orifice in a compact, uninflated state;
- (b) inflating the inflatable volume with a fluid so as to deploy the bag within the body;
- (c) inserting into the bag the tissue to be removed from the body;
- (d) extending said access sleeve out through the incision or body orifice;
- (e) performing via the access sleeve reduction and removal of the tissue;
- (f) deflating the inflatable volume while maintaining part of the access sleeve extending out through the incision or body orifice; and
- (g) removing the device via the incision or body orifice.

31. The method of claim 30, wherein insertion of the device is performed via a laparoscopic incision.

32. The method of claim 30, wherein said inflation is performed using saline solution.

33. The method of claim 30, wherein said bag further comprises at least one instrument insertion branch implemented as a flexible access tube communicating with said containment compartment, the method further comprising extending said at least one instrument insertion branch out through an incision or body orifice.

34. The method of claim 33, further comprising inserting an instrument through said at least one instrument insertion branch.

35. The method of claim 34, further comprising heat sealing said at least one instrument insertion branch prior to reintroduction of said instrument insertion branch into the body.

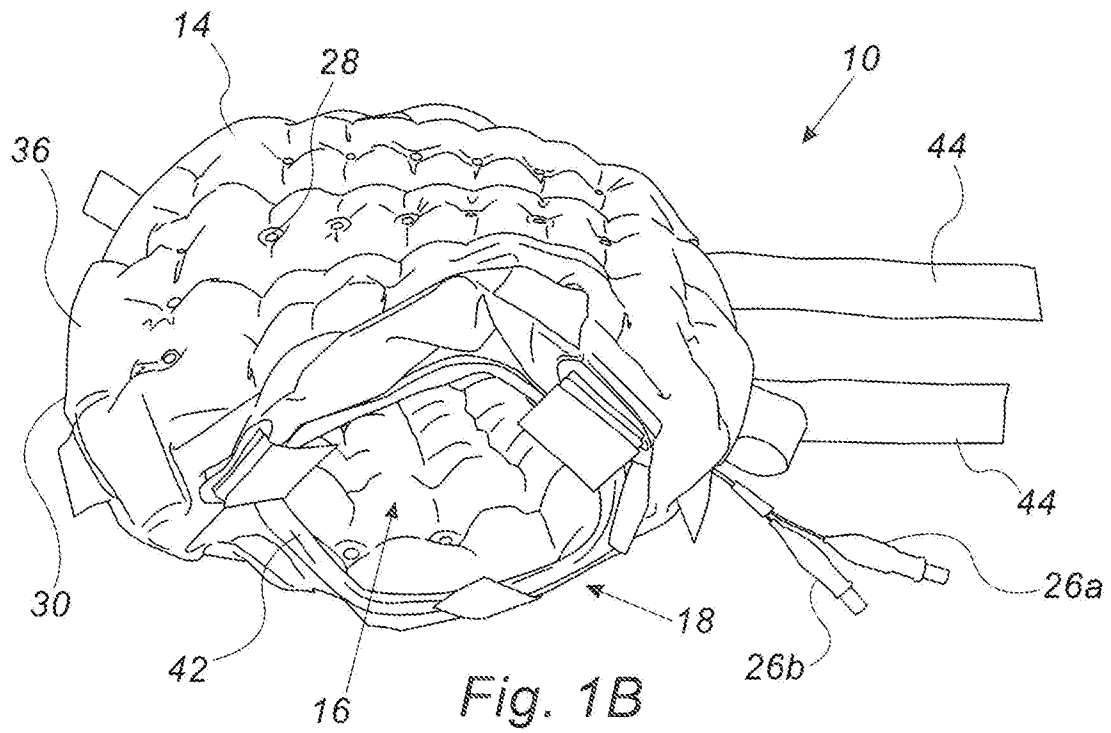
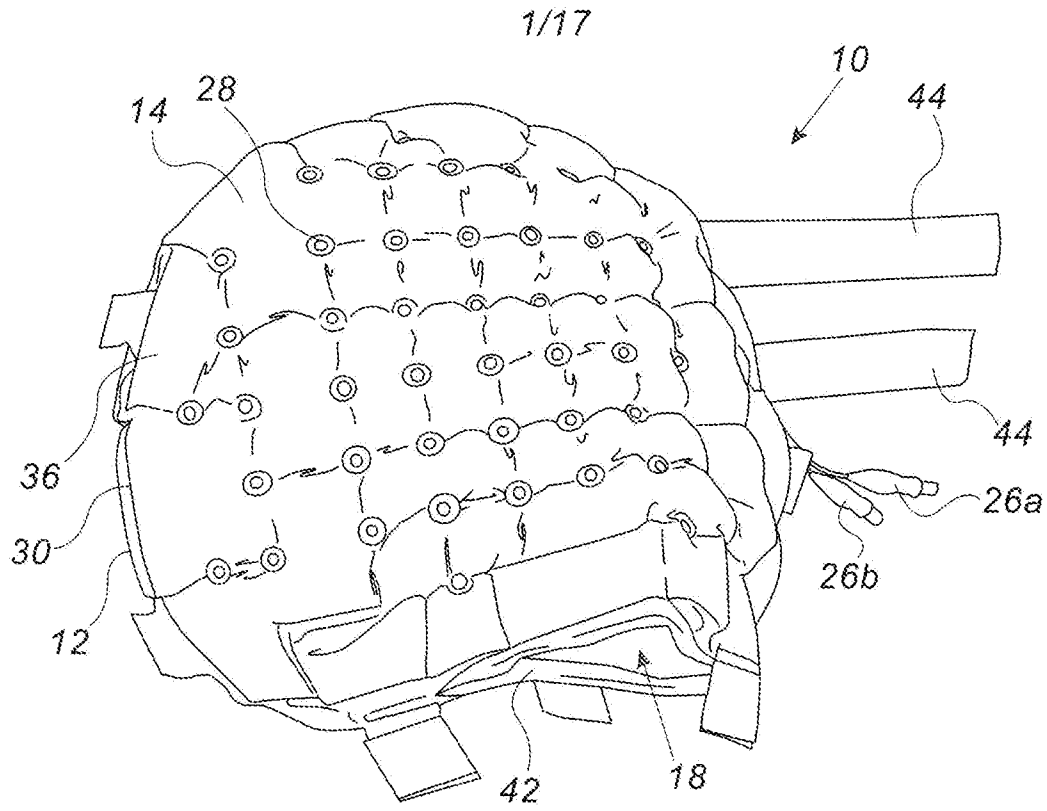
36. The method of claim 30, wherein said device is formed with at least one loop element, the method further comprising inserting at least one instrument through said at least one loop element, and rolling at least part of said device around said instrument.

37. The method of claim 30, further comprising sensing a pressure within said at least one inflatable volume and monitoring variations in said pressure to determine whether variations in said pressure are indicative of a malfunction condition of said bag.

38. The method of claim 37, further comprising insufflating an abdominal cavity exterior to said bag and sensing a pressure within the abdominal cavity exterior to said bag.

39. The method of claim 37, further comprising insufflating the containment compartment of said bag and sensing a pressure within the containment compartment of said bag.

40. The method of claim 37, further comprising determining if a layer of said bag has been breached and, in response to such breaching, initiating a corrective action, said corrective action including introducing a fluid into the inflatable volume and/or into the abdominal cavity exterior to said bag.



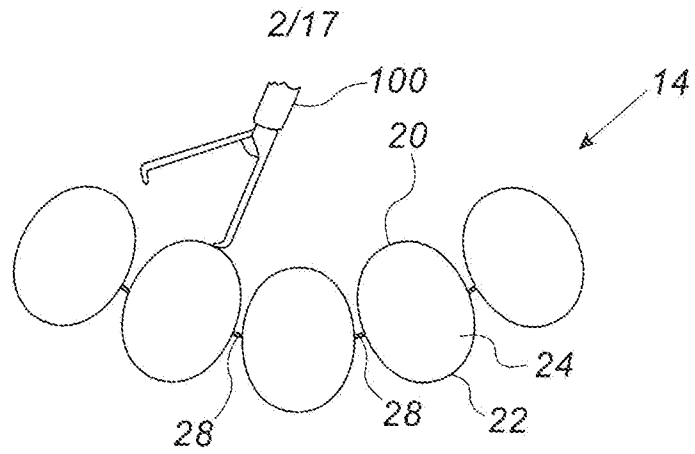


Fig. 2A

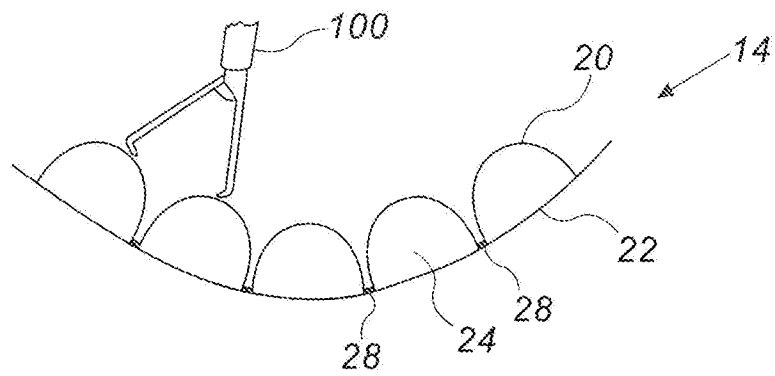


Fig. 2B

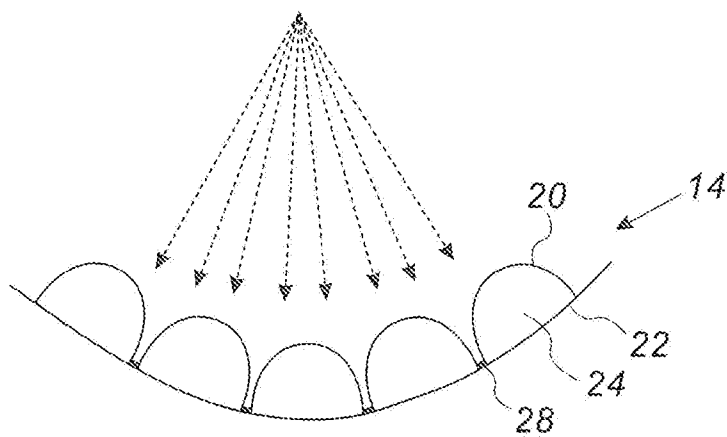


Fig. 3

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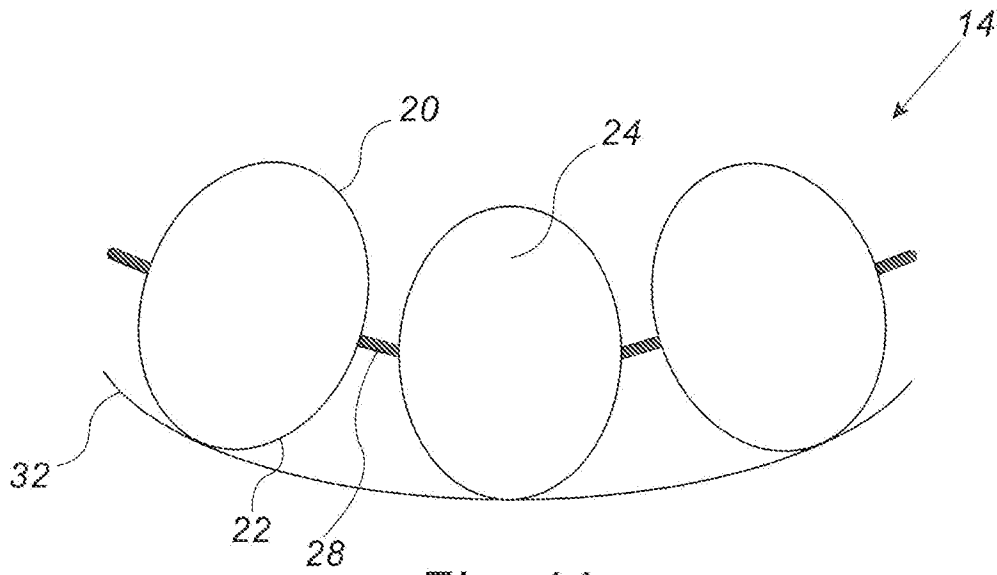


Fig. 4A

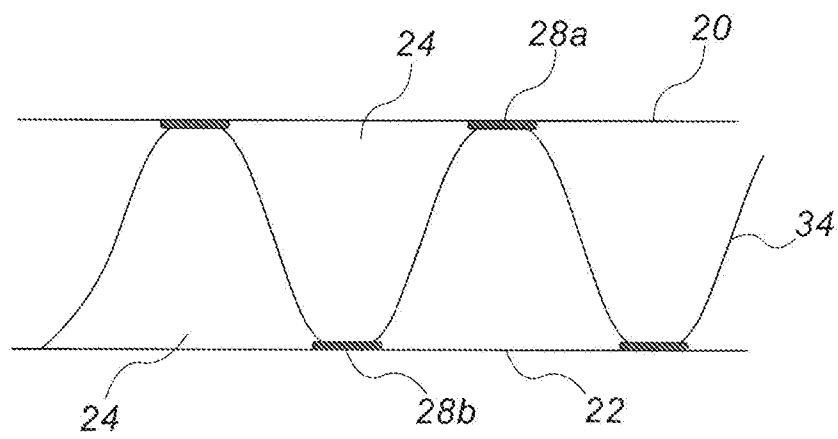


Fig. 4B

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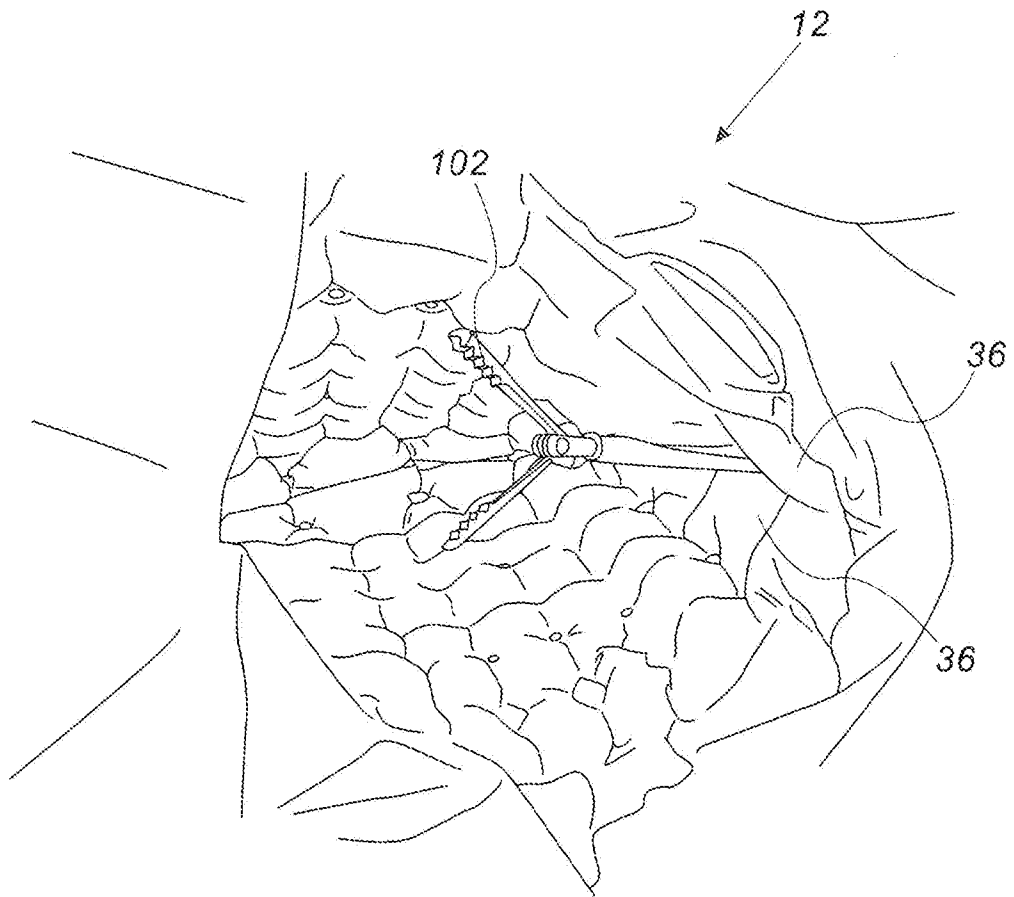
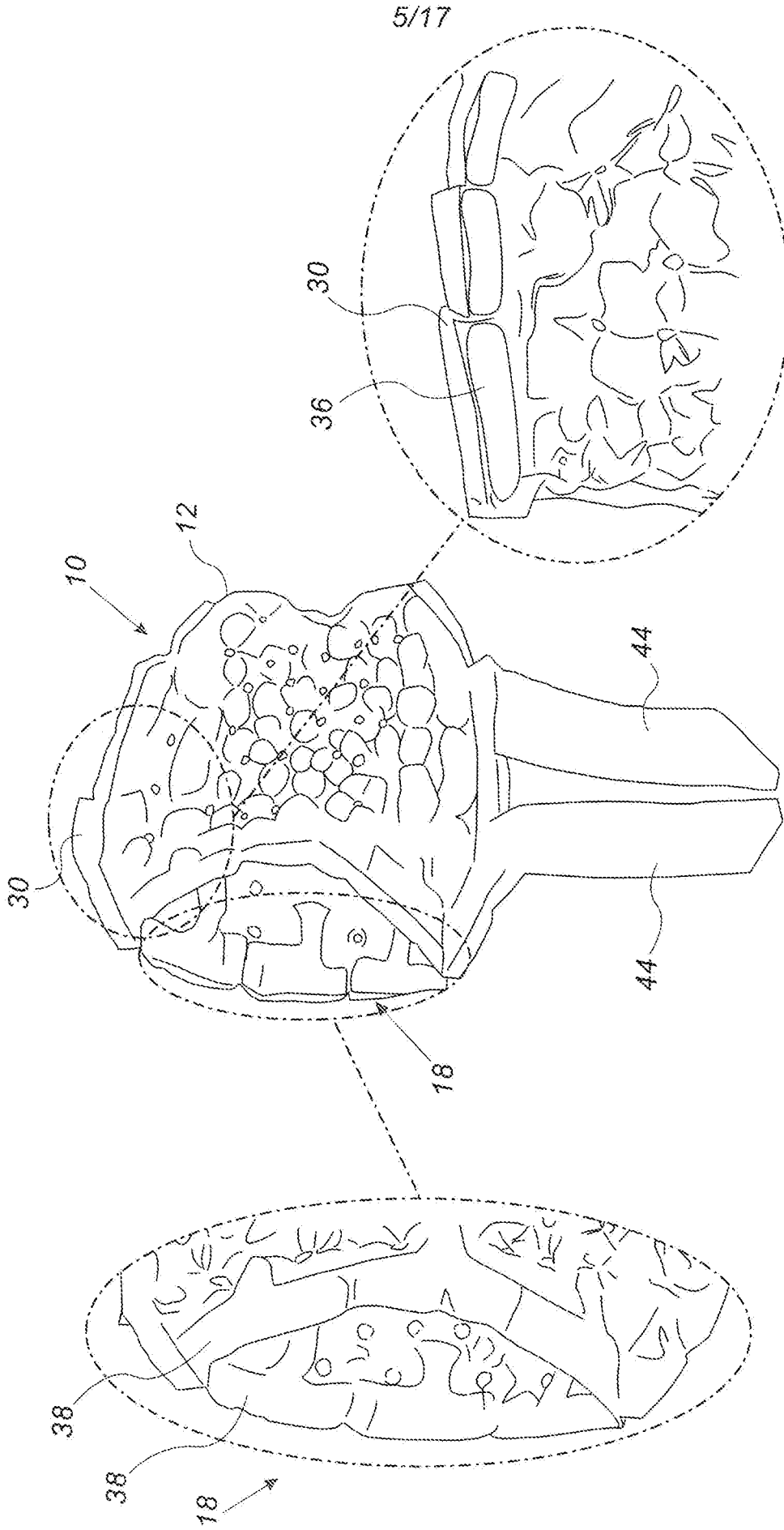


Fig. 5



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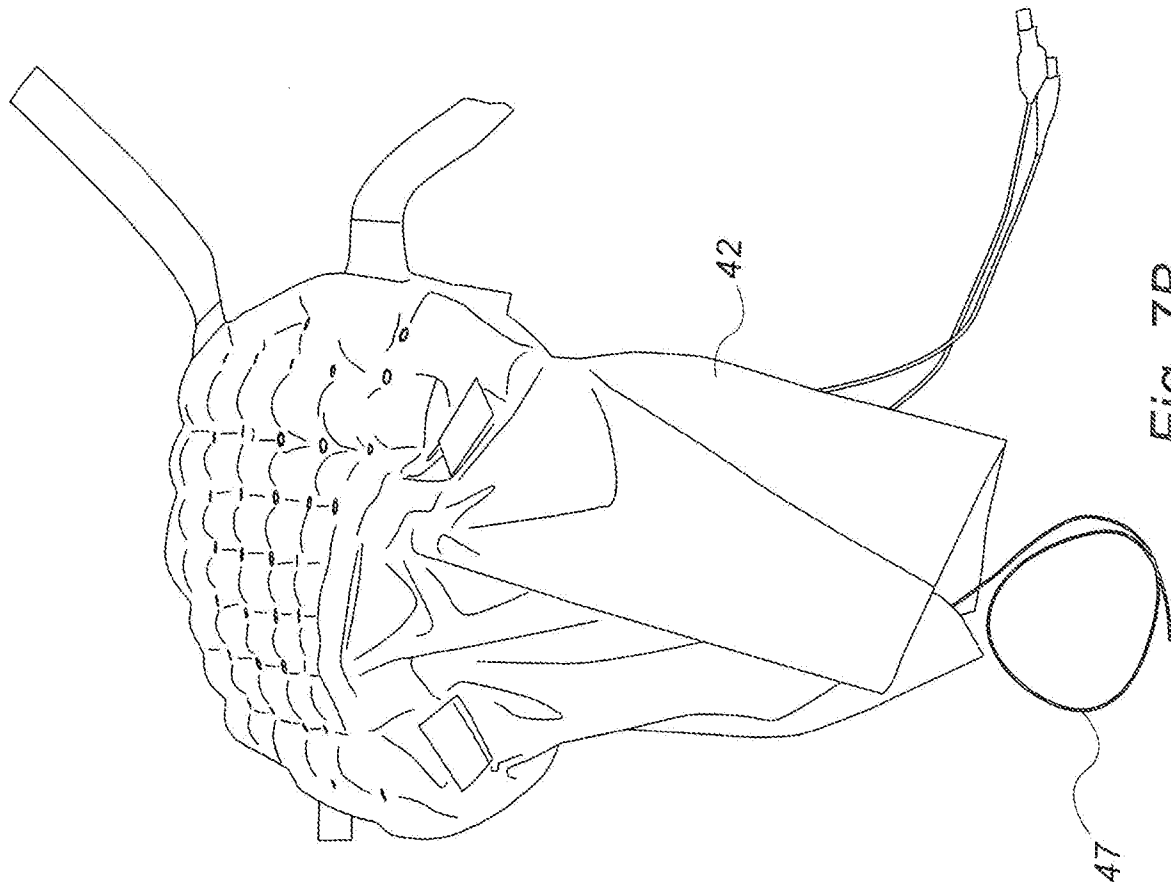


Fig. 7B

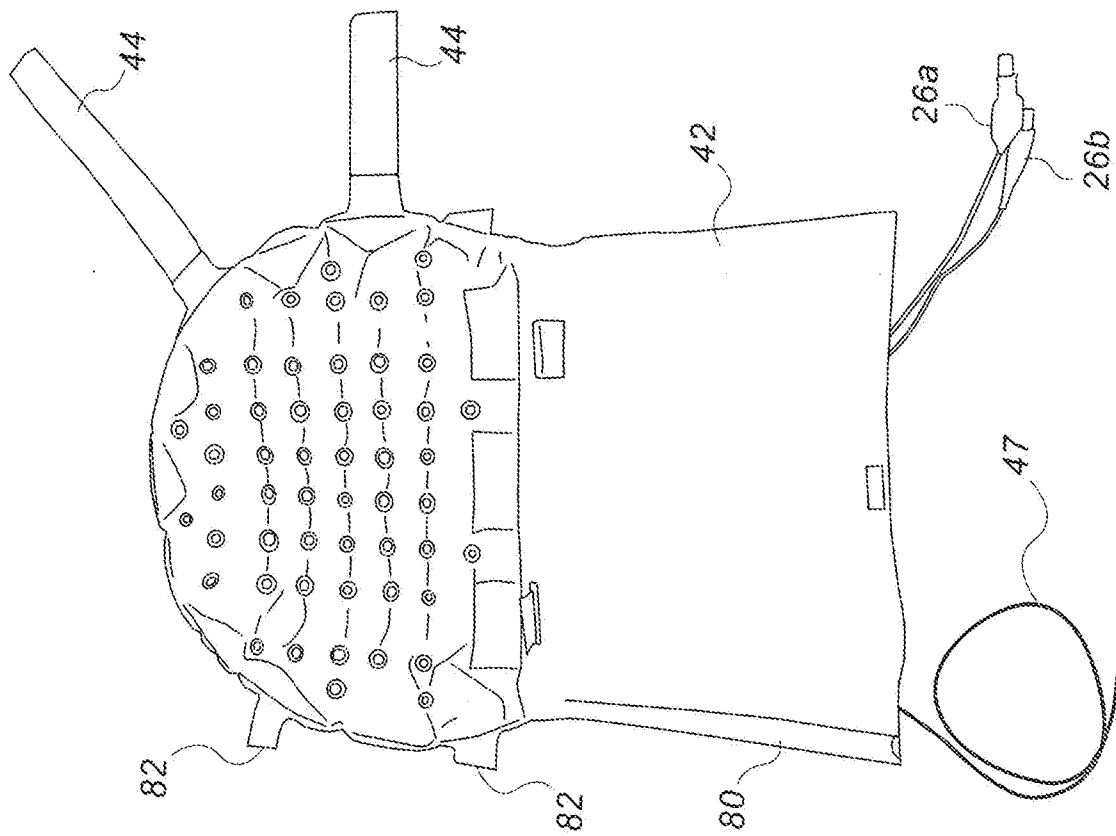


Fig. 7A

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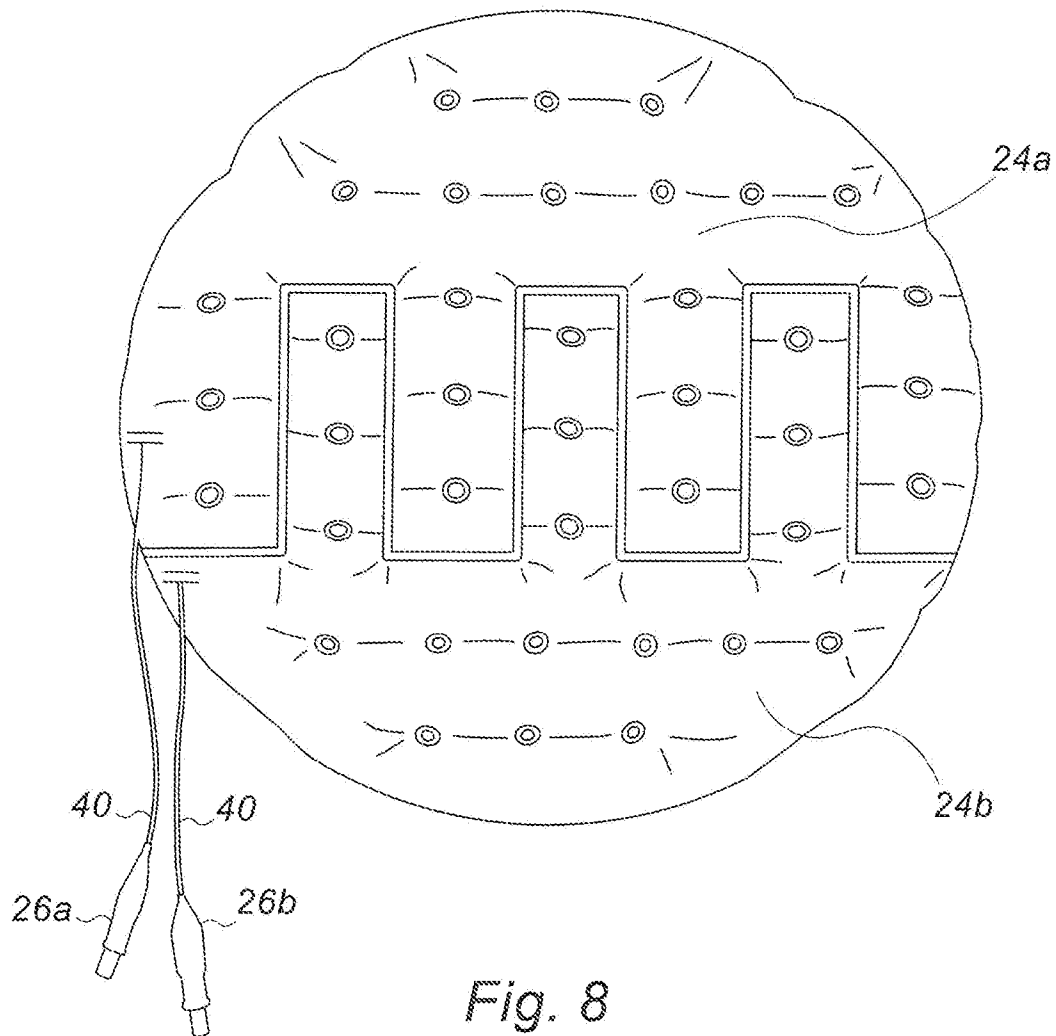


Fig. 8

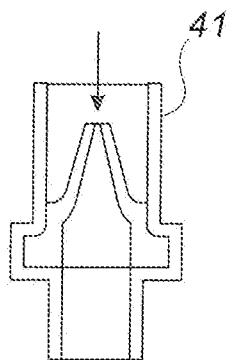


Fig. 9A

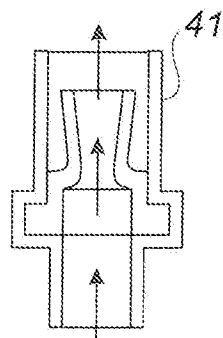


Fig. 9B

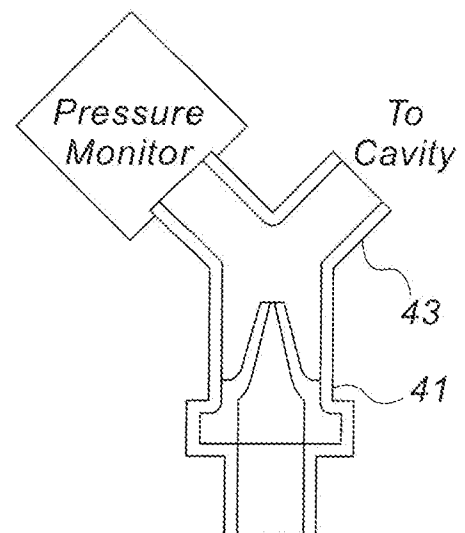


Fig. 9C

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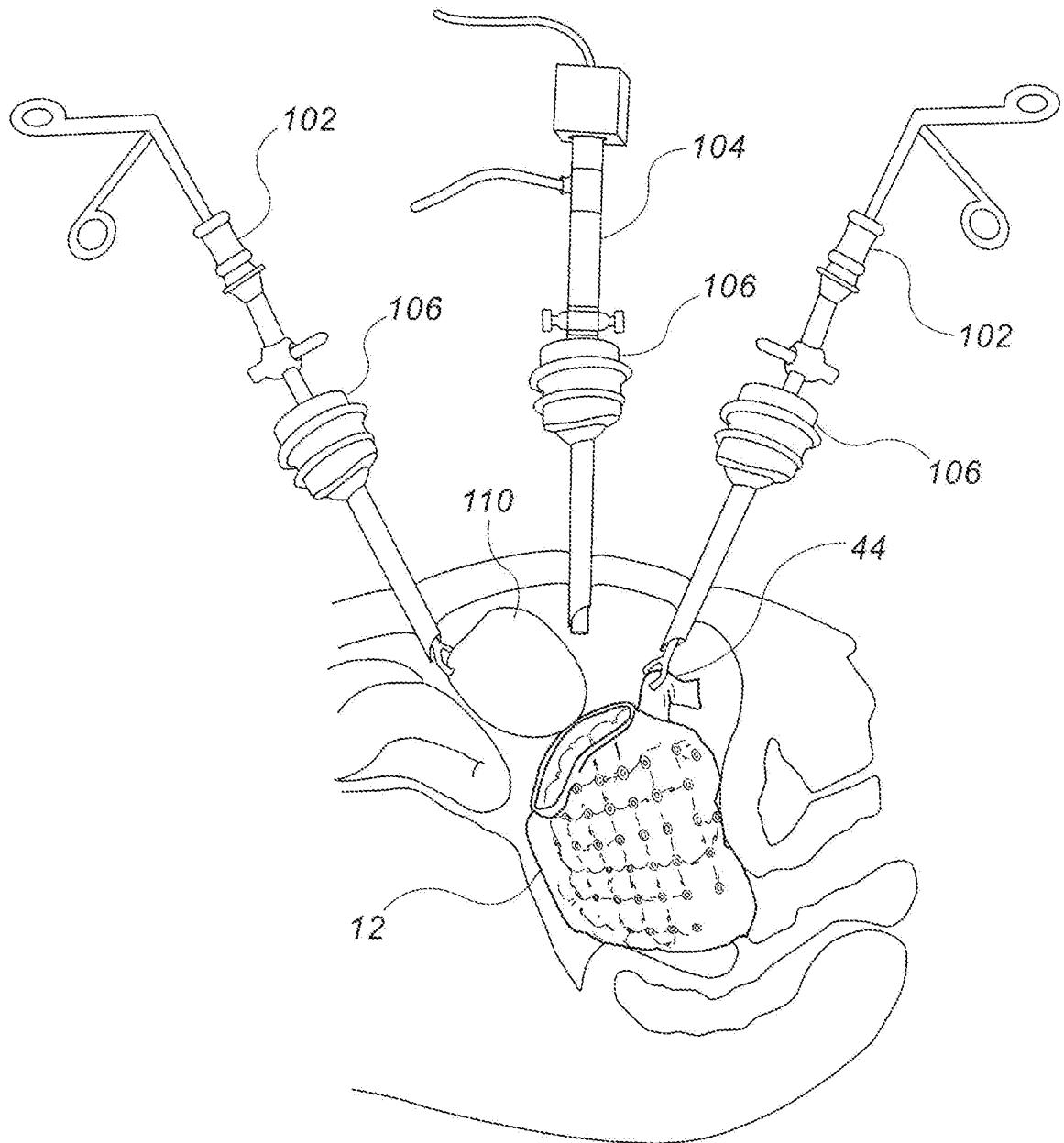


Fig. 10A

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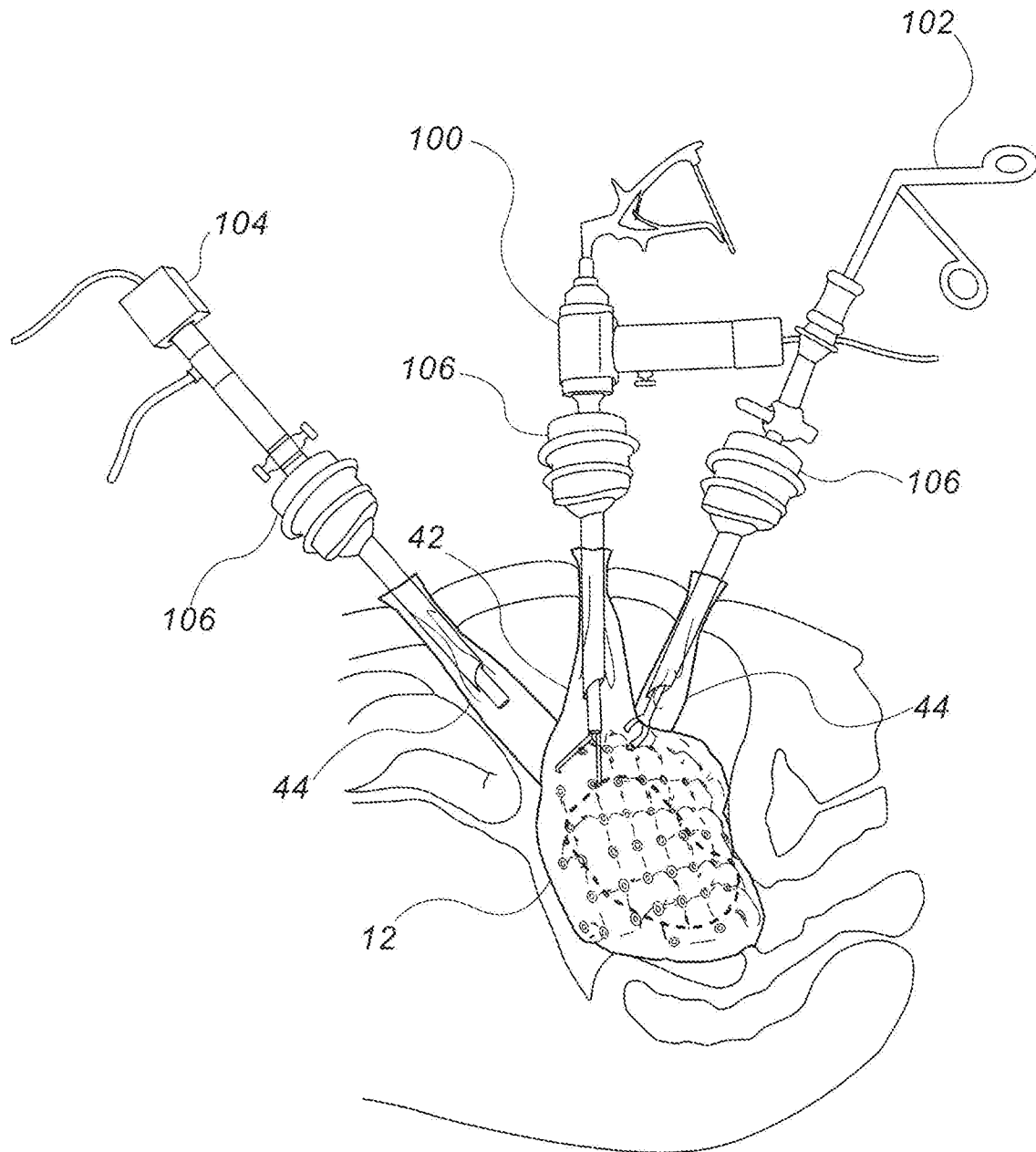


Fig. 10B

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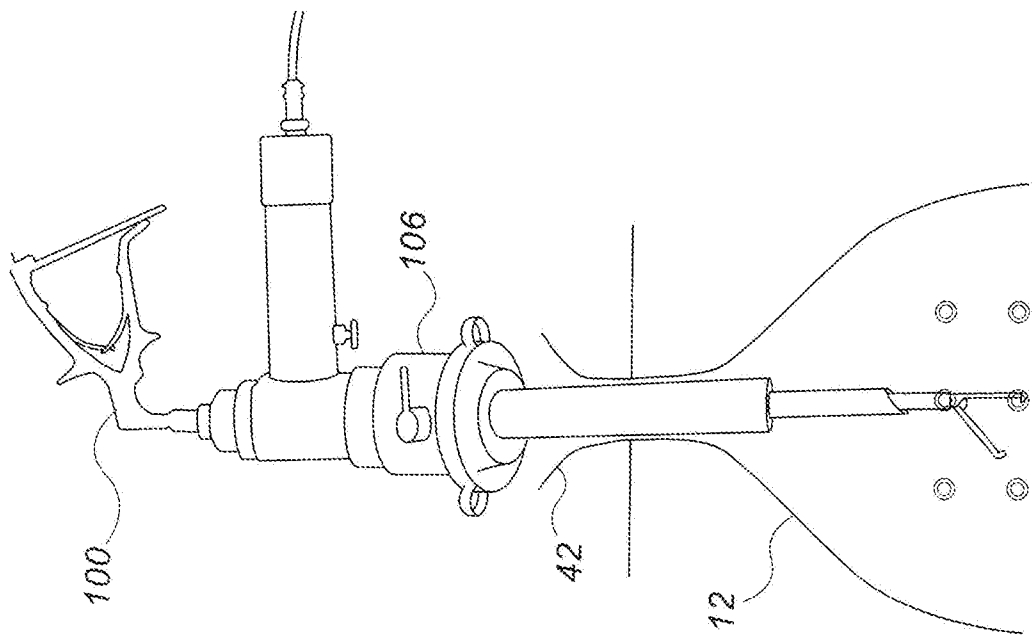


Fig. 12

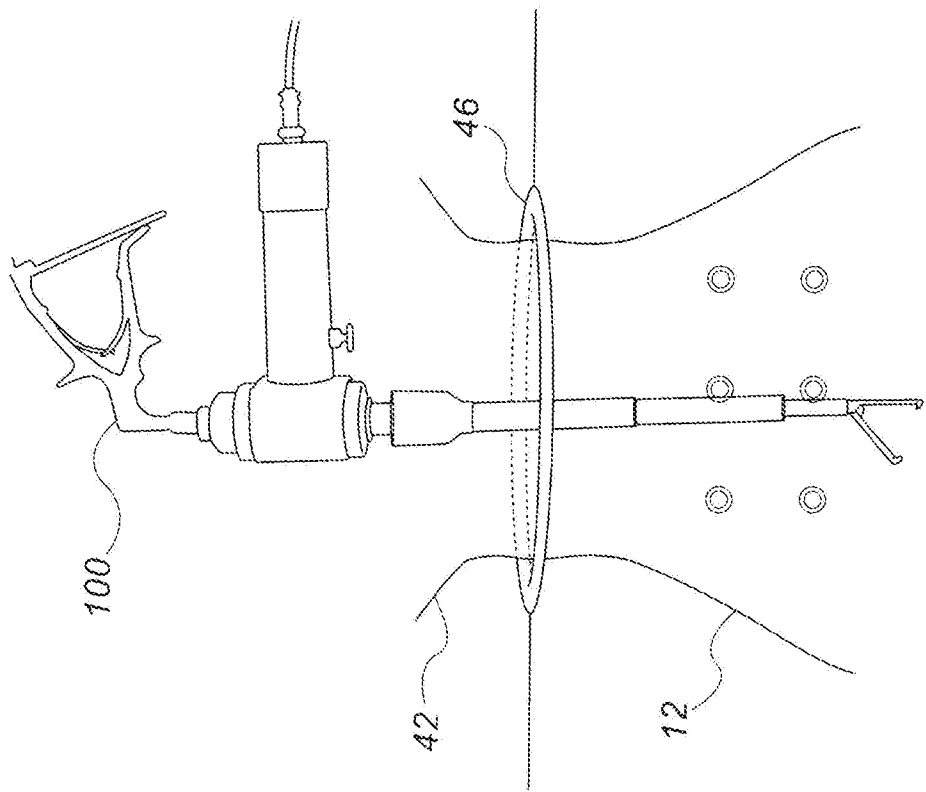


Fig. 11

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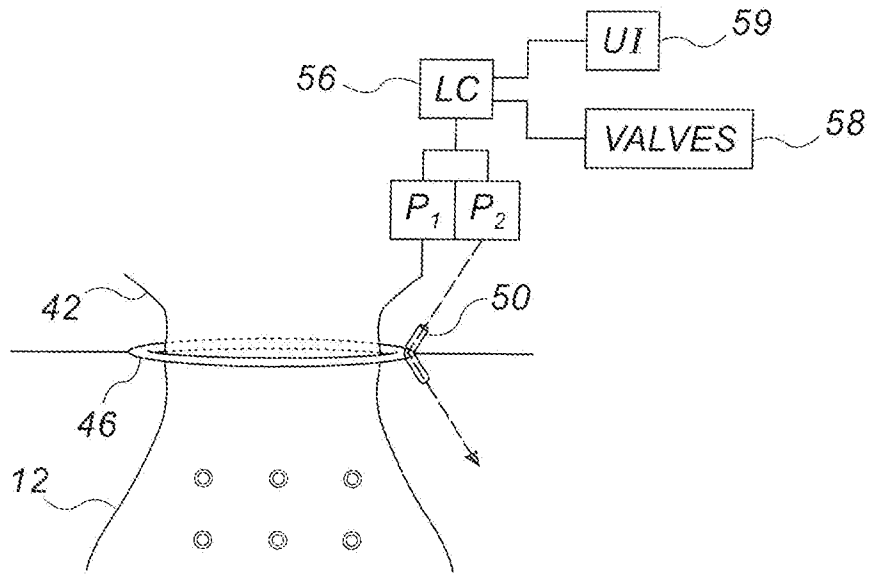


Fig. 13A

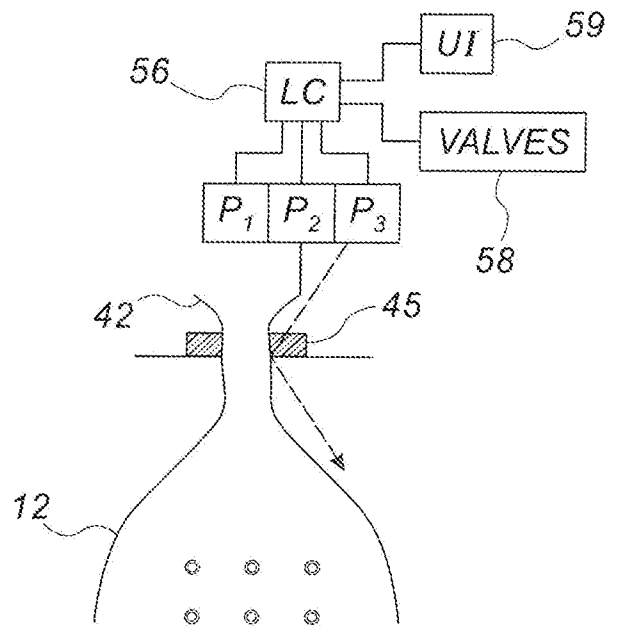


Fig. 13B

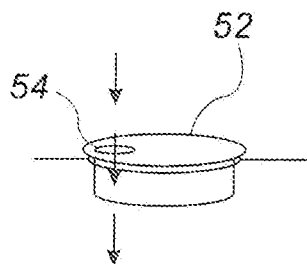
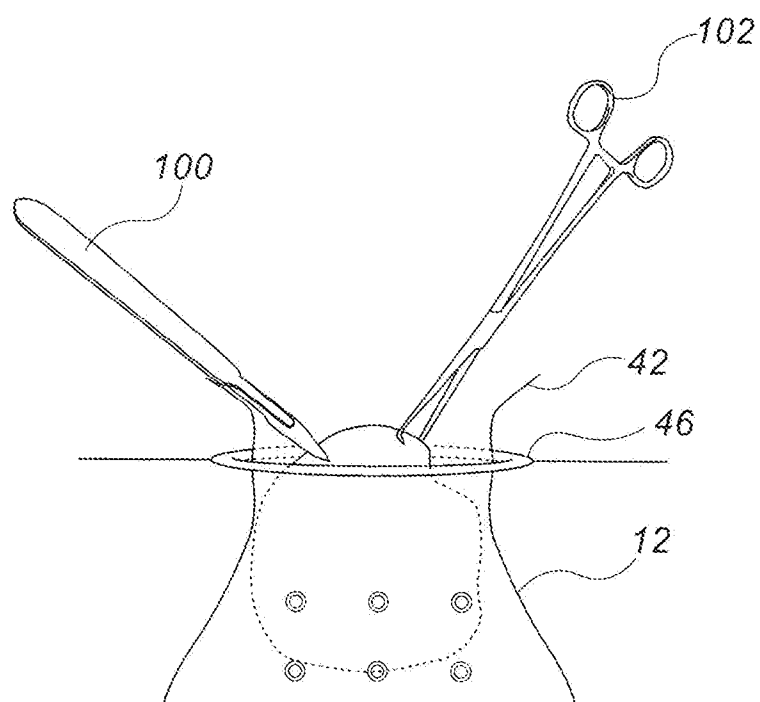


Fig. 13C

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*Fig. 14*

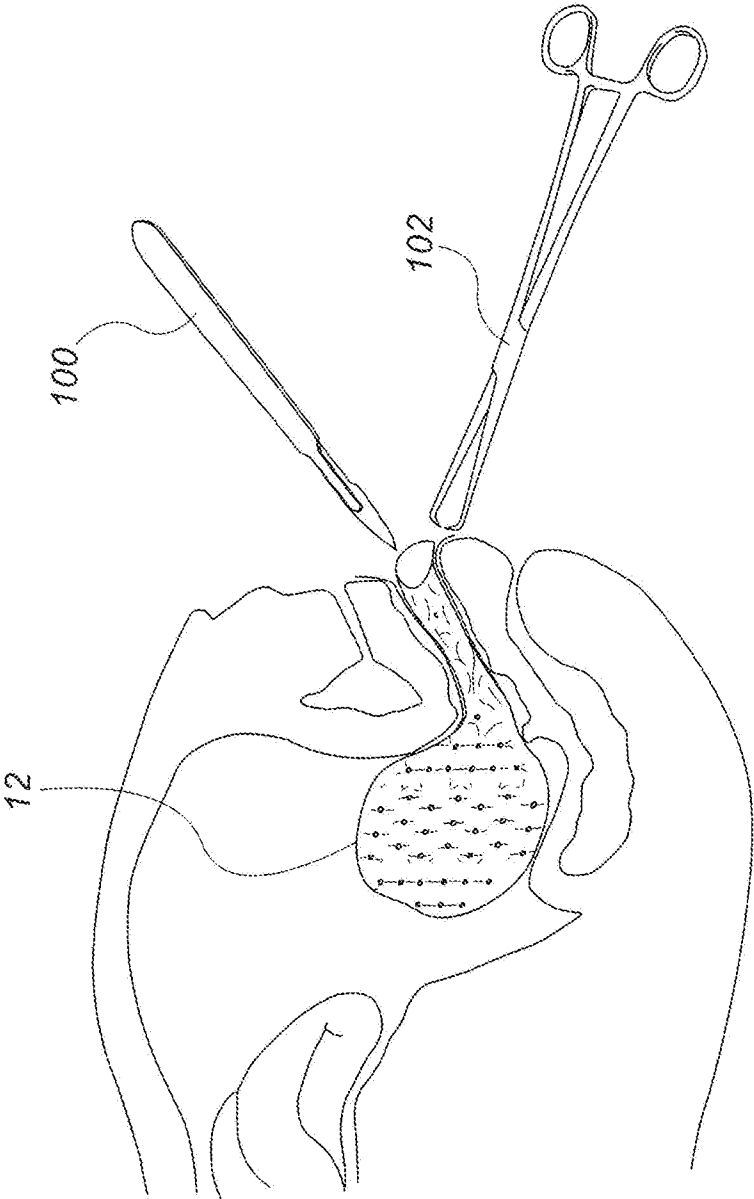


Fig. 15

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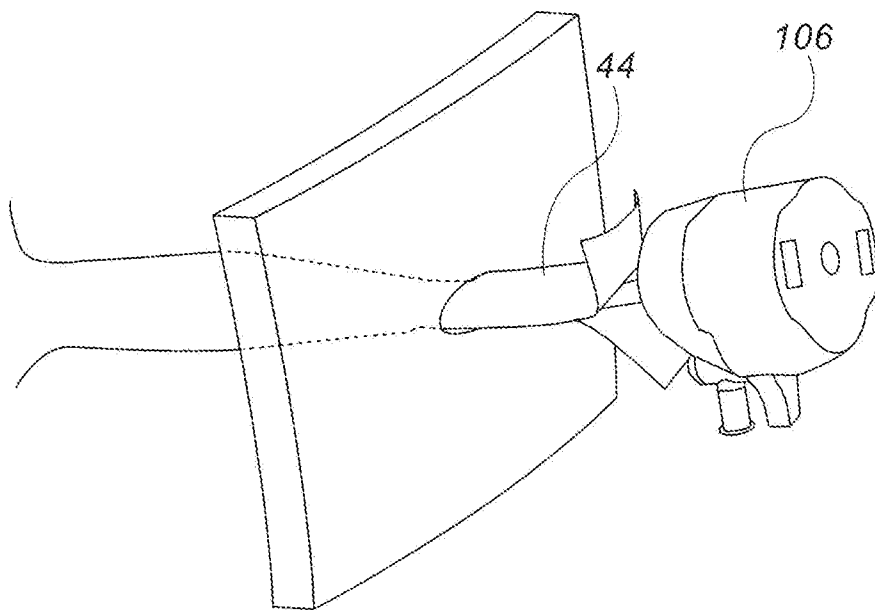


Fig. 16

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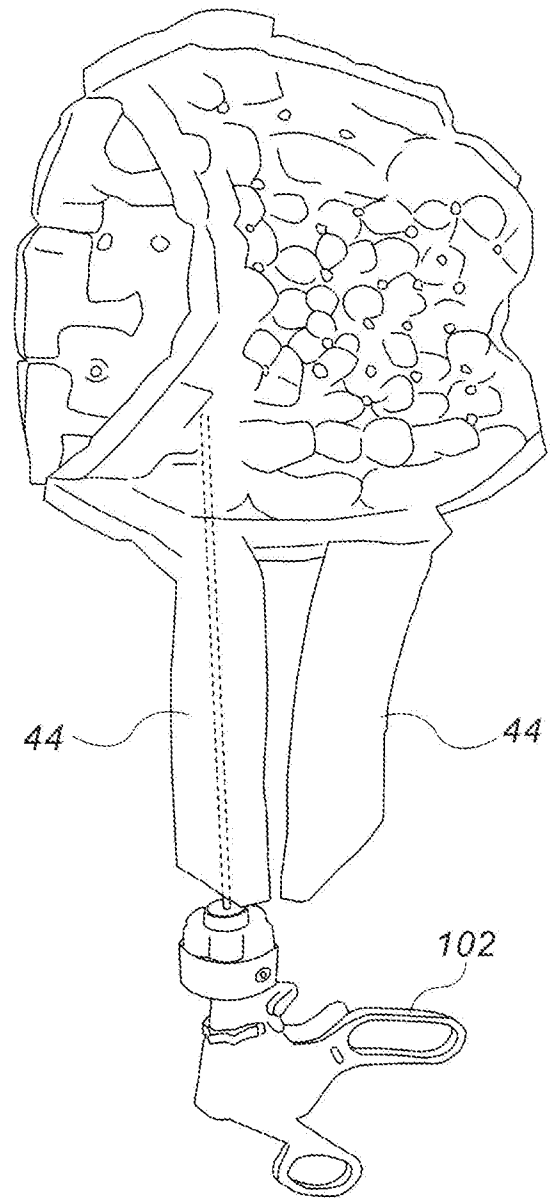


Fig. 17

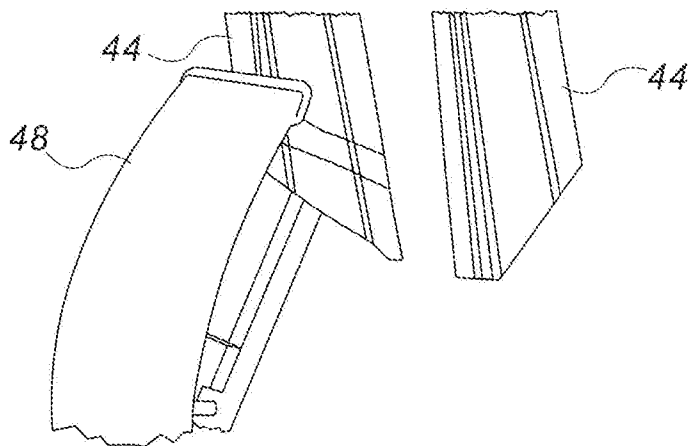


Fig. 18

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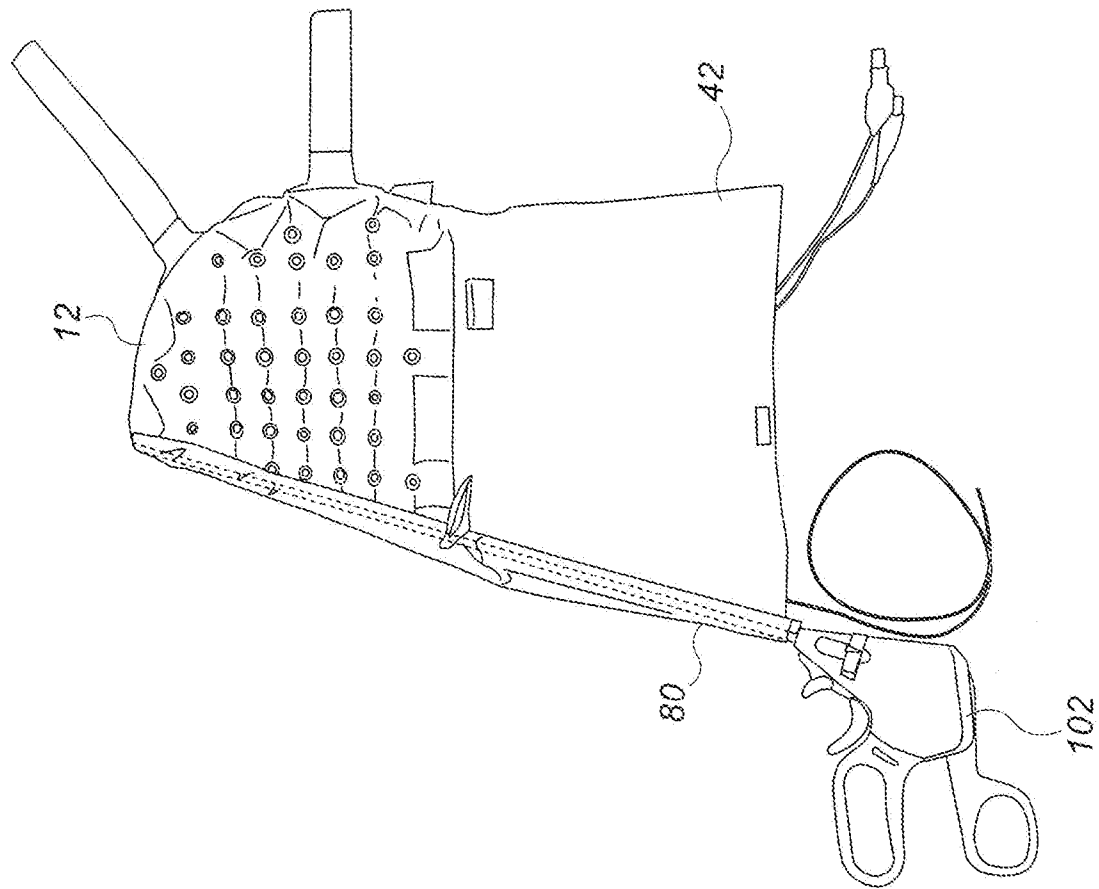


Fig. 19B

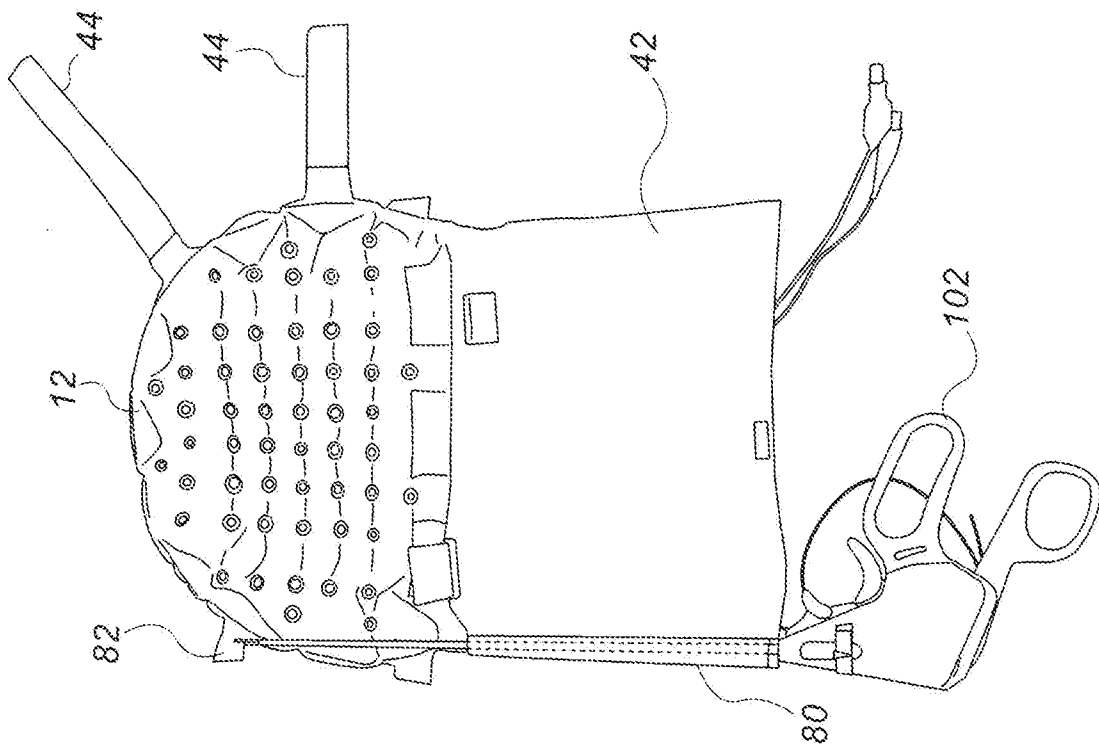


Fig. 19A

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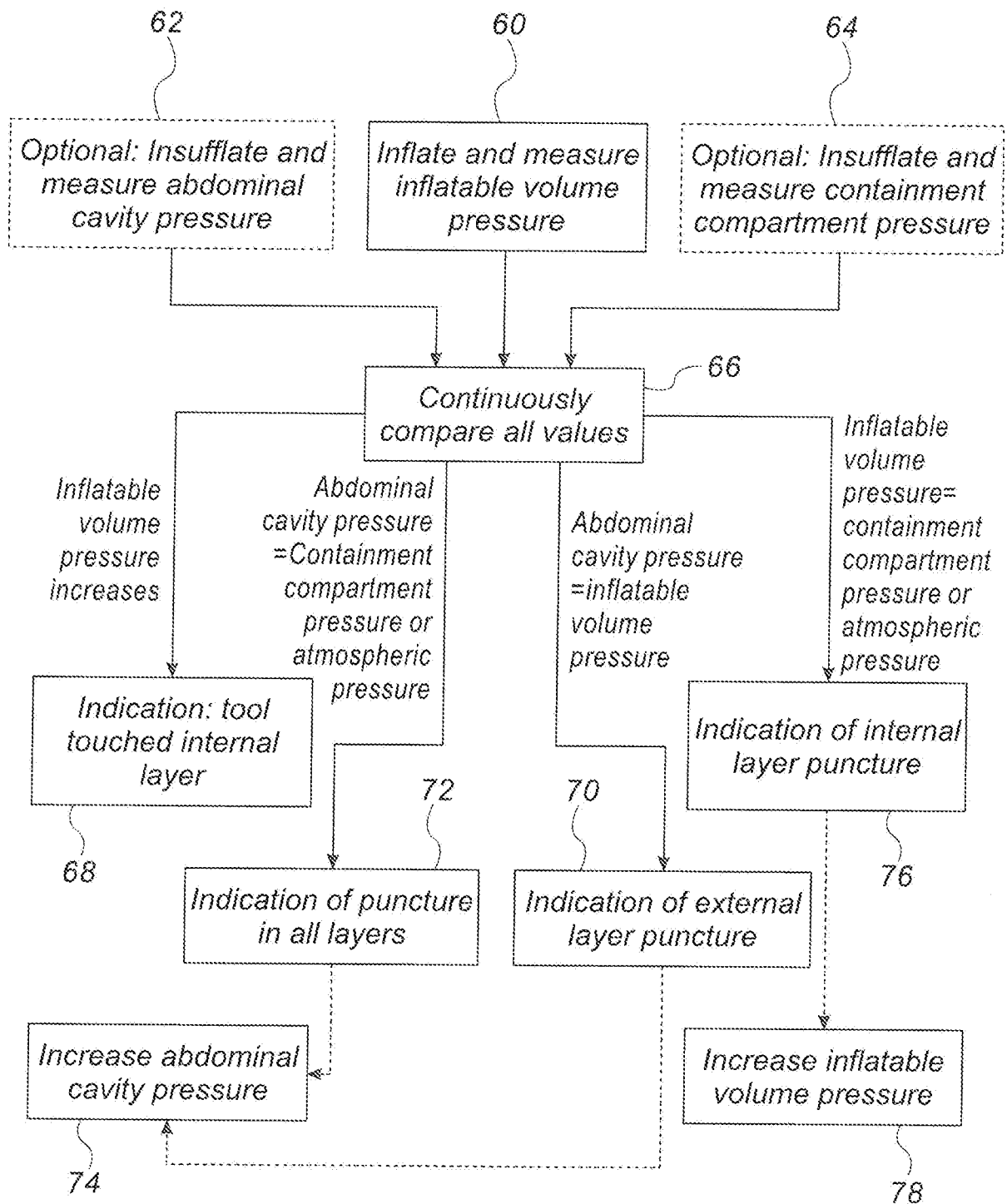


Fig. 20

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2017/050674

A. CLASSIFICATION OF SUBJECT MATTER IPC (2017.01) A61B 17/00 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC (2017.01) A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Databases consulted: FamPat database, PatBase		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/09569 A1 (UNIVERSITY OF MASSACHUSETTS) 12 Mar 1998 (1998/03/12) page 1, lines 5 - page 2, line 14; page 12, line 6 - page 14, line 29; figures 10A-C	1-6,8,10,12,13,15, 18,20-23
Y		16,17,19,24-35, 37-40
X	US 5524633 A (ADVANCED SURGICAL, INC.) 11 Jun 1996 (1996/06/11) the whole document	1-6,15,18,20-23
Y	WO 2015/084769 A1 (BRIGHAM AND WOMEN'S HOSPITAL, INC.) 11 Jun 2015 (2015/06/11) Abstract; paragraphs [0021], [0058], [0061]; figures 1, 9	16,17,19,24-35, 37-40
A	WO 2016/068825 A1 (T.C. EGE UNIVERSITESI) 06 May 2016 (2016/05/06) the whole document	1-40
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 17 Sep 2017		Date of mailing of the international search report 18 Sep 2017
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Facsimile No. 972-2-5651616		Authorized officer SEGAL Liviu Telephone No. 972-2-5651782

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2017/050674

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2016/028429 A1 (COVIDIEN LP) 25 Feb 2016 (2016/02/25) the whole document	1-40

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IL2017/050674

Patent document cited search report			Publication date	Patent family member(s)		Publication Date	
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IL2017/050674

Patent document cited search report	Publication date	Patent family member(s)	Publication Date
		US 2017231611 A1	17 Aug 2017

专利名称(译)	用于外科手术的组织封闭装置		
公开(公告)号	EP3471627A4	公开(公告)日	2020-02-19
申请号	EP2017812894	申请日	2017-06-18
[标]发明人	BAR YOSEPH GILL BLEICHER DAVID		
发明人	BAR-YOSEPH, GILL BLEICHER, DAVID		
IPC分类号	A61B17/00		
CPC分类号	A61B17/00234 A61B90/90 A61B2017/00119 A61B2017/00287 A61B2017/00526 A61B2017/00557 A61B2090/064 A61B2090/08021 A61B17/221 A61B90/06 A61B90/08 A61B2017/00818 A61B2017/00955 A61B2017/22062 A61B2017/2215 A61B2090/0809		
优先权	62/350745 2016-06-16 US		
其他公开文献	EP3471627A1		
外部链接	Espacenet		

摘要(译)

一种用于在外科手术过程中将组织与周围组织隔离以去除组织的组织容纳装置 (10) , 包括一个袋 (12) , 该袋由一个或多个壁 (14) 形成 , 该壁限定了一个容纳室 (16) 和一个开口 (18) , 用于 进入安全壳舱。每个壁 (14) 由至少两层形成 , 包括面向容纳室的内层 (20) 和从袋 (12) 向外面向的外层 (22) 。 这些层在它们之间限定一个或多个可充气容积 (24) 。 层 (20) 和层 (22) 在间隔开的连接区域 (28) 处相互连接 , 该间隔区域被布置成使得当将流体引入可充气容积 (24) 中时 , 在连接区域之间的至少两层的区域形成。 围绕容纳室的内部容积的壁腔区域。