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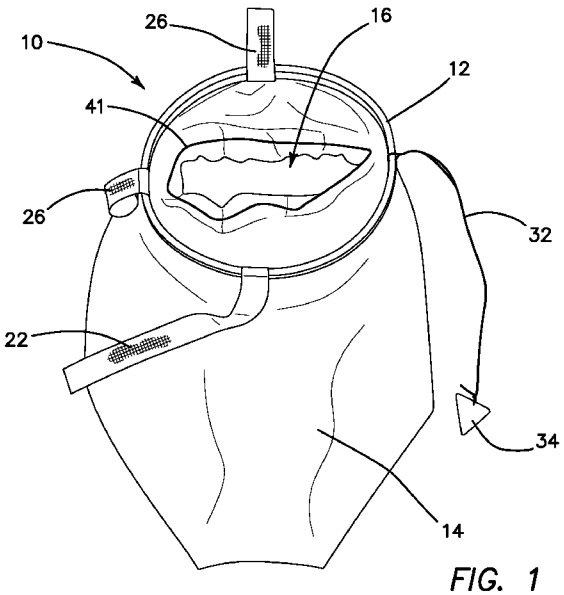


FIG. 1

(57) Abstract: The tissue removal containment system is provided that includes a tissue removal and/or containment bag arranged to be inserted through an opening into a confined space. The bag has a support or ring having a compressed, partially compressed and/or uncompressed state or position. The bag can also include an enclosure or film defining the enclosure connected to the support with the enclosure having a confined state and a deployed or unconfined state.

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Tissue Removal Containment Systems

Cross-Reference to Related Applications

[0001] This application claims the benefit of US Provisional Application No. 62/734,093, filed on September 20, 2018, the entire disclosure of which is hereby incorporated by reference as if set in full herein.

Background

[0002] The present application is generally directed to tissue removal systems and methods and more particularly to systems and methods for the containment of tissue prior to and/or during morcellation procedures.

[0003] Specimens retrieved during certain surgical procedures require specimen containment and extraction. In one such exemplary surgical operation, single site gynecological procedures such as laparoscopic hysterectomies have limited visualization of the surgical space and surroundings, especially in large uteri cases, as the volume of the specimen can occupy a vast majority of the surgical space. As such, full visualization of the specimen from the access site is not achieved in such cases, requiring the laparoscope to be constantly manipulated proximal to the access site to allow for visualization. Also, due to the limited surgical space, repositioning or generally moving the specimen within the confined surgical space is also difficult. Additionally, in a laparoscopic hysterectomy, a uterus is dissected, mobilized and collected. The uterus is removed through a trocar or an incision, ranging in size from 2.5cm to 4cm, thus adding to the difficulty in collecting and containing the specimen. Methods and systems of collecting and containing such a specimen in this or other procedures have shortcomings and improvements of such methods and systems desired.

Summary

[0004] In accordance with various embodiments, a containment system is provided. The containment system comprises a containment bag arranged to be inserted through a body opening and in various embodiments is arranged to accommodate a range of specimen sizes that is larger than a trocar incision size. The containment bag is configured to mitigate the potential spread or displacement of unwanted tissue during morcellation or other similar surgical procedures.

[0005] In accordance with various embodiments, a tissue containment bag comprises a support or ring having an inner periphery delimiting an open end, the ring being deformable from an initial uncompressed state in which the open end delimited by the ring is unobstructed to a compressed state in which the open end delimited by the ring is partially obstructed. The bag further comprises a film connected to the ring to form an enclosure having an interior and a closed end, the interior of the enclosure being accessible through the open end delimited by the ring. The film and the interior of the enclosure is extendable to a deployed state in which a distalmost end of the film extends away from the ring from a confined state in which the film including the distalmost end is confined to a position adjacent to ring. The bag in various embodiments further comprises a strap connected to the ring with the strap having a fastened state in which the strap in the fastened state secures the ring in the compressed state and, simultaneously, the film in the confined state. In various embodiments, the strap has an unfastened state in which the strap simultaneously releases the ring from its compressed state and the film from its confined state. In various embodiments, the strap has a fastener attachment releasably connected the strap to itself. In various embodiments, the bag has a tab connected to the ring at a position opposite of a strap. In various embodiments, the bag has a first tab connected to a position on the ring to the position of the strap and a second tab connected to at a position on the ring between the first tab and a strap.

[0006] In accordance with various other embodiments, a tissue containment system is provided. The system comprises a tissue containment bag and a surgical tool or instrument arranged to insert or facilitate insertion of the tissue containment bag into a patient's body cavity, convert a ring of the tissue containment bag from a compressed state to an uncompressed state and a film of the tissue containment bag from a confined state to a deployed state, and/or convert the ring of the tissue containment bag from an uncompressed state to a partially compressed state.

[0007] In accordance with various embodiments, a method of preparing a tissue containment bag for deployment comprises providing a tissue containment bag comprising a ring and a film connected to the ring with the film defining an enclosure, placing the ring in a compressed state, placing the film in a confined state, and/or securing the ring in its compressed state and the film in its confined state.

[0008] In accordance with various embodiments, a method of deploying a tissue containment bag is provided. The method comprises providing a tissue containment bag comprising a ring or support, a film connected to the ring and a strap connected to the ring and the film with the film defining an enclosure, placing the ring in a compressed state and the film in a confined state, wrapping the strap

connected to the ring around portions of the ring and portions of the film, fastening the strap to itself, inserting the tissue containment bag into a confined space with the ring in a compressed state and the film in a confined state, the entire film being gathered and placed adjacent to the ring and secured within an outer periphery of the ring with the ring defining a narrowed opening and having a hourglass shape, and/or unfastening the strap from itself releasing the film from its confined state and the ring from its compressed state.

[0009] In accordance with various embodiments, a method of removing a specimen is provided. The method comprises providing a tissue containment bag comprising a ring or support and a film connected to the ring with the film defining an enclosure, placing the ring in a compressed state and the film in a confined state, securing the ring in its compressed state and the film in its confined state, inserting the tissue containment bag into a patient's cavity with the ring in a compressed state and the film in a confined state, releasing the film from its confined state to its deployed state and the ring from its compressed state to its uncompressed state, placing a specimen through an opening defined by the ring in its uncompressed state and into the enclosure defined by the film in its deployed state, partially closing the opening defined by the ring to secure the ring in a partially compressed state while the film remains in its deployed state, removing the ring in its partially compressed state out of the patient's cavity with the film remaining within the patient's cavity, releasing the ring from its partially compressed state to move to its uncompressed state, and/or removing the specimen from the enclosure and out through the opening of the ring. The above methods in various embodiments can also comprise of closing a portion of the enclosure between the ring or support and the film and/or closing a portion of the enclosure between the ring or support and the film by pulling a cinch way from the film, the cinch being connected to the film and positioned below the ring.

[0010] In accordance with various embodiments, a tissue containment bag is provided. The bag comprises a support or ring connected to an enclosure or a film defining an enclosure and at least one of a strap, a tab, a cord and/or a cinch or any combination thereof.

[0011] Many of the attendant features of the present inventions will be more readily appreciated as the same becomes better understood by reference to the foregoing and following description and considered in connection with the accompanying drawings.

Brief Description of the Drawings

[0012] The present inventions may be better understood taken in connection with the accompanying drawings in which the reference numerals designate like parts throughout the figures thereof.

[0013] FIG. 1 is a top perspective view of a containment bag in accordance with various embodiments of the present invention.

[0014] FIG. 2 is a top view of a containment bag in accordance with various embodiments of the present invention.

[0015] FIG. 3 is a side view of a containment bag in accordance with various embodiments of the present invention.

[0016] FIG. 4 is a side perspective view of a containment bag in accordance with various embodiments of the present invention.

[0017] FIG. 5 is a top perspective view of a containment bag in accordance with various embodiments of the present invention.

[0018] FIG. 6 is a bottom perspective view of a containment bag in accordance with various embodiments of the present invention.

[0019] FIG. 7 is a top view of a containment bag in an insertion or compressed/confined state in accordance with various embodiments of the present invention.

[0020] FIGS. 8-11 are side views of various embodiments of a containment bag in various states, positions or configurations in accordance with various embodiments of the present invention.

[0021] FIG. 12 is a side view of various embodiments of a containment bag in a compressed/confined position or state in conjunction with a surgical instrument or tool being inserted into a confined space through a covering or body wall in accordance with various embodiments of the present invention.

[0022] FIGS. 13-14 are perspective side views of the strap and/or grip and support or ring of the containment bag in accordance with various embodiments of the present invention.

[0023] FIG. 15 is a top view of a strap and fastener attachment in accordance with various embodiments of the present invention.

[0024] FIGS. 16-18 are side views of a cinch and film in accordance with various embodiments of the present invention.

[0025] FIG. 19 is a top perspective view the strap of the containment bag threaded through a loop in a grip or tab in accordance with various embodiments of the present invention.

Detailed Description

[0026] Specimens retrieved during certain surgical, e.g., gynecological, procedures require specimen containment and extraction. In accordance with various embodiments, a specimen is placed in a containment bag prior to being reduced in size and extracted. In one such exemplary surgical operation, e.g., a laparoscopic hysterectomy, a specimen, e.g., a uterus, is dissected, mobilized and collected within the containment bag. The specimen is exteriorized to the surface of the body wall through a laparoscopic access port, trocar or through an incision in the body wall or opening in the patient. The incision size or length can range from 2.5cm to 4cm.

[0027] Placement of the containment bag and containment of a specimen inside the surgical space can be challenging especially involving large specimens, e.g., uteri greater than 20 weeks and/or 1,000 grams, and in some surgical procedures, such as laparoscopic hysterectomies. Limited space in the abdomen minimizes the space to place the containment bag. Single site gynecological procedures such as laparoscopic hysterectomies also have limited visualization of the surgical space and surroundings, especially in large uteri cases, as the volume of the specimen can occupy a vast majority of the surgical space. As such, full visualization of the specimen from the access site is not achieved in such cases, requiring the laparoscope to be constantly manipulated proximal to the access site to allow for visualization. The visualization of the surgical space may be further hindered by the addition of the containment bag, which can also occupy a large volume of the surgical space. Also, due to the limited surgical space, repositioning or generally moving of the bag relative to the specimen within the confined surgical space is also difficult. As such, the specimen size and containment bag size in a deployed state can limit visibility and a surgeon's working space.

[0028] Additionally, containment of a large specimen can require more manipulation of the bag in order to place the specimen in the bag. Furthermore, manipulation of the bag can be limited due to the bag itself and in particular its composition, size and/or shape. The film of the bag in one example provides a smooth yet durable surface and is arranged to minimize rough or abrasive surfaces to avoid potential tissue trauma or issues. However, such surfaces also minimize the ability to grasp and manipulate the containment bag. Moreover, the ring of the containment bag in various embodiments encloses the perimeter of the specimen before retrieval. As such, containment of the specimen includes a majority of the specimen volume occupying the containment bag. With the film encasing or otherwise covering the ring of the containment bag, the manipulation of the opening of the bag, e.g., up to the incision or body opening, is also difficult. Without friction on the film, slippage or unintended releasing

of the bag may occur. As such, specimen placement, containment and retrieval can be dependent on the bag and the ease and ability to manipulate the containment bag.

[0029] In accordance with various embodiments and as shown for example in FIGS. 1-7, the containment bag 10 comprises a support or ring 12 and a film or a plurality of films 14 attached to the ring 12 to form an enclosed space or enclosure 16. In various embodiments, the support is a dual lumen ring and in other embodiments the support is shaped, sized and arranged to define or delimit the opening or proximal end of the containment bag. In various embodiments, the film is made of the same material as the ring and in one embodiment, the film is made of thermoplastic polyurethane. In various embodiments, the ring has a thickness or width greater than the thickness or width of the film. In various embodiments, the ring has an inner diameter and an outer diameter and the enclosure has a defined inner and outer diameter. In various embodiments, the enclosure's inner and outer diameters are greater than the inner and outer diameters of the ring. The film is therefore arranged to enclose a specimen inserted within an enclosure 16 defined or delimited by the film 14. In accordance with various embodiments, the enclosure defined by the film and/or ring has various shapes, dimensions, and is configured to capture and contain a particular specimen or a range of specimen sizes that is larger than a trocar incision size and/or to mitigate the potential spread or displacement of unwanted tissue. In various embodiments, the enclosure, defined by the film and/or ring, is arranged to have various shapes and/or dimensions to assist in the deployment, manipulation and/or removal of the containment bag within and/or out of the body cavity.

[0030] The support or ring 12 is compressible or deformable and, in various embodiments, compressible only in a direction traverse to a longitudinal axis of the containment bag. As such, the ring has an initial uncompressed state in which it delimits a pattern, e.g., circular, and a compressed state in which the ring delimits a narrowed or closed opening, e.g., an elongate oval or flatten hourglass pattern. In accordance with various embodiments, the film 14 is compressible and arranged to be rolled or gathered in a direction along or parallel to the longitudinal axis of the containment bag. In various embodiments, the containment bag is rolled, folded, gathered or fan-folded to collect, draw, bunch or compress the film, e.g., the length of the film, up to and/or within an inner periphery delimited by the ring and in various embodiments, when the ring is in a compressed state. The film of the containment bag in various embodiments has a rolled state where the film is rolled up to and/or against the ring and a deployed or unconfined state where the film is permitted to roll or extend away from the ring. Such states, configurations and operations are illustrated in FIGS. 8-12.

[0031] The containment bag further comprises one or more elongate strips, tabs or straps 22 arranged on or around the support or ring 12, the film 14 or any combination thereof. In various embodiments, the elongate straps are polyurethane film or polyester laminated fabric straps. In accordance with various embodiments, the film is confined or kept in its gathered or confined state by the one or more straps. In various embodiments, a strap is wrapped around a portion of the gathered film and the ring to retain the ring in its compressed state and the film in its confined state. Operationally, in one embodiment, a surgeon wraps the strap around the gathered film and the ring in its elongated shape for insertion into or through an incision or opening in a patient.

[0032] The containment bag further comprises one or more fasteners or connectors 24 attached to or integrated with the one or more straps 22. In various embodiments, the one or more fasteners are attached to the ring 12, film 14 or any combination thereof. The fastener or connector is attached to or integrated into one of the straps 22 and in various embodiments operationally secures the ring in its compressed state and the film in its confined state and as such, in various embodiments, places and/or maintains the containment bag in an insertion state. Once the bag is inserted into and placed in the body cavity of the patient, the fastener is released to allow the bag to expand into its deployed state. In various embodiments, the entire bag is arranged to be inserted and placed in its entirety within a patient's body. In various embodiments, the fastener is released or disengaged by using a grasper or a similar surgical or laparoscopic instrument to grab and pull against the strap having the fastener 24. In various embodiments, the fastener is snap type arrangement having a snap or connection portion disposed on one portion of the strap and a receiver portion disposed on another portion of the strap distal from the connection portion. In various embodiments, the fasteners arrangement is configured to remain covered by the strap or tab 22 and thus be unexposed to not interfere with insertions and manipulation of the bag.

[0033] In various embodiments, the containment bag includes or further comprises a pull cord or loop 32 and a tether tag 34. The pull cord and tether tag remain outside of the body while the remainder of the bag is entirely inserted into the body cavity. In accordance with various embodiments, the pull cord and tether tag provide outside user access, i.e., not within the body cavity, to manipulate the bag and assist in removal of the bag and any specimen with the bag from the patient.

[0034] In accordance with various embodiments, the containment bag further comprises one or more strips, projections, tabs or grips 26 arranged on or around the support or ring 12, the film 14 or any combination thereof. In various embodiments, the grips are polyurethane film or polyester laminated

fabric grips. In accordance with various embodiments, the one or more grips provide anchors or grasping points to assist in the removal of the bag out of the patient's body. In various embodiments, the one or more grips or tabs 26 is formed as a loop and/or have textured or other surface features to provide grip access for a grasper or other similar surgical instruments to assist in the removal or manipulation of the containment bag. The grips are also configured to not interfere with the opening and/or the enclosure of the bag and any specimen contained therein. The grips are also provided in various embodiments to not snag or interfere with the removal, placement or manipulation of the bag and/or the specimen. Once the captured specimen is brought to the surface or outside the body along with a proximal portion of the containment bag, in various embodiments, the specimen may be extracted by grasping and pulling it out of the bag and/or by performing extracorporeal manual morcellation. In various embodiments, at least two grips or tabs are provided at about ninety degrees from each other and/or the one or more tabs to assist in providing a level and/or stable area to manipulate the bag from various angles or by using one or more instruments.

[0035] In accordance with various embodiments and illustrated for example in FIGS. 7-12, inserting the containment bag into the surgical space in a compressed/confined state does not impair visualization of the containment bag or other anatomical features. The elongated or narrowed shape created by securing the film of the bag via the strap and fastener arrangement facilitates the insertion of the bag through a small incision, placement into a surgical space and minimizes its obstruction of a surgeon's view or visualization.

[0036] In various embodiments, the user or surgeon is able to gather, roll, fold or fan-fold the film of the containment bag and secure it using the strap and fastener. The position of the strap and fastener allows the user to confine the film 14 as shown for example in FIG. 7. Once confined, the surgeon can introduce and place the containment bag via incision or access platform into a space that does not obstruct other anatomical features that require access. The confined bag can be deployed or released by undoing the fastener using for example a grasper to grasp and pull an excess or a portion of the tab or strap away from the fastener. Once released, the containment bag returns to its original or initial shape, state, or configuration.

[0037] In various embodiments, as specimen placement and containment are dependent on manipulation, having one or more tabs or grips 26 attached to the mouth or opening of the containment bag eases placement and containment of the specimen into and within the bag. In various embodiments, the positioning of the one or more grips, straps and/or cord loop eases control of the mouth or opening of

the containment bag and/or to enclose the perimeter of the specimen, the bag or any combination thereof and/or allow the surgeon to control manipulation of the bag to facilitate specimen placement. In various embodiments, the one or more grips and/or straps are made from a laminated fabric providing additional friction properties to assist in the ability to grasp the grips and/or straps and control manipulation of the bag. Additionally, in accordance with various embodiments, an opening through or a loop formed on or by the grip and/or strap allow a surgeon to grab or insert a laparoscopic instrument there through to manipulate the bag.

[0038] In various embodiments, the one or more elongate straps is operationally inserted into and through an opening, aperture or a formed loop of a grip or tab as shown for example in FIG. 19. As such, a connection is formed and thus aid in the containment and/or removal of the specimen and bag from the patient. In various embodiment, the connection assists in the removal for the bag to the surface of the abdomen in a parallel fashion with the aid of the cord loop outside of the abdomen also being moved distally or away from the patient or out of the patient cavity, thereby reducing or eliminating the possibility of the specimen or portions thereof from falling or spilling out from the bag if removal for example occurs at an extreme angle from the surgical or access site.

[0039] In accordance with various embodiments, the fastener and strap provides the ability for a quick engagement and disengagement of the containment bag. In various embodiments, straps and/or grips are provided across from each other and sized and/or shaped to allow them to be separately grasped and tied together. In various other embodiments, a pin or projection on one side of a strap is provided to be inserted into a key slot, hole, opening or aperture on the other side of the strap to be removably secured and thereby provide an engagement and release arrangement for the confinement and deployment of the containment bag.

[0040] In accordance with various embodiments, the strap and/or grip are made of a laminated fabric. In various embodiments, the strap and/or grip have specific texture and/or friction properties to facilitate and not interfere with the grasping or manipulation of the tab and/or grip within and outside the patient. In various embodiments, an inner periphery of the ring has a diameter and the strap has a length greater than the diameter of the inner periphery of the ring. In various embodiments, the strap has a length longer than a length of the grip or tab. In various embodiments, the tab defines or has a loop attached thereto in which the loop defines an opening through which the strap is threadable there through. In various embodiments, the loop of the tab is formed by the tab being connected to itself and in various embodiments with the strap threaded through the loop, the ring is in a partially compressed

state in which the open end delimited by the ring is obstructed, no longer unobstructed in its initial uncompressed state, and less obstructed than the ring in the compressed state. In various embodiments, the loop of the tab has a diameter equal or greater than a width of the strap. In various embodiments, the strap has a width greater than a diameter of the loop of the tab. In various embodiments, the bag comprises of two/three tabs located in two/three different quadrants along the ring or support and the strap located at a third/fourth quadrant along the ring not occupied by any of the two/three tabs to facilitate support, deployment, securement and/or manipulation of the bag.

[0041] In accordance with various embodiments, the containment bag comprises a cinch 41. The cinch in various embodiments is a string, thread or cord disposed around the film between the open end and the closed end of the bag. Once the specimen is within the containment bag, the surgeon is able to close a top or proximal portion of the bag near the mouth or opening of the bag by drawing or pulling on the cinch. In various embodiments, the cinch is a dual cinch and by simultaneously pulling both ends of the cinch or cinch grasping regions in opposite directions using for example laparoscopic instruments or graspers, the surgeon can close a portion of the containment bag. The cinch in various embodiment can prevent a specimen or portions thereof from falling from the containment bag and can assist with the removal of the bag, as portions of the bag, e.g., at the mouth or opening of the bag, is in a closed or more confined state.

[0042] In various embodiments, one or more tabs or grips has a length of about 1.5 inches to 2.0 inches and in various embodiments is about 1.75 inches. The one or more straps have a length of about 4.25 inches to about 7.0 inches and in various embodiments is about 6.7 inches. The straps and/or grips have a thickness of about 0.018 inches to about 0.023 inches and in various embodiments is about 0.019 inches. In various embodiments, the at least one grip has a width of about 0.50 inches to 1.25 inches and in various embodiments is about 0.75 inches. The at least one strap has a width of about 0.50 inches to about 0.75 inches and in various embodiments is about .625 inches. As such, the strap and/or grip are arranged to facilitate the insertion, manipulation and removal of the containment bag and/or a specimen or portions thereof. In addition, in accordance with various embodiments, the size and/or shapes of straps and/or grips are configured to ensure or facilitate the manipulation, engagement and disengagement of the grips by a laparoscopic instrument. Furthermore, in accordance with various embodiments, the length of straps are configured to ensure or facilitate the capture or confinement of the film and ring in their confined/compressed state and the engagement and/or release of the fastener and/or tab to confine or release or deploy the bag.

[0043] In various embodiments, the distance from the bottom of the ring or support to the cinch and/or its cord's location is about 1.5 to 2.25 inches and in various embodiments about 1.5 inches. The location of the cinch in various embodiments ensures that the majority of the specimen volume is captured and not too high, e.g., less than 1.5 inches, that may make it more difficult for a surgeon to operate the cinch, as the ring or support can counteract the motion of closing the bag.

[0044] In accordance with various embodiments, one or more straps and/or grips are attached to the support 12 by one or more heat seals as illustrated in FIG. 13. The distance 21 between the heat seal is greater than the width and/or height of the support 12. In other embodiments, one or more seals or bonds on the strap and/or grips running along the top or one or more side edges of the support can be made to achieve fixation of the one or more straps and/or grips to the ring as illustrated in FIG. 14. As such, one end of the strap and/or grip forms a lumen through which a portion of the support is disposed there through. In various embodiments, the one or more straps and/or grips are bonded or adhered directly to the support. In accordance with various embodiments, the distance between the heat seal and/or the attachment of the strap to the support ensures that the straps remain in position on the support and yet does not interfere with its operation or the connection between the film and the support.

[0045] In FIG. 15, in accordance with various embodiments, a strap 22 and fastener 24 is illustrated. As illustrated, the fastener 24 in one embodiment comprises an attachment portion 25 having one or more projections or pins extending from the tab to be removably connected to apertures or openings on a receiver portion 27 of the fastener. In various embodiments, the attachment portion and/or the receiver portion are integrated or adhered to the strap and in various embodiments, the positioning of each portion is reversed. In accordance with various embodiments, the projection and aperture connection is a friction fit. In various embodiments, the fastener is a hook and loop style arrangement. In various embodiments, the attachment portion and/or receiver portion is welded to the strap and in various embodiments, the attachment portion and/or receiver portion one or more boss pins piercing the strap and press fitted through holes or apertures of a respective attachment or receiver portion.

[0046] In reference to FIGS. 16-18, in various embodiments, the containment bag comprises a cinch 41. In various embodiments, one or more strips of film 43 are sealed to the film of the containment bag. In various embodiments, the film strips are made of the same material as the film of the containment bag. In various embodiments, the film strips have a length of about 7.5 inches and width of about 0.75 inches and are sealed at the top and bottom to the film of the containment bag to thereby enclose and capture portions of the cinch. In various embodiments, openings or thru holes are provided or made at

one or both ends of the film strips and/or the film of the bag to allow the one or more cord loops to be fed in and through the film strips. In various embodiments, the cord loops are fixed, adhered or tied off on opposite ends, exposing only single cord loop per side. In various embodiments, one or more clips, tabs, or grips are attached to the cord to provide a larger area to grasp or access the cord of the cinch. In various embodiments, the film strips are provided to cover or keep the cinch unexposed to not interfere with any surrounding tissue or the insertion, removal or manipulation of the bag.

[0047] In various embodiments, as illustrated in FIG. 18, a sealed cord region 45 to enclose or capture the cord of the cinch is provided by folding the film of the bag onto itself and creating the cord region. After sealing off or forming the cord region, the excess or additional portion of the film is used to attach the ring with the opposite end of the film and is sealed in the same manner. Once the edges of the film of the bag are sealed, strands of cord or cord loop can be inserted and tied off or attached to form the cinch. In accordance with various embodiments, a cinch 41 may be formed by feeding a cord or cord loops through a plurality of openings or apertures in the film of the film or film strips of the bag and in other embodiments covered by an additional film or film strip to cover or keep the cinch unexposed to not interfere with any surrounding tissue or the insertion, removal or manipulation of the bag.

[0048] In various embodiments, the cinch is a dual cinch with one end disposed outside the film and another end disposed on an opposing side outside the film in which movement of the ends of the dual cinch away from the bag in opposing directions constricts the film, closing a pathway from the closed end of the bag to the open end of the bag. In various embodiments, the cinch is disposed within film strips attached and heat sealed to the film and/or the film strips having opening through which one or more ends of the cinch extends there through.

[0049] In various embodiments, the support or ring can be oval or non-circular and defining an open end or opening having a similar shape. In various embodiments, the support or ring has a thickness greater than a thickness of the film and in various embodiments, the ring is deformable only in a direction traverse to a longitudinal axis of the bag. In various embodiments, the ring or support has a predefined resiliency or spring rate to spring back from the compressed state to an initial uncompressed state. In various embodiments, the ring in the initial uncompressed state defines a circular opening and the ring in the compressed state defines a narrowed opening.

[0050] In various embodiments, the film connected to the ring covers an entire periphery of the ring. In various embodiments, the film is a monolithic film sheet being impermeable and having no apertures

or openings there through. In various embodiments, the film has pre-formed creases to induce folding of the film into an insertion configuration. In various embodiments, the film comprises a plurality of films connected to each other and to the ring to form sidewalls and a closed end and defining the interior of the enclosure. In various embodiments, the film is folded over itself with a pair of first side edges being attached to each other and a pair of second side edges being attached to each other to form side walls and a closed end and defining the interior of the enclosure. In various embodiments, the enclosure of the bag has an inner diameter defined by the inner periphery of the ring and/or the enclosure has an outer diameter greater than an outer diameter of the ring defined by an outer periphery of the ring. In various embodiments, the film is in contact with the ring and the ring is not able to roll the film around the ring and/or the film is gatherable in a direction along a longitudinal axis of the tissue containment bag. In various embodiments, the film, in the confined state, is gathered up to and within an outer periphery of the ring. In various embodiments, the film, in a deployed state, is extended away from and outside an outer periphery of the ring. In various embodiments, the enclosure has a minimum fillable volume with the film being in the confined state and a maximum fillable volume with the film being in the deployed state.

[0051] In accordance with various operational aspects of the tissue containment bag, the bag may be prepared for deployment, deployed in a confined space, such as patient's body cavity or a surgical simulator or trainer, and/or utilized to remove a specimen, simulated or not, from the confined space. As such, in accordance with various embodiments, the ring or support in a compressed state and the film in a confined state can be placed, secured and inserted into the confined space with the ring in a compressed state and the film in a confined state. In various embodiments, the film is released from its confined state to its deployed state and the ring from its compressed state to its uncompressed state and/or a specimen can be placed through an opening defined by the ring in its uncompressed state and into the enclosure defined by the film in its deployed state. In various embodiments, the opening or open end defined by the ring can be partially closed and/or the ring secured in a partially compressed state while the film remains in its deployed state. In various embodiments, the ring is removed in its partially compressed state out of the confined space with the film remaining within the confined space, releasing the ring from its partially compressed state to move to its uncompressed state. The specimen can be removed from the enclosure and out through the opening of the ring. In various embodiments, the enclosure between the ring or support and the film can be closed and/or closed by pulling a cinch way from the film. In various embodiments, a surgical instrument or tool can be utilized to insert,

interact and/or manipulate the bag and portions thereof and such a tool or device may be a grasper or the like and/or a specific set of tools or instruments to separately perform some or all of these actions may be provided.

[0052] Examples of bags and related accessories and their operational use are described in US Patent Application Nos. 14/885,072; 15/068,366; and 15/498,157, the entire disclosures of which are hereby incorporated by reference as if set in full herein. The above description is provided to enable any person skilled in the art to make and use the tissue containment devices or systems and perform the methods described herein and sets forth the best modes contemplated by the inventors of carrying out their inventions. Various modifications, however, will remain apparent to those skilled in the art. It is contemplated that these modifications are within the scope of the present disclosure. Different embodiments or aspects of such embodiments may be shown in various figures and described throughout the specification. However, it should be noted that although shown or described separately each embodiment and aspects thereof may be combined with one or more of the other embodiments and aspects thereof unless expressly stated otherwise. It is merely for easing readability of the specification that each combination is not expressly set forth.

[0053] Although the present invention has been described in certain specific aspects, many additional modifications and variations would be apparent to those skilled in the art. It is therefore to be understood that the present invention may be practiced otherwise than specifically described, including various changes in the size, shape and materials, without departing from the scope and spirit of the present invention. Thus, embodiments of the present invention should be considered in all respects as illustrative and not restrictive.

Claims:

1. A tissue containment bag comprising:

a ring having an inner periphery delimiting an open end, the ring being deformable from an initial uncompressed state in which the open end delimited by the ring is unobstructed to a compressed state in which the open end delimited by the ring is partially obstructed;

a film connected to the ring to form an enclosure having an interior and a closed end, the interior of the enclosure being accessible through the open end delimited by the ring, the film and the interior of the enclosure being extendable to a deployed state in which a distalmost end of the film extends away from the ring from a confined state in which the film including the distalmost end is confined to a position adjacent to ring; and

a strap connected to the ring, the strap having a fastened state in which the strap in the fastened state secures the ring in the compressed state and, simultaneously, the film in the confined state.

2. The tissue containment bag of claim 1 wherein the strap has an unfastened state in which the strap simultaneously releases the ring from its compressed state and the film from its confined state.

3. The tissue containment bag of claim 2 wherein the strap is attached to the ring and the film.

4. The tissue containment bag of claim 3 wherein the strap is heat-sealed to itself connecting the strap to the ring and the film.

5. The tissue containment bag of claim 1 wherein the inner periphery of the ring has a diameter and the strap has a length greater than the diameter of the inner periphery of the ring.

6. The tissue containment bag of claim 2 wherein the strap comprises a fastener attachment to releasably attach the strap from the fastened state to the unfastened state.

7. The tissue containment bag of claim 6 wherein the fastener attachment releasably connects the strap to itself.

8. The tissue containment bag of claim 6 wherein the strap has an outer surface and an inner surface and the fastener attachment comprises a connector and a receiver disposed on the inner surface of the strap.

9. The tissue containment bag of claim 8 wherein the connector is disposed near a first end of the strap and the receiver is located near a second end of the strap.

10. The tissue containment bag of claim 8 wherein the first end of the strap is connected to the ring and the second end of the strap is not connected to the ring.

11. The tissue containment bag of claim 8 wherein the second end of the strap is connected to the ring and the first end of the strap is not connected to the ring.

12. The tissue containment bag of claim 1 or 11 further comprising a tab connected to the ring at a position opposite of the strap.

13. The tissue containment bag of claim 1 or 11 further comprising a first tab connected to a position on the ring to the position of the strap and a second tab connected to at a position on the ring between the first tab and the strap.

14. The tissue containment bag of claim 12 wherein the strap has a length longer than a length of the tab.

15. The tissue containment bag of claim 12 or 14 wherein the tab has a loop defining an opening through which the strap is threadable there through.

16. The tissue containment bag of claim 15 wherein, with the strap threaded through the loop, the ring is in a partially compressed state in which the open end delimited by the ring is obstructed, no longer unobstructed in its initial uncompressed state, and less obstructed than the ring in the compressed state.

17. The tissue containment bag of claim 16 wherein the loop of the tab is formed by the tab being connected to itself.

18. The tissue containment bag of claim 15, 16 or 17 wherein the loop of the tab has a diameter equal or greater than a width of the strap.

19. The tissue containment bag of claim 15, 16 or 17 wherein the strap has a width greater than a diameter of the loop of the tab.

20. The tissue containment bag of claim 15, 16 or 17 wherein the tab extends away from the ring and the strap extends away from the ring and the tab.

21. The tissue containment bag of claim 1 or 11 further comprising three tabs located in three different quadrants along the ring and the strap located at a fourth quadrant along the ring not occupied by any of the three tabs.

22. The tissue containment bag of claim 12 wherein the tab is made of a laminated fabric.

23. The tissue containment bag of claim 1 or 12 further comprising a cord attached to the ring.

24. The tissue containment bag of claim 23 wherein the strap has a length shorter than a length of the cord.

25. The tissue containment bag of claim 23 further comprising a tag and one end of the cord not attached to the ring is attached to the tag.

26. The tissue containment bag of claim 25 wherein the tag and portions of the cord attached to the tag is positioned outside a patient's body cavity with the ring and film being positioned within the patient's body cavity.

27. The tissue containment bag of claim 1 or 26 wherein the ring has a thickness greater than a thickness of the film.

28. The tissue containment bag of claim 1 or 27 wherein the ring is deformable only in a direction traverse to a longitudinal axis of the tissue containment bag.

29. The tissue containment bag of claim 1 or 28 wherein the open end of the ring in the initial uncompressed state defines a circular opening.

30. The tissue containment bag of claim 1 or 29 wherein the open end of the ring in the compressed state defines a narrowed opening.

31. The tissue containment bag of claim 1 or 30 wherein the film connected to the ring covers an entire periphery of the ring.

32. The tissue containment bag of claim 1 or 31 wherein the film is made of a thermoplastic polyurethane.

33. The tissue containment bag of claim 1 or 31 wherein the film comprises a plurality of films connected to each other and to the ring to form sidewalls and a closed end and defining the interior of the enclosure.

34. The tissue containment bag of claim 1 or 31 wherein the film is folded over itself with a pair of first side edges being attached to each other and a pair of second side edges being attached to each other to form sidewalls and a closed end and defining the interior of the enclosure.

35. The tissue containment bag of claim 1 or 31 wherein the enclosure has an inner diameter defined by the inner periphery of the ring.

36. The tissue containment bag of claim 1 or 35 wherein the enclosure has an outer diameter greater than an outer diameter of the ring defined by an outer periphery of the ring.

37. The tissue containment bag of claim 1 or 36 wherein the film being in contact with the ring and the ring is not able to roll the film around the ring.

38. The tissue containment bag of claim 1 or 37 wherein the film is gatherable in a direction along a longitudinal axis of the tissue containment bag.

39. The tissue containment bag of claim 1 or 38 wherein the film, in the confined state, is gathered up to and within an outer periphery of the ring.

40. The tissue containment bag of claim 1 or 39 wherein the film, in a deployed state, is extended away from and outside an outer periphery of the ring.

41. The tissue containment bag of claim 1 or 40 wherein the film has pre-formed creases to induce folding of the film into an insertion configuration.

42. The tissue containment bag of claim 1 or 41 wherein the ring has a predefined resiliency to spring back from the compressed state to an initial uncompressed state.

43. The tissue containment bag of claim 1, 21 or 42 further comprising a cinch attached to the film and disposed between the ring and the closed end.

44. The tissue containment bag of claim 43 wherein the cinch is disposed near and below the ring.

45. The tissue containment bag of claim 43 or 44 wherein the cinch is a dual cinch with one end disposed outside the film and another end disposed on an opposing side outside the film in which movement of the ends of the dual cinch away from the bag in opposing directions constricts the film, closing a pathway from the closed end of the film to the open end of the ring.

46. The tissue containment bag of 43 or 45 wherein the cinch is disposed within film strips attached and heat sealed to the film.

47. The tissue containment bag of claim 46 wherein the film strips having opening through which one or more ends of the cinch extends there through.

48. The tissue containment bag of claim 43 or 45 wherein the cinch is disposed within a folded portion of the film.

49. A tissue containment system comprising:

a tissue containment bag; and

a surgical instrument arranged to facilitate insertion of the tissue containment bag into a patient's body cavity, convert a ring of the tissue containment bag from a compressed state to an uncompressed state and a film of the tissue containment bag from a confined state to a deployed state, or convert the ring of the tissue containment bag from an uncompressed state to a partially compressed state.

50. A tissue containment system comprising:

a tissue containment bag; and

means for inserting the tissue containment bag into a patient's body cavity with a support of the tissue containment bag being in a compressed state and the film of the tissue containment bag being in a confined state.

51. A tissue containment system comprising:

a tissue containment bag; and

means for converting a support of the tissue containment bag from a compressed state to an uncompressed state and a film of the tissue containment bag from a confined state to a deployed state.

52. A tissue containment system comprising:

a tissue containment bag; and

means for converting a support of the tissue containment bag from an uncompressed state to a partially compressed state with a film of the tissue containment bag being in a deployed state.

53. A method of preparing a tissue containment bag for deployment, the method comprising

providing a tissue containment bag comprising a ring and a film connected to the ring, the film defining an enclosure;

placing the ring in a compressed state;

placing the film in a confined state; and

securing the ring in its compressed state and the film in its confined state.

54. The method of claim 53 wherein the securing the ring in its compressed state and the film in its confined state further comprises wrapping a strap connected to the ring around portions of the ring and portions of the film.

55. The method of claim 54 further comprising fastening the strap to itself.

56. A method of deploying a tissue containment bag, the method comprising

providing a tissue containment bag comprising a ring, a film connected to the ring and a strap connected to the ring and the film, the film defining an enclosure;

placing the ring in a compressed state and the film in a confined state;

wrapping the strap connected to the ring around portions of the ring and portions of the film;

fastening the strap to itself;

inserting the tissue containment bag into a confined space with the ring in a compressed state and the film in a confined state, the entire film being gathered and placed adjacent to the ring and secured within an outer periphery of the ring with the ring defining a narrowed opening and having a hourglass shape; and

unfastening the strap from itself releasing the film from its confined state and the ring from its compressed state.

57. A method of removing a specimen, the method comprising

providing a tissue containment bag comprising a ring and a film connected to the ring, the film defining an enclosure;

placing the ring in a compressed state and the film in a confined state;

securing the ring in its compressed state and the film in its confined state;

inserting the tissue containment bag into a patient's cavity with the ring in a compressed state and the film in a confined state;

releasing the film from its confined state to its deployed state and the ring from its compressed state to its uncompressed state;

placing a specimen through an opening defined by the ring in its uncompressed state and into the enclosure defined by the film in its deployed state;

partially closing the opening defined by the ring to secure the ring in a partially compressed state while the film remains in its deployed state;

removing the ring in its partially compressed state out of the patient's cavity with the film remaining within the patient's cavity;

releasing the ring from its partially compressed state to move to its uncompressed state; and

removing the specimen from the enclosure and out through the opening of the ring.

58. The method of claim 57 wherein the securing the ring in its compressed state and the film in its confined state further comprises wrapping a strap connected to the ring around portions of the ring and portions of the film and fastening the strap to itself.

59. The method of claim 58 wherein the releasing the film from its confined state to its deployed state and the ring from its compressed state to its uncompressed state further comprises unfastening the strap from itself.

60. The method of claim 59 wherein the partially closing the opening defined by the ring to secure the ring in a partially compressed state while the film remains in its deployed state further comprises threading the strap through a loop defined by a tab connected to the ring and pulling the strap through the loop to narrow the opening defined by the ring.

61. The method of claim 60 wherein the removing the ring in its partially compressed state out of the patient's cavity with the film remaining within the patient's cavity further comprises grasping an end of the strap threaded through the loop and a cord connected to the ring and pulling the end of the strap and the cord out of the patient's cavity.

62. The method of claim 61 wherein the releasing the ring from its partially compressed state to move to its uncompressed state further comprises releasing the cord and the strap allowing the strap to be unthreaded from the loop as the ring springs back to its uncompressed state.

63. The method of claim 57 and 62 further comprising closing a portion of the enclosure between the ring and the film.

64. The method of claim 63 wherein the closing a portion of the enclosure between the ring and the film further comprise pulling a cinch way from the film, the cinch being connected to the film and positioned below the ring.

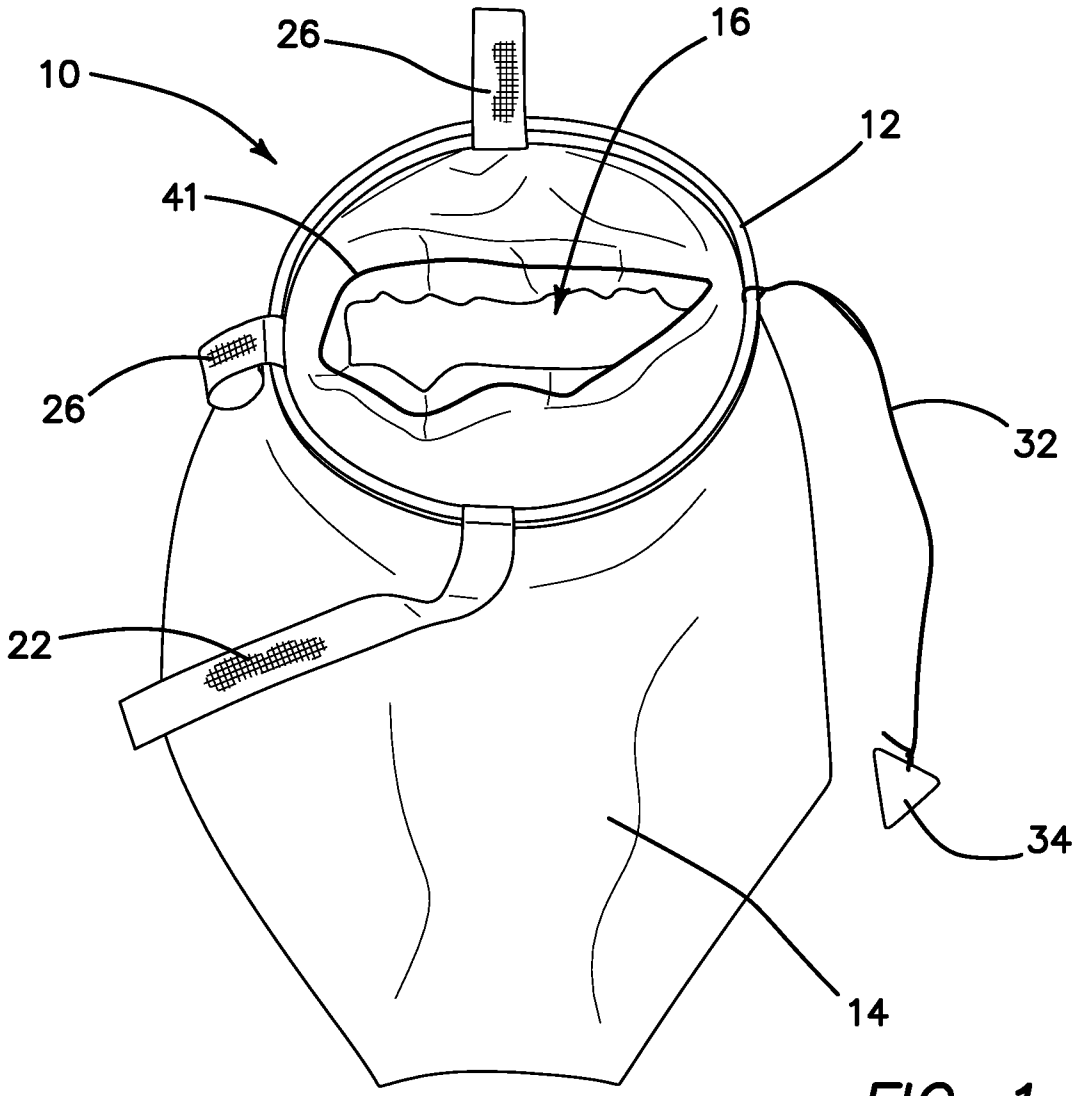


FIG. 1

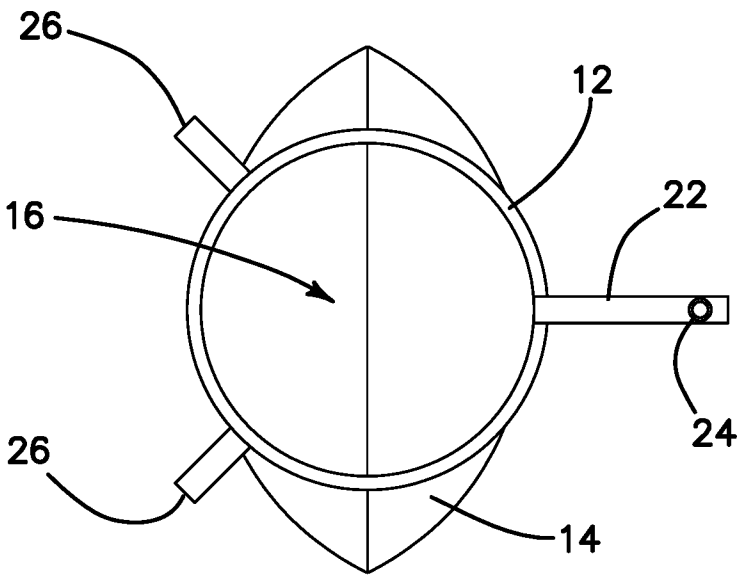


FIG. 2

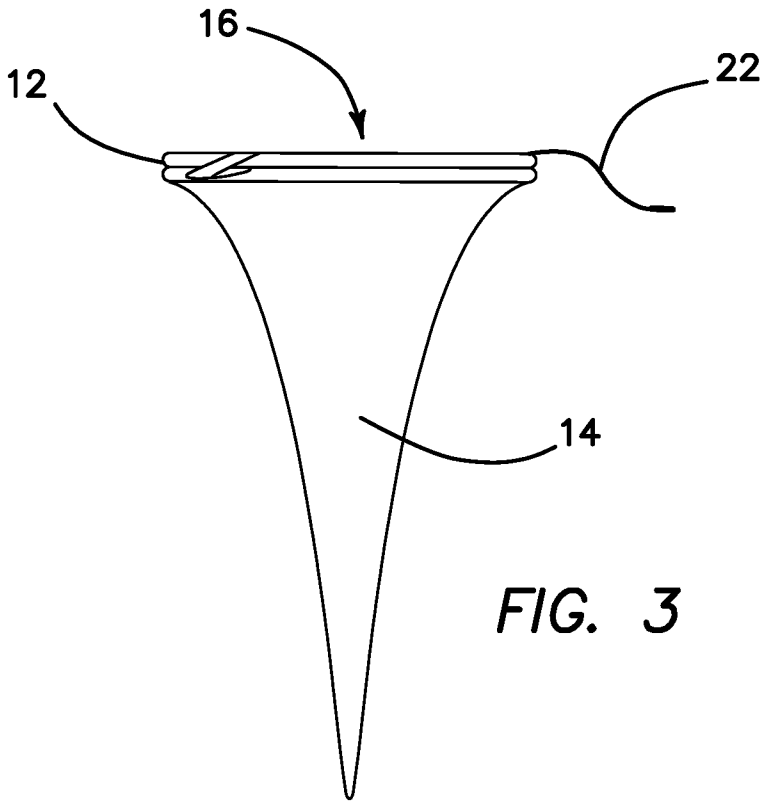


FIG. 3

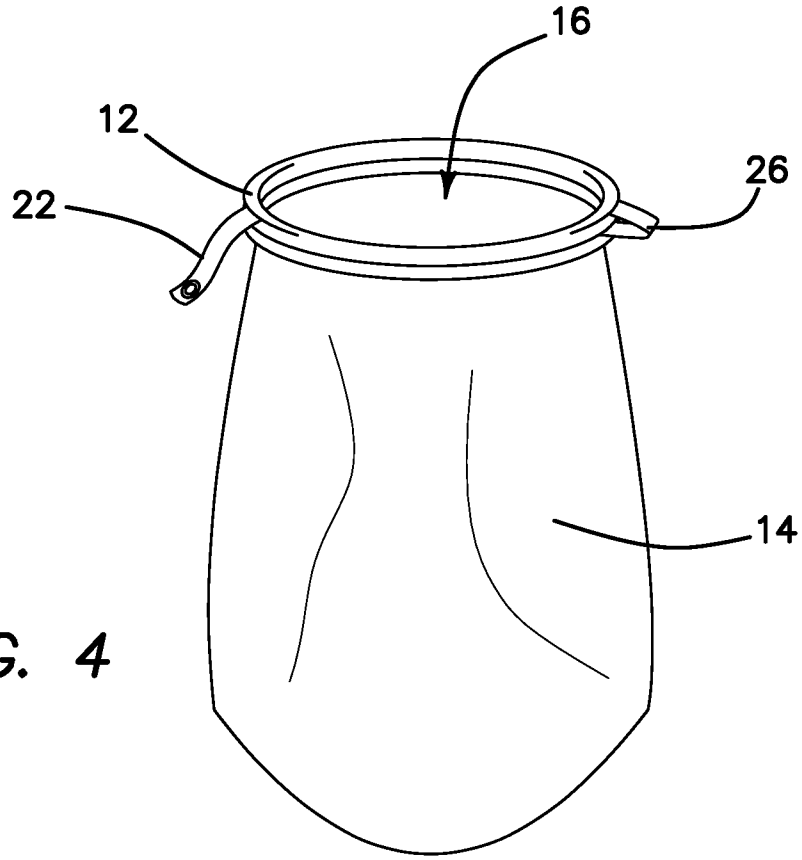


FIG. 4

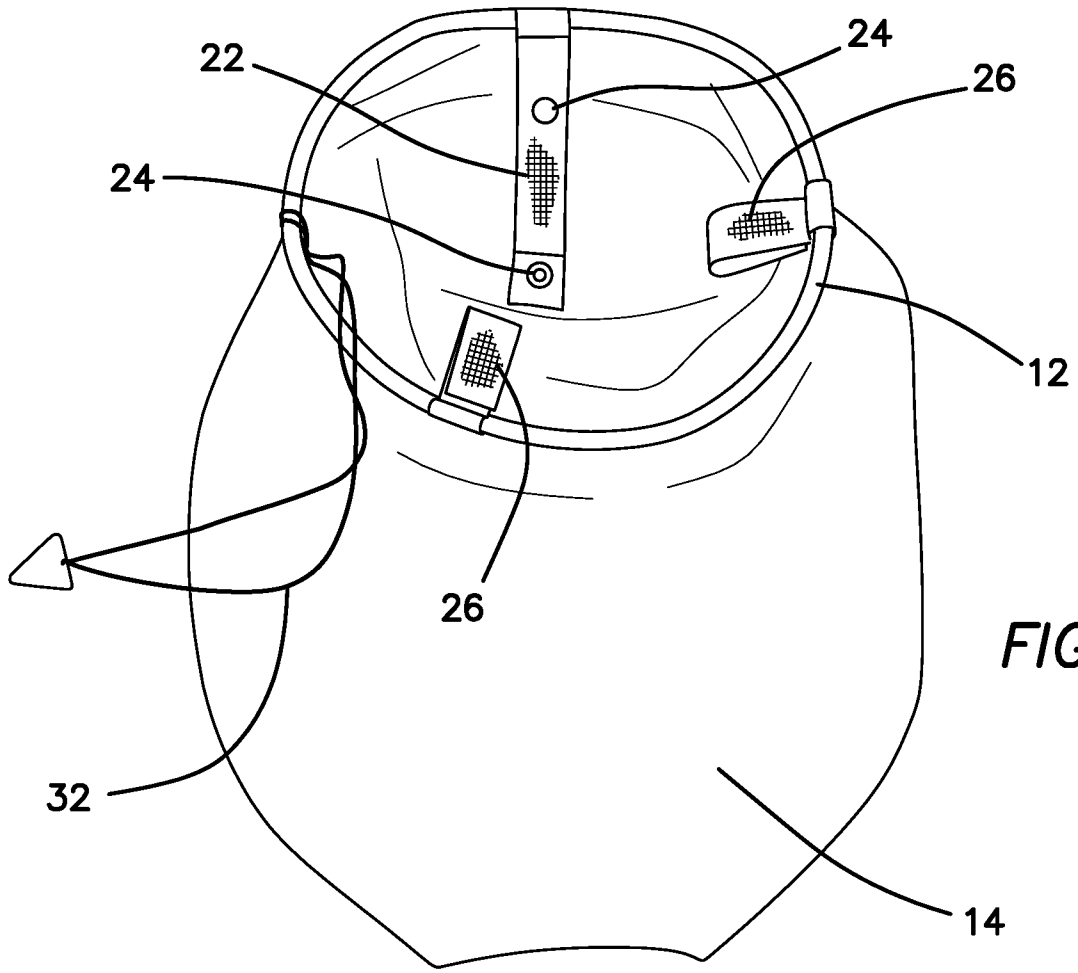


FIG. 5

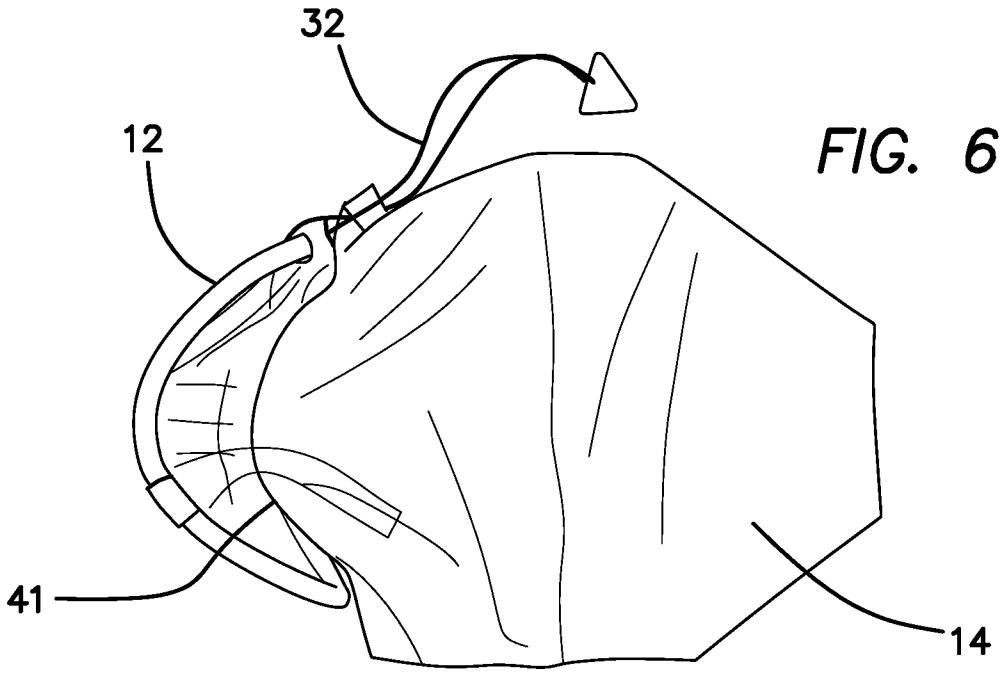


FIG. 6

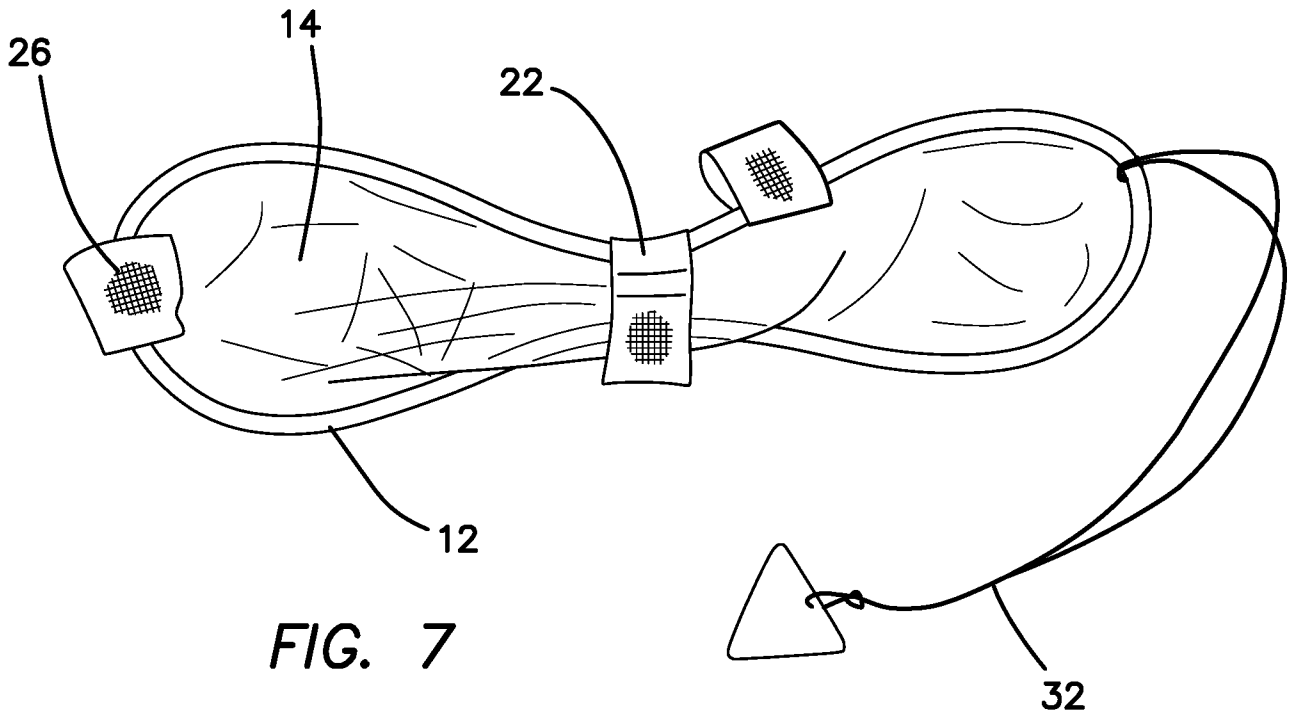


FIG. 7

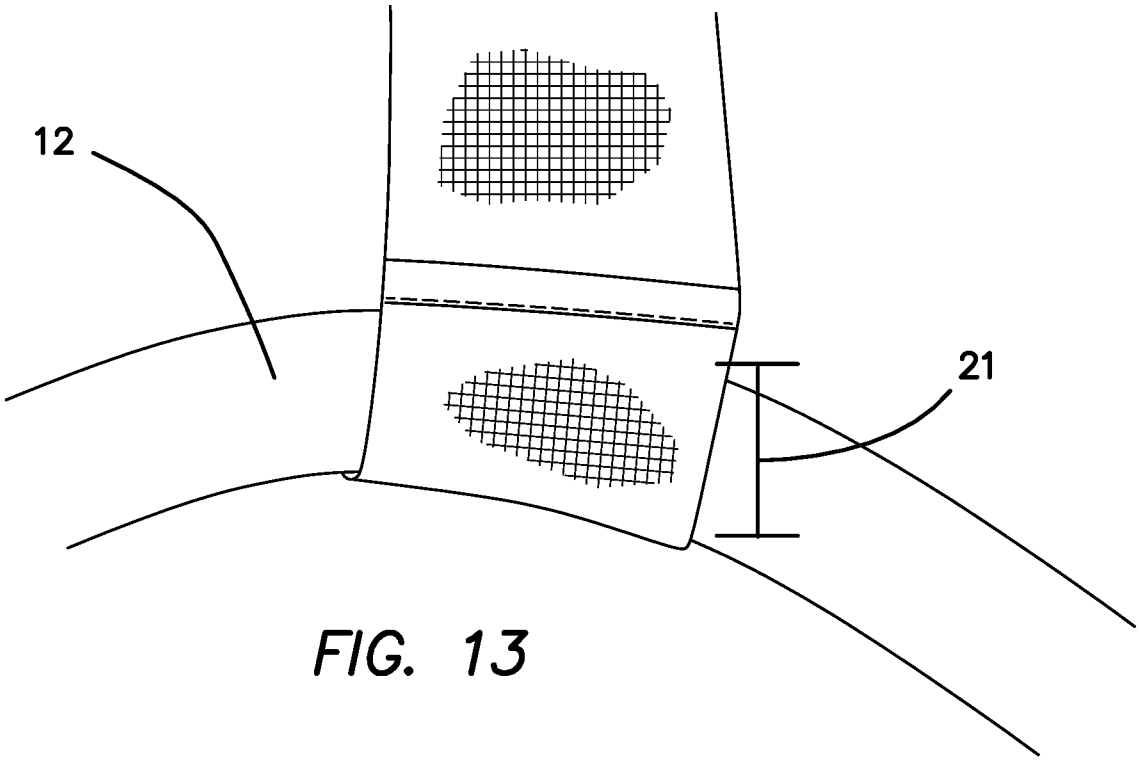


FIG. 13

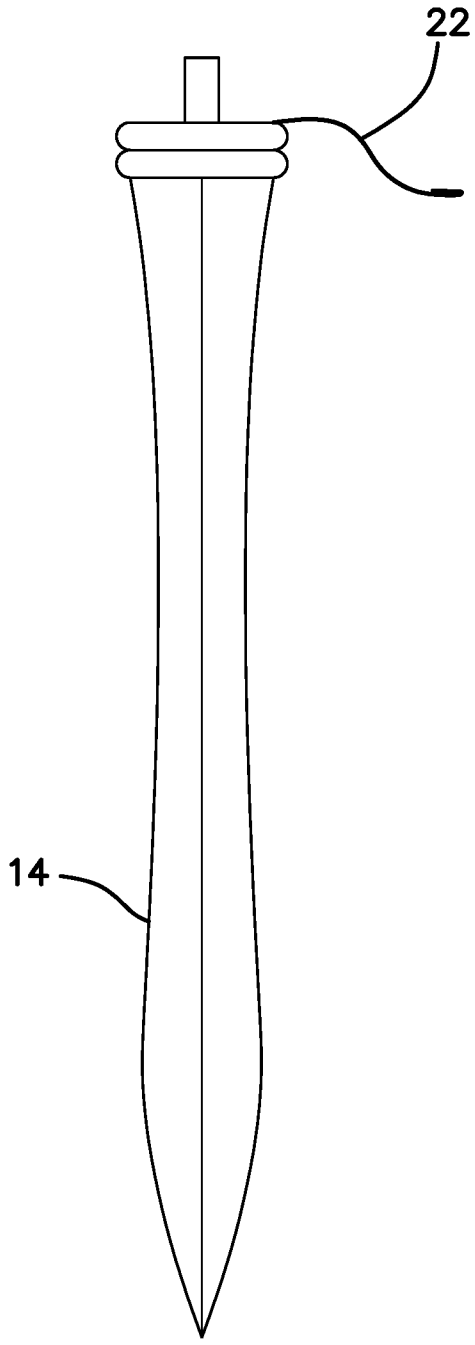


FIG. 8

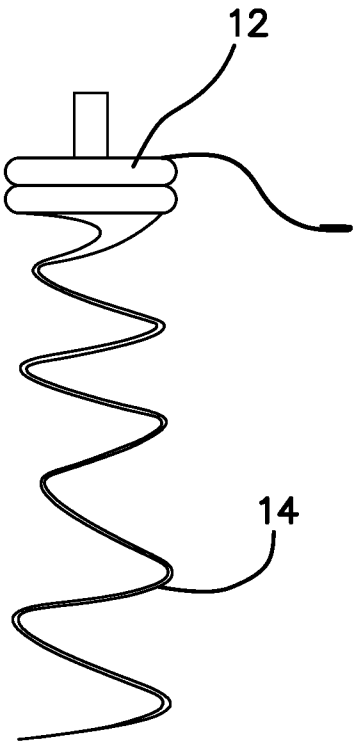


FIG. 9

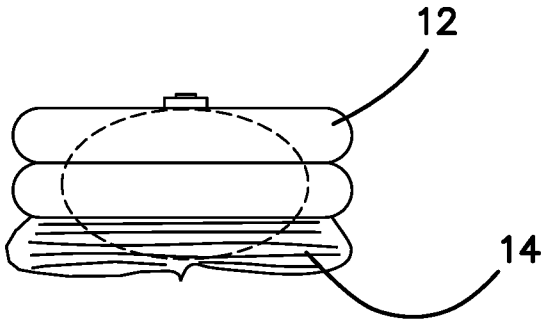


FIG. 10

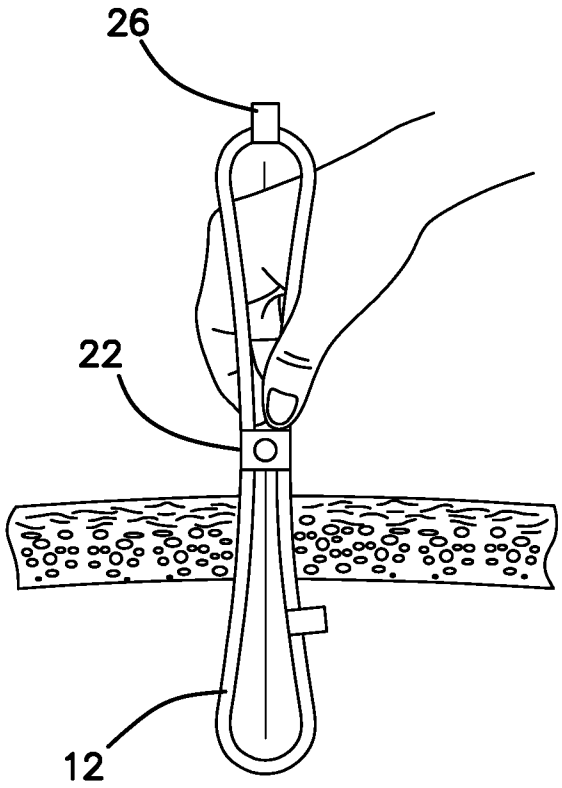


FIG. 11

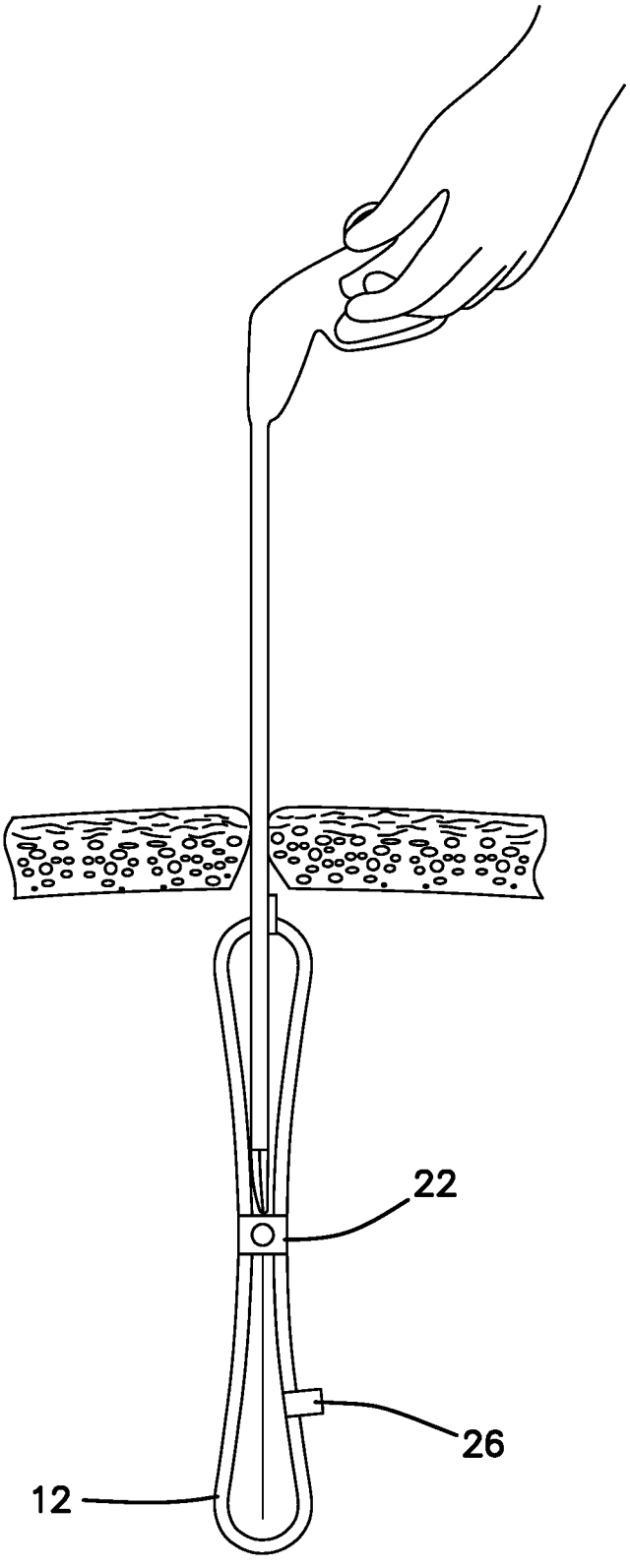


FIG. 12

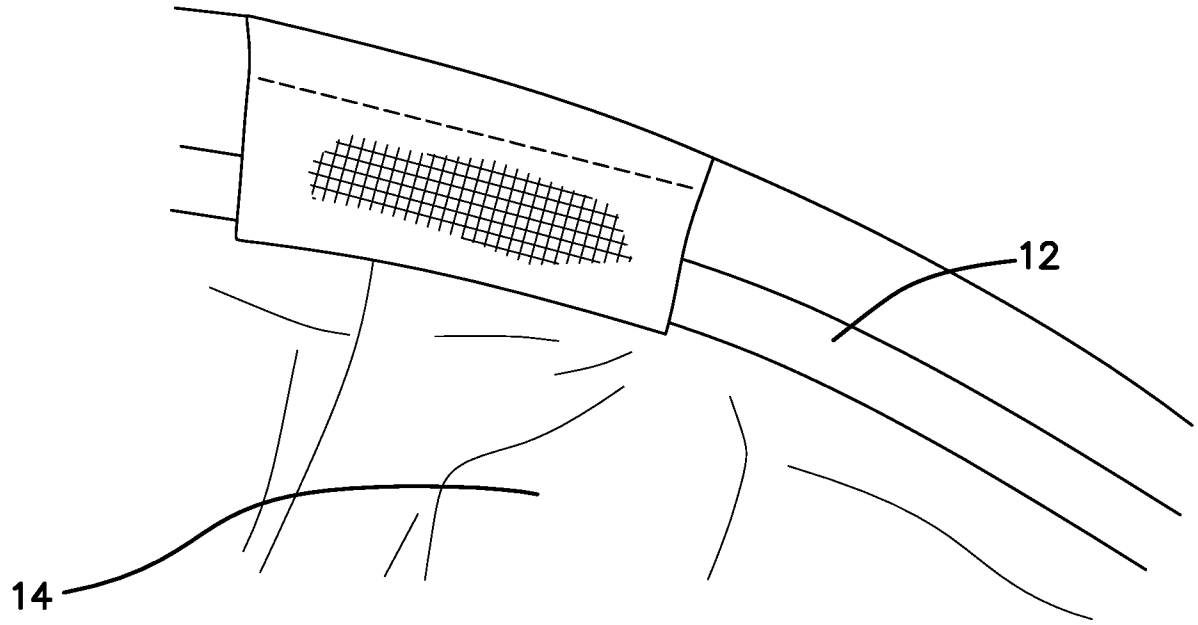


FIG. 14

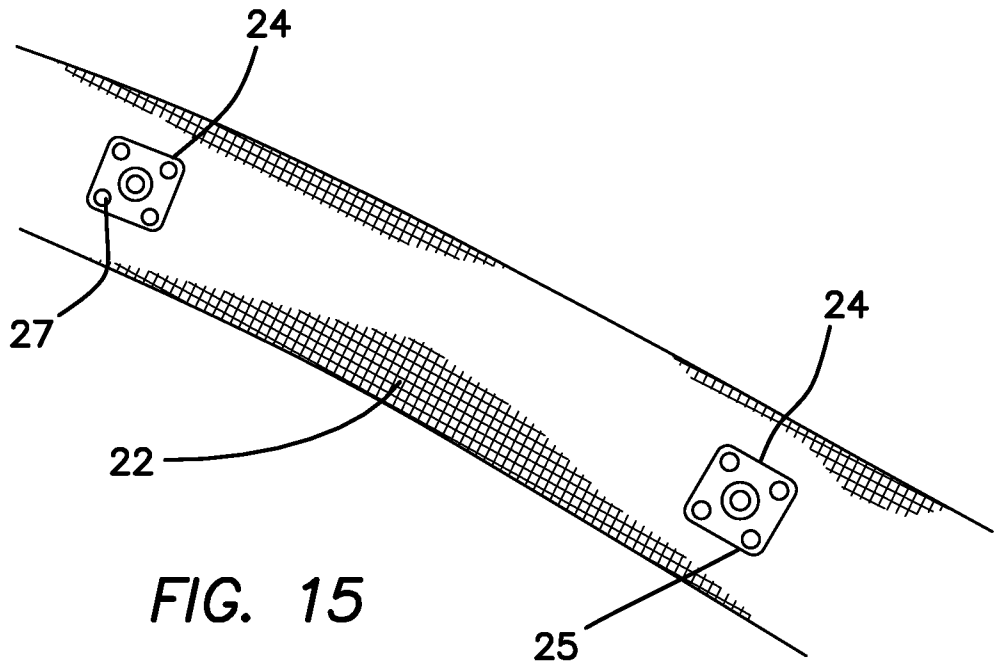


FIG. 15

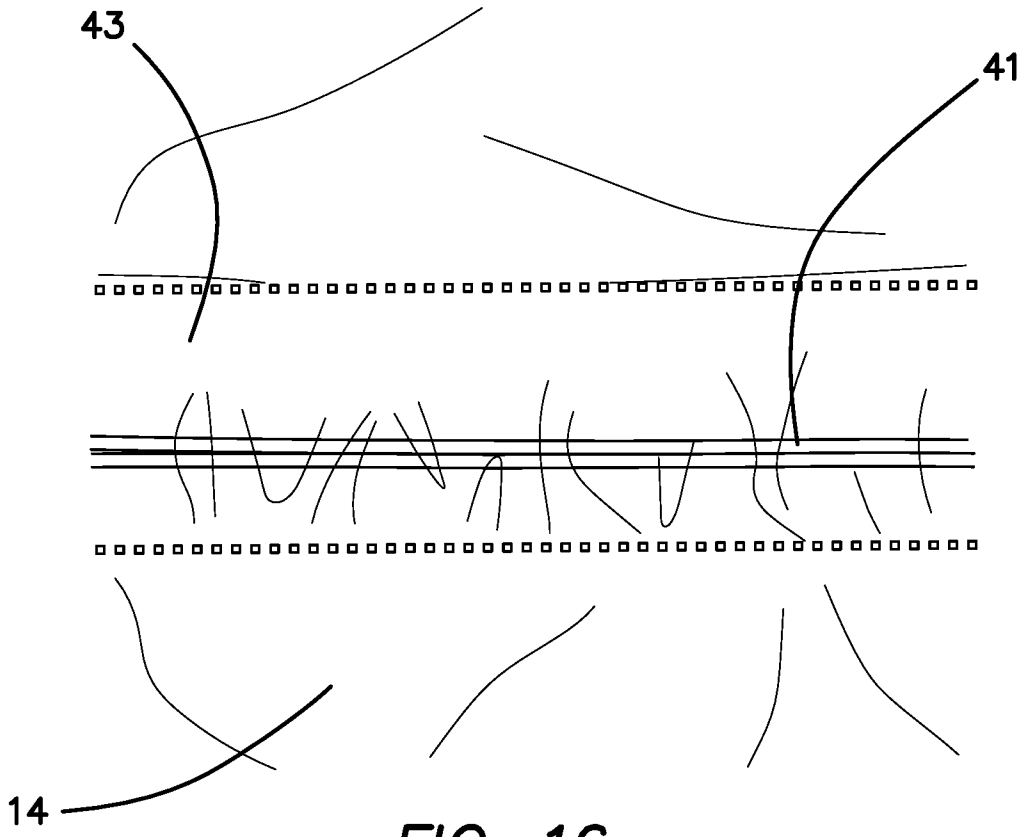


FIG. 16

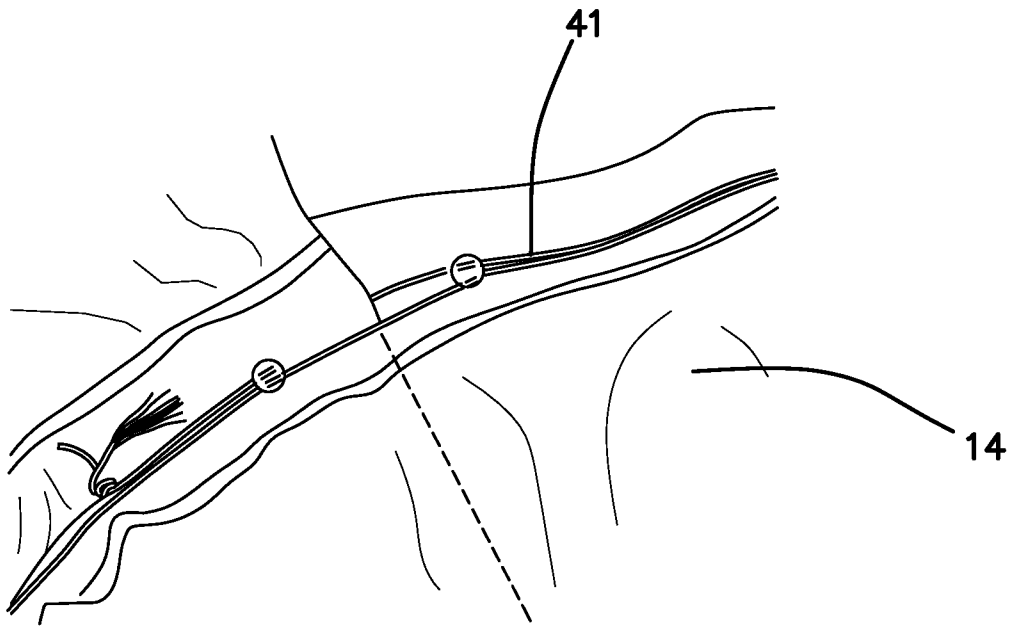


FIG. 17

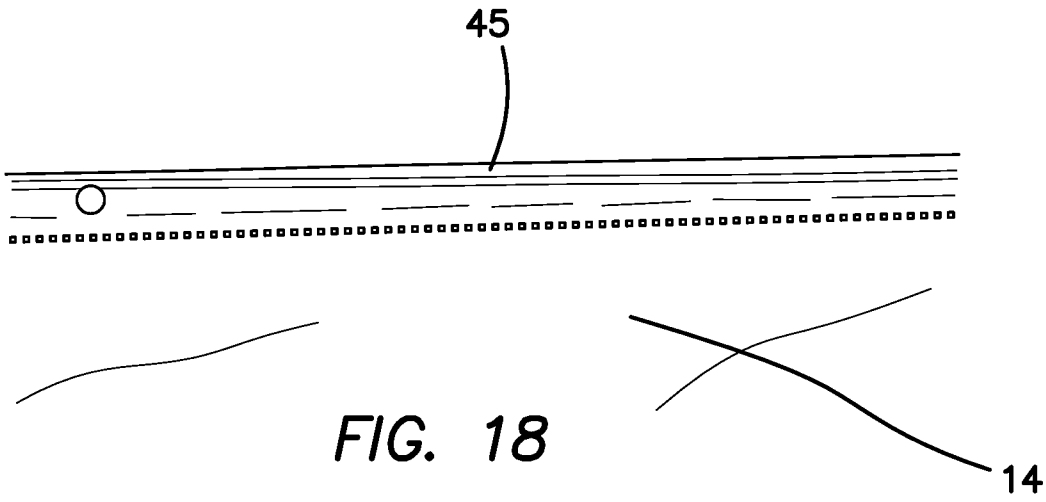


FIG. 18

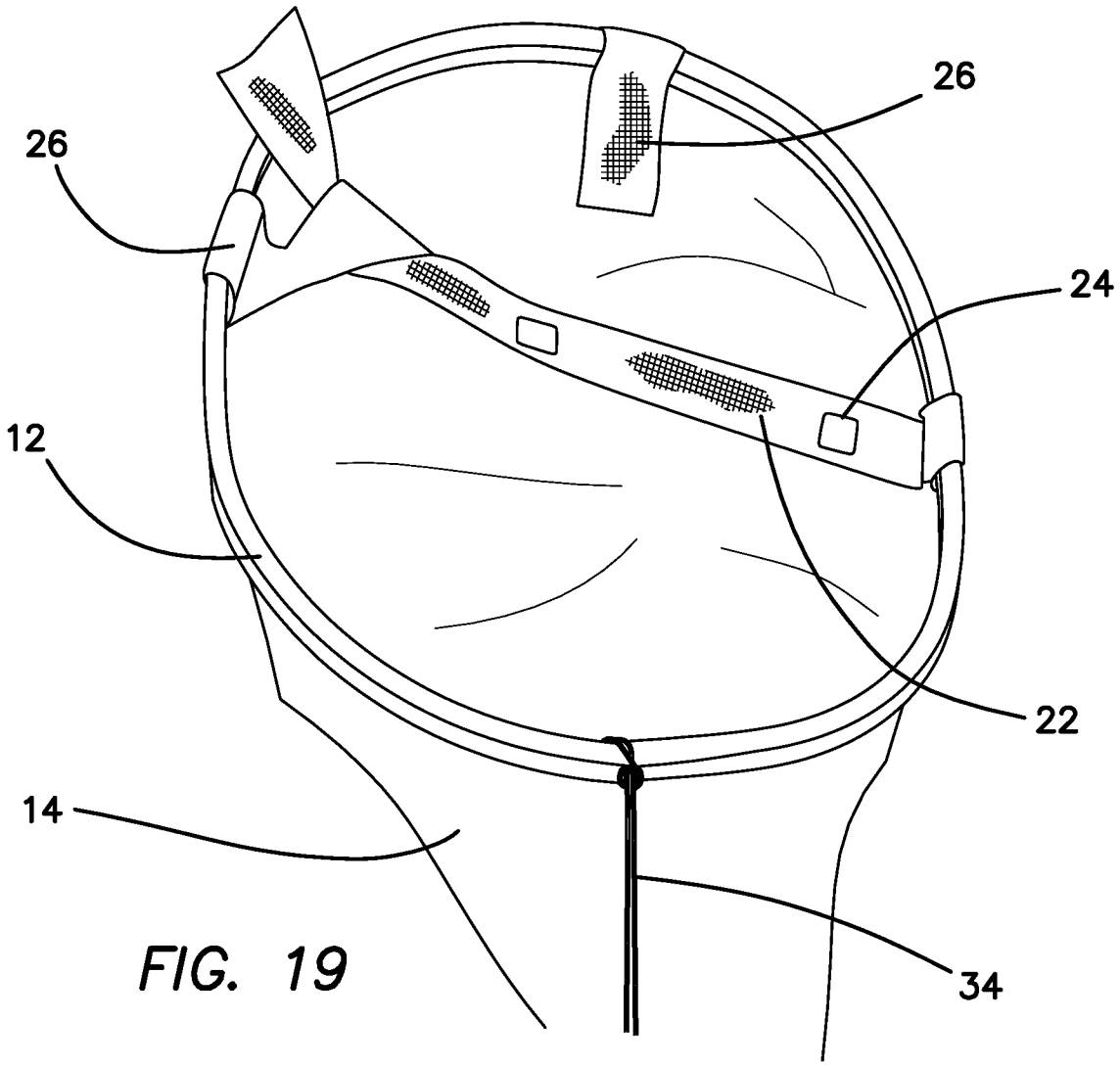


FIG. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/052221

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B90/00 A61B17/00
ADD.

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)
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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/100857 A1 (WACHLI SERENE [US] ET AL) 14 April 2016 (2016-04-14)	1-3,5-7, 32,34, 38-41, 43,44, 49-53
A	figures 44,45 paragraph [0251] paragraph [0253] paragraph [0259] paragraph [0265] - paragraph [0266] paragraph [0272] - paragraph [0275] paragraph [0307] - paragraph [0312] ----- -/--	4,8-26, 37

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
21 February 2020	04/03/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lüddemann, Tobias

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/052221

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/066934 A1 (ANTONELLI JODI A [US] ET AL) 10 March 2016 (2016-03-10)	1-4,6,7, 49-52
A	figures 1-6 paragraph [0043] - paragraph [0045]	5,8-26, 32,34, 37-48, 53-55

X	US 2014/236167 A1 (SHIBLEY KIRK ANTHONY [US] ET AL) 21 August 2014 (2014-08-21)	1,2,4, 12-26, 43,44, 53,54
A	figures 121,70,107-111 paragraph [0203] - paragraph [0204] paragraph [0184] - paragraph [0185]	3,5-11, 32,34, 37-42, 45-52,55

A	US 2017/252026 A1 (GUPTA ARVIND KUMAR [IN] ET AL) 7 September 2017 (2017-09-07) figure 53 paragraph [0100] - paragraph [0102]	1-26,32, 34,37-55

X	WO 2017/189442 A1 (CLARIA MEDICAL INC [US]) 2 November 2017 (2017-11-02)	1,2,8,9
A	figures 6A-C,10A-C paragraph [0081]	3-7, 10-26, 32,34, 37-55

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/052221

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 56-64
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 56-64 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT as they relate to surgical methods (see claim 56 and 57 "insertion into a confined space/patient cavity" and para.22,36). Therefore, these claims have not been searched.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [X] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

1-26, 32, 34, 37-41, 43-55

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7, 49-52

   a tissue containment bag with a ring, film and strap, having the special technical features that the strap is heat sealed to itself to connect the strap to the ring (claim 4), solving the problem of providing an attachment means of the strap to the ring irrespective of the ring material

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2. claims: 8-11, 53-64

   a tissue containment bag with a ring, film and strap, having the special technical features that the strap comprises a connector and receiver as fastener attachment (claim 8) or a method of compressing the containment bag (claim 53), solving the problem of providing a simple and reproducible attachment means for insertion of the bag compared to a knot

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3. claims: 12-26, 32, 34, 37-41, 43-48

   a tissue containment bag with a ring, film and strap, having the special technical features of comprising one or several tabs or a cord or a cinch connected to the ring (claims 12,13,21,23,43) solving the problem of allowing improved removal and manipulation of the bag

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4. claims: 27-31, 35, 36, 42

   a tissue containment bag with a ring, film and strap, having the special technical features that the ring is deformable only in a direction traverse the longitudinal direction (claim 28), solving the problem of improved stability of the ring and thereby for the containment bag

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5. claim: 33

   a tissue containment bag with a ring, film and strap, having the special technical features that the film is made of a plurality of films (claim 33), solving the problem of providing increased protection against accidental punctures of the film by other instruments

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/052221

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