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(71) Applicant *(for all designated States except US)*: **INNOVIA, LLC** [US/US]; 12415 SW 136 Avenue, Unit 3, Miami, FL 33186 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **EDELMAN, David, S.** [US/US]; 10125 SW 71st Avenue, Miami, FL 33156 (US). **PINCHUK, Leonard** [US/US]; 13704 SW 136 Avenue, Miami, FL 33176 (US). **MARTIN, John, B.** [US/US]; 7975 SW 73 Avenue, Miami, FL 33143 (US). **PINCHUK, Bryan, M.** [US/US]; 13704 SW 136 Avenue, Miami, FL 33176 (US). **RAMER, Marc** [US/US]; 1460 Garden Road, Weston, FL 33326 (US).

(74) Agents: **GORDON, David, P.** et al.; Gordon & Jacobson, P.C., 60 Long Ridge Road, Suite 407, Stamford, CT 06902 (US).

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[Continued on next page]

(54) Title: FLEXIBLE DISPOSABLE SURGICAL PORT

(57) Abstract: A surgical apparatus for introduction of laparoscopic instruments into an anatomical cavity through tissue at an entry site. The apparatus includes a body with a frustoconical-shaped wall. The body defines an interior cavity, an open bottom, and a substantially closed top wall with openings from which a plurality of ports extend upward therefrom. The ports are adapted to receive the laparoscopic instruments for introduction through the interior cavity and open bottom of the body into the anatomical cavity. In the preferred embodiment, the frustoconical-shaped wall of the body is placed through an incision in the umbilicus. In one aspect of the invention, the body is a unitary one-piece molded structure. A reinforcing belt or plate formed from a relatively hard material can be integral to the body, and separately formed port caps each having a septum may be bonded to the ports.

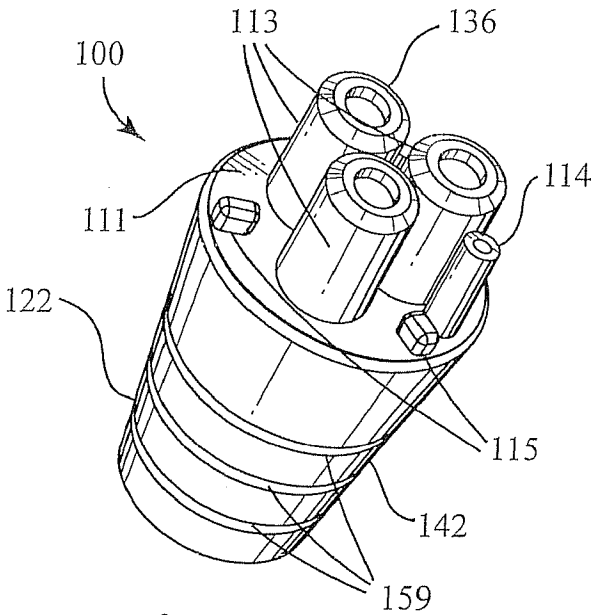

Fig. 1

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FLEXIBLE DISPOSABLE SURGICAL PORT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority benefits from U.S. Provisional Patent Application No. **61/094,706**, filed September 5, 2008, and from U.S. Patent Application No. 12/468,219 filed May 19, 2009, the contents of both of which are hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The invention broadly relates to surgical ports. The invention more particularly relates to surgical ports for abdominal surgery, although it is not limited thereto.

2. State of the Art

[0003] Endoscopic or laparoscopic surgery has existed for over two decades. The surgery usually involves making three small incisions in the abdomen, into which endoscopic surgical tools such as scissors, graspers etc., are introduced through trocar sleeves. Surgical trocars generally include a cylinder with a sharply pointed end and a sleeve around the cylinder. The pointed end of the cylinder is used to make a hole in the abdomen and facilitates entry of the sleeve into the body cavity. When the cylinder is removed from the sleeve, the sleeve provides a port through which instrumentation may be introduced.

[0004] Instrumentation for laparoscopic surgery may include an insufflation means (usually a carbon dioxide source and tubing), a fiber optic light, a forceps (grasper), a scissors, a stapler, a clip applier, a video camera, etc., depending upon the nature of the surgery. The proximal end of the trocar may include one or more valves such as flapper valves or washer valves which are attached to the cylinder for preventing escape of gas (desufflation) from the abdominal cavity as the instrumentation is placed into and removed from the trocar sleeve.

SUMMARY OF THE INVENTION

[0005] The present invention provides a flexible surgical port device which can be placed through an incision in the belly button (umbilicus). The device of the invention incorporates three or more ports in the device so that laparoscopic surgery requiring three ports can be conducted through the device without the necessity of making additional incisions in the abdomen.

[0006] According to an aspect of the invention, a molded flexible elastic disposable port includes a hollow generally frustoconical body having an open bottom and a generally closed top defining at least three and preferably four port holes, and at least three and preferably four ports integral with the body, including three ports with valves for receiving surgical instruments, and one for receiving an insufflation source extending upwards from the top which are in fluid communication with the port holes. In use, a plurality of endoscopic instruments are passed through the ports and through the central cavity defined by the frustoconical body into the abdominal cavity to allow for manipulation of the instruments inside the abdominal cavity.

[0007] According to one aspect of the invention, the flexible disposable port is a single piece which is molded from an elastic material, and valves are formed in the elastic material.

[0008] According to another aspect of the invention, the flexible disposable port is an insert molded piece formed of an elastic molded material and having a belt or plate formed from a relatively hard material inserted therein, where the valves are formed in the molded elastic material.

[0009] According to an additional aspect of the invention, the flexible disposable port is a molded piece having a hollow generally frustoconical body having an open bottom and a generally closed top defining at least three and preferably four port holes and at least three and preferably four ports integral with the body, and a cap which adheres to the ports and provides septa through which endoscopic instruments are passed.

[0010] According to a further aspect of the invention, the flexible disposable port formed of an elastic molded material is provided with a compression band around each septum to impart a continuous radial compressive force on the septum.

[0011] According to yet a further aspect of the invention, the flexible disposable port including the port valves is molded from a material having a Shore Hardness of between 30A and 65A, a tensile strength of greater than 3MPa, a tear strength of greater than 20 KN/m, and an elongation percentage at break of greater than 600%.

[0012] It will be appreciated that the umbilicus is a unique structure as a large incision can actually be hidden in it as it is already just a big scar. In addition, it stretches more than most tissue. For example, one can make a 15mm incision in the umbilicus and stretch the opening to approximately 30mm. The fascia underneath the umbilicus may be more tense than the umbilicus tissue. However, the fascia can be cut to allow a larger opening without concern of a visible cosmetic scar.

[0013] Objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Fig. 1 is perspective view of a first embodiment of a flexible port device in accordance with the present invention.

[0015] Fig. 2 is a top view of the device of Fig. 1.

[0016] Fig. 3 is a bottom view of the device of Fig. 1.

[0017] Fig. 4 is an enlarged view of the suture catch of the device of Fig. 1.

[0018] Fig. 5 is a perspective view of a second embodiment of a flexible port device in accordance with the present invention.

[0019] Fig. 6 is a top view of the device of Fig. 5.

[0020] Fig. 7 is a bottom view of the device of Fig. 5.

[0021] Fig. 8 is a sectional view through the device of Fig. 5 along line 8-8 of Fig. 6.

[0022] Fig. 9 is a perspective view of a third embodiment of a flexible port device in accordance with the present invention.

[0023] Fig. 10 is sectional view of the device of Fig. 9.

[0024] Fig. 11 is a perspective view of a fourth embodiment of a flexible port device in accordance with the present invention.

[0025] Fig. 12 is a side view of the device of Fig. 11.

[0026] Fig. 13 is a top view of the device of Fig. 11.

[0027] Fig. 14 is a bottom view of the device of Fig. 11.

[0028] Fig. 15 is a perspective view of a plate molded into the device of Fig. 11.

[0029] Fig. 16 is a two-dimensional cross-sectional view of the device of Fig. 11 along line B-B shown in Fig. 13.

[0030] Fig. 17 is a three-dimensional cross-sectional view of the device of Fig. 11 along line C-C shown in Fig. 13.

[0031] Fig. 18 is a perspective view of a fifth embodiment of a flexible port device in accordance with the present invention.

[0032] Fig. 19 is a cut off cross-sectional view of the device of Fig. 18.

[0033] Fig. 20 is a perspective view of the device of Fig. 5 shown sutured in place in an abdomen with tools extending through two of the ports.

[0034] Fig. 21 is a graph comparing the sliding force required for a laparoscopic instrument through lubricated and non-lubricated SIBS valves.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0035] A first embodiment of a flexible disposable port 100 in accordance with the present invention is shown in Figures 1-4. The port 100 is formed of a single molded piece of flexible material and includes a flexible top wall 111 having three working ports 113, an insufflation port 114 (for insufflation/desufflation) and suture retention means 115 integral therewith and extending outwardly therefrom, and a hollow frustoconical body 122 which is open at the bottom and is closed by the flexible top wall 111.

[0036] The working ports 113 each have an inner diameter of approximately 7mm, although ports of different diameters can be utilized. As will be discussed hereinafter, the working ports are provided with seals or valves which are designed to seal about nominally 5mm laparoscopic tools. The inner diameter of the insufflation port 114 is approximately 3-5mm, and insufflation port 114 is adapted to receive a tube (not shown) which is coupled to a source of gas

[0037] As seen best in Fig. 2, three suture retention means 115 are provided and are spaced at one hundred twenty degree intervals, although a different number of suture retention means may be utilized and/or different spacings could be used. As seen in Figure 4, each of the suture retention means 115 defines a slot 128 at its base. The slot is provided such that a suture may be snagged in the slot between the top wall 111 and the suture retention means 115.

[0038] Each of the working ports 113 can be fitted with a valve to prevent pressure loss when an instrument is removed from the port. In the illustrated embodiment, the entrance to the working ports 113 are fitted with a flexible O-shaped seal 136, which is preferably realized as a thin stretchable membrane having an open circular hole (approximately 4mm in diameter) in its center as shown in Figures 1 - 3. The O-seal 136 is preferably molded as part of the port 100 and configured to seal against an instrument passing therethrough during use. The O-seal 136 may be used in conjunction with a flapper valve (not shown) as is known in the trocar arts. Alternatively, if desired, the valve may be formed as part of the molded port 100 by causing the top of each port 113 to be closed, and then by slitting the top to generate a slit valve (e.g., an X, Y, I or arcuate slit). As another alternative, a tricuspid valve or a duck-bill valve may be formed as part of the mold or may be separately provided and fit to the ports as is well known in the industry. In yet another alternative embodiment, little plugs which can fit into the ports 113 and having associated arms (not shown) attached to top wall 111 can be molded as part of the port 100 and can be used to close ports 113 when tools are not extending through the ports 113.

[0039] As shown in Figure 3, the hollow frustoconical body 122 extends distally from the perimeter of the top wall 111 and is configured for insertion into a single incision in the umbilicus. The frustoconical body 122 has a tapered sidewall 142 which defines a central cavity 152 with an opening 153 opposite the top wall 111. In the shown embodiment, the tapered sidewall 142 includes circumferential grooves or dents 159 which are spaced apart along the exterior surface of the tapered sidewall 142. The grooves 159 can assist a surgeon in

cutting or otherwise trimming the tapered sidewall 142 to a desired length with a scissors or sharp scalpel if so desired.

[0040] Figures 5-8 show an alternate embodiment of a port device 200. In the alternate embodiment of Figures 5-8, like numerals (increased by 100) are used to refer to the structural elements that are similar to those of the embodiment described above with respect to Figures 1-4. In this embodiment, the working ports 213 of port 200 have different diameters. For example, as shown, the working port 213A is larger in diameter than the working ports 213B and 213C. In the preferred embodiment, port 213A is approximately 12mm in diameter to accept a 10mm-12mm diameter stapler, clip applier, or other nominally 10mm tools, while ports 213B and 213C are 7mm in diameter for smaller (5mm diameter or smaller) instruments such as scissors and graspers. Each of the working ports 213A, 213B, 213C is shown molded with a membrane 217 which can be slit to form a slit valve (e.g., an X or Y slit) or may be left as a blank and punctured by instrumentation at the time of use. Alternatively, each port may be molded with a tricuspid or duck-bill valve, or the O-shaped seal having an open circular hole in its center as shown in the first embodiment. As another alternative, each port may be fitted with a valve (not shown) to prevent pressure loss (desufflation) when an instrument is removed from the port.

[0041] The port 200 also preferably includes a plurality of suture retention means 225 (for example, two shown) disposed about the periphery of the top wall 211. The suture retention means 225 comprises a tab or ear that extends radially outward beyond the perimeter of the top wall 211 (preferably in or substantially parallel to the plane of the top wall as shown). The tab defines slots 229 that preferably extend parallel to the central axis 216 of the port 200. The slots 229 are disposed radially outward from the perimeter of the top wall 211 and tapered sidewall 222 of body as best shown in Figures 6 and 7. The slots 229 are adapted to grab or otherwise hold sutures inserted therein for fixation of the port 200 during use.

[0042] Figures 9 and 10 show an alternate embodiment of a port device 300. In the alternate embodiment of Figures 9 and 10, like numerals (increased by 200) are used to refer to the structural elements that are similar to those of the embodiment described above with respect to Figures 1-4. In the embodiment of Figures 9 and 10, a suture plate 370 has a circular portion 371 which is fitted over top wall 311 of the port device 300. The plate 370 has holes to accommodate the working ports 313A, 313B, 313C, and the insufflation port 314. The plate

370 also includes suture ears 326 which extend outwardly from the circular portion 371 and are connected to the circular portion 371 by a neck portion 372. The suture ears 326, necks 372, and circular portion 371 define suture grooves 327 which receive sutures for suturing the device 300 to tissue adjacent the entrance site. The suture plate 370 can be made substantially rigid when formed from a metal, polyoxymethylene such as Delrin, polycarbonate, polyurethane, acrylics, acrylates, poly(acrylonitrile-butadiene-styrene) which is commonly referred to as ABS, etc. Suture plate 370 can be adhered to surface 311 or held in place by mechanical locking means (not shown). When substantially rigid, the suture plate 370 will not bend or stretch much when held down with sutures. Alternatively, the suture plate 370 can be made more flexible when formed from a more flexible material.

[0043] The port device 300 of Figure 9 includes a reinforcement belt 380 (Figure 10) placed in the upper section of the flexible tapered wall 342 so as to reinforce the wall 342 to maintain it round when inserted into the umbilicus. The length of the reinforcement belt 380 can be 5% to 33% of the axial length of the tapered wall 342. The thickness of the belt 380 is preferably between 0.5mm and 1.5mm. The belt 380 can be insert-molded in place or placed in the taper after completion of the device 300. It can also be glued in place. It can also be appreciated that the thickness of the tapered frustoconical wall of any of the embodiments can be made thicker in the proximal area to accomplish the same reinforcement purpose. Ribs, both circumferential and longitudinal can be incorporated to function similarly.

[0044] Figures 11-17 show yet another embodiment of a port device 400. In the alternate embodiment of Figures 11-17, like numerals (increased by 300) are used to refer to the structural elements that are similar to those of the embodiment described above with respect to Figures 1-4. In this embodiment, the working ports 413 of port 400 have the same inner diameter (for example, 7mm in diameter for smaller 5mm diameter instruments such as scissors and graspers). Each of the working ports 413 is shown molded with a membrane 417 which can be slit to form a slit valve (e.g., an X or Y slit) or may be left as a blank and punctured by instrumentation at the time of use. Alternatively, each port may be molded with a tricuspid or duck-bill valve, or the O-shaped seal having an open circular hole in its center as shown in the first embodiment. As another alternative, each port may be fitted with a valve (not shown) to prevent pressure loss (desufflation) when an instrument is removed from the port.

[0045] The port 400 also preferably includes a reinforcement plate 480 (Figure 15) formed as part of the top wall 411 of the frustoconical body 422 as best shown in Figures 16 and 17. The reinforcement plate 480 reinforces the tapered wall 442 of the body 422 to maintain it round when inserted into the umbilicus. In the preferred embodiment, the plate 480 is realized of a moldable or thermoformable polymeric material such as polycarbonate, stiff polyurethanes, metal, polymethylmethacrylate (Plexiglas®), polyacetal (Delrin®), ABS, acrylics or other suitable material. The plate 480 is preferably insert molded in place or otherwise placed in position adjacent the top wall 411 of the body 422 of the device 400. When insert molded, the material of the plate 480 is required to withstand the heat and pressure of the injection molding of the frustoconical body 422. The reinforcement plate 480 includes a first set of through-holes 470 that are aligned to corresponding ports 413 and sized to accommodate the tool(s) inserted through the respective corresponding port 413 and through-hole 470. In the preferred embodiment, the through-holes 470 are oversized relative to the diameter of the corresponding port 413, and during insert molding, the material that forms the top wall 411 and ports 413 form a central opening inside the oversized through-hole 470. This central opening matches (and is aligned to) the inside diameter of the corresponding port molded thereabove. Also note that the plate 480 is preferably held in place under and adjacent to the top wall 411 of the body 422 by a ledge 481 formed in the interior surface of the tapered sidewall 442 as shown in Figure 17. Moreover, the material that is molded to form the top wall 411, sidewall 422 and ports 413 of the device 400 may be allowed to encapsulate the plate 480 by a thin layer 482 as shown in Figure 17. The reinforcement plate 480 operates a pivot point about which to pivot the respective tool passing therethrough. The reinforcement plate 480 also preferably includes a through-hole 473 aligned with the insufflation port 414 to allow for gas to pass between the insufflation port 414 and the interior cavity 452 of the body 422. The plate 480 also preferably includes a second set of through-holes 474 that allows for inflow of material therein during insert molding to join the plate 480 to the top wall 411 of the body 422. The thickness of the plate 480 is preferably between 0.05in and 0.25in, and most preferably approximately .125in. ± 20%.

[0046] The plate 480 also has a plurality of suture ears 426 (for example, two shown) which extend outwardly from the circular portion 471 and are connected to the circular portion 471 by a neck portion 472. The suture ears 426, necks 472, and circular portion 471 define suture grooves 427 (Figure 15) which receive sutures. The suture ears 426 will not bend or stretch

much when held down with sutures. The suture ears 426 extend radially outward beyond the periphery of the top wall 411 of the body 422 such that suture grooves 427 are disposed about the periphery of the top wall 411 of the body. The suture grooves 427 are adapted to grab or otherwise hold sutures inserted therein for fixation of the port 400 during use. In the illustrative embodiment shown in Figure 15, the plate 480 has two suture ears 426 that are disposed diametrically apart. During use, the ears 426 are sutured to the incision and the ears 426 joined through the plate 480 act as a rigid axle that allows the port 480 to rock back and forth in the incision. This freedom of movement allows for greater control of the surgical tools.

[0047] Figures 18 and 19 show a presently preferred embodiment of a port device 500. In the embodiment of Figures 18 and 19, like numerals (increased by 100) are used to refer to the structural elements that are similar to those of the embodiment described above with respect to Figures 11-17. The port device 500 is substantially identical to port device 400 except for the construction of the working ports 513 (and optionally the insufflation port 514). Thus, a reinforcement plate 580 identical to plate 480 is provided under the top wall 511, with the reinforcement plate 580 having ears 526 extending outwardly therefrom, and the body 522 with sidewall 542 and bottom opening 553 is identical. As a result, for purposes of brevity, all of the details of those aspects of the port device need not be repeated. However, the working ports 513 of port device 500 are constructed differently from the working ports 413 of port device 400. In particular, as seen in Figs. 18 and 19, extending from top wall 511 (shown in Figure 18 and not shown in Figure 19) are working port bases 584 which have a base section 584a adjacent top wall 511 having a first thickness and step down to a much narrower thickness for an upper section 584b. Extending around the upper section 584b is a cap 585 having a top septum 586 and a cylindrical wall 587 extending downward therefrom, and a base section 588. The cap 585 with the septum 586 is preferably a one piece compression molded element. The top of septum 586 defines a central well 586a. As seen in Fig. 19, the septum 586 is also slit (from the bottom up) so that the slit 586b extends entirely through the septum in the central well area (slit 586b being shown as visible from the top in Fig. 18) but does not extend entirely through the septum beyond the central well area. In this manner, the septum will seal around a tool shaft when a tool is inserted through the slit and well 586a of the septum 586.

[0048] The cap 585 of the working port 513 is bonded to the working port base 584 by bonding the cap to upper section 584b. As shown in Fig. 19, a bonding agent 589 is provided in a gap 590 between the upper section 584b of base 584 and the cylindrical wall 587 of the cap

585, with the inside face of the base section 588 of the cap in close proximity to the upper section 584b. A heat shrink tubing 591 is optionally provided and shrunk down over the cylindrical wall 587 of the cap and over the base section 584a of the base working port base 584 in order to cover any adhesive that may have extruded out from the gap 590 past the base section 588 of the cap. Heat shrink tubing can also provide some integrity to the port.

[0049] Working port 513 is also provided with a compression band 594 which extends around the septum 586. The compression band 594 is preferably adhered under tension to the septum 586 such that it imparts a continuous radial compressive force on the septum denoted by arrows A, thereby keeping the septum closed when the endoscopic tool is removed from the port. The compression band 594 provides a closing force on the septum which also prevents leakage from around the tool when the tool traverses the septum.

[0050] The ports 100, 200, 300, 400, 500 of the embodiments as described herein have sidewalls which are frustoconical in shape. The sidewall (142, 242, 342, 442, 542) of the respective port device as described herein preferably has a major outside diameter (measured at or near the perimeter of the top wall) in a range between 30-45mm (most preferably 35-40mm) and tapers in diameter to a minor outside diameter (measured at or near the distal opening 153, 253, 353, 453, 553) in a range between 10-20mm (most preferably 15 to 18mm). The length of the sidewall (142, 242, 342, 442, 542) as measured from the center axis of the top wall to the center of the distal opening preferably has a range from 40 to 60mm; however, it can be cut to length *in situ* by the surgeon, preferably at grooves 159, 259. Such configurations provide a slope angle α of the sidewall (142, 242, 342, 442, 542) in a range between 5° and 20°, preferably 8° - 12° (a 16° angle being shown in Figure 8). The wall thickness of the sidewall is sufficiently thick so that the wall will not readily buckle when placed in the umbilicus and when dilating the incision, yet sufficiently flexible to allow distortion when an instrument is forced against it. The sidewall (142, 242, 342, 442, 542) is not meant to hug the instrumentation nor provide a seal against the instrumentation. Typical wall thicknesses are 0.5mm to 3mm; preferably, 1mm to 2mm. If desired, the sidewall (142, 242, 342, 442, 542) may be tapered in wall thickness with the sidewall adjacent the top wall having a relatively larger thickness (e.g., 2mm), and the sidewall near the distal opening being relatively thinner (e.g., 1mm in thickness). Also, as shown in Figs. 5, 8 and 10, if desired, the sidewall at the distal opening can taper sharply (shown as 222a) down to a minimal thickness. With the frustoconical sidewall being tapered in thickness, the portion of the sidewall which is subject to the most compressive force

in the umbilicus will not easily buckle, and at the same time, as suggested by Figure 20, the distal portion of the sidewall will be more flexible to permit a wider freedom of movement to the laparoscopic tools 264, 265 extending through the working ports of the port device. Further, as shown in Figures 5 to 8, when larger diameter ports are used, the overall dimensions of the major outer diameter can be increased 10% to 20% to fit these oversized ports. Similarly, in order to retain the same slope angle of the sidewall, the length of the device can be increased proportionally. Still further, for pediatric applications, the entire device may be reduced by approximately 50% in all dimensions. For example, the ports may be sized to accommodate 3 mm tools.

[0051] The port device 100, 200 as described herein can be made as a single injection molded piece in an injection or compression molding machine. As such, it is relatively inexpensive to make and is therefore disposable. Similarly, port devices 300, 400 and 500 which include reinforcement plate and/or belts can be simply formed through insert molding with the mold formed over the reinforcement plates or belts. In the case of port device 500, the cap is separately molded and then attached by bonding agent. Likewise, the heat shrink tubing and the compression band are separately formed and attached to the port device.

[0052] The ports of the present invention function as follows: First, an incision 10-25 mm wide is made in the umbilicus or elsewhere in the body using the Hassan procedure. If entered into the abdominal cavity, the incision is continued through the fascia of the abdomen wall into the abdominal cavity. The narrow end of the tapered sidewall (142, 242, 342, 442, 542) of the device is inserted into the incision and forced downward such that the incision is stretched sufficiently by the tapered sidewall to engage the tissue and provide a seal between the tissue and the tapered sidewall. If desired, the top wall of the port and working ports can remain above the skin, or if desired, for example for obese patients, the entire device can be inserted below the skin with the seal formed in the fascia of the abdominal wall. The working ports, central cavity and opening opposite the top wall of the port provide a passageway for three laparoscopic instruments (which have approximately 5mm or 10mm or greater cannulas) to be inserted into the abdominal cavity. In addition, the insufflation port provides a means by which the abdominal cavity may be inflated. The port device may be sutured in place if desired. An operation may then be conducted through the working ports. Upon conclusion of the operation, and if for example the operation involved removal of an organ (e.g., infected gall bladder), the organ can be pulled into the hollow frustoconical structure, the sutures removed from the ears

and the entire port with the organ housed in the hollow structure removed. In this manner the organ does not touch the fascia or epidermis, which may otherwise result in infection of the incision site. Once the port is removed, the sutures can be further used to close the incision in any manner known in the art. Alternatively, the port may be removed from the incision, the organ removed sequentially and the incision closed in any manner known in the art.

[0053] Figure 20 shows the flexible disposable port 200 of Figures 5-8 placed in an incision in the umbilicus, comprised of epidermis 61 and fascia 62. The tapered (frustoconical) sidewall 242 of the port 200 both seals the incision in the umbilicus such that gas used to inflate the abdominal cavity does not leak between the umbilicus and taper, and dilates the opening to allow a larger working area. If the surgeon so desires, the tapered sidewall 242 can be cut with a scissors or blade at the circumferential rings 259 (Figure 7) to shorten the tapered sidewall 242 and to provide a wider area of unrestricted movement of the instruments. Instruments 264 and 265 are pierced through membranes 217 that cover the entrance to the working ports 213B and 213A, respectively. The instruments 264, 265 pass through the working ports 213B, 213A and transcend the central cavity 252 defined by the tapered sidewall 242 and exit through the distal opening 253 into the abdominal space 72. Note that the flexible tapered sidewall 242 is deformable about its distal portion to enable maneuvering of the instrumentation 264 and 265 over a broader area. The port 200 is held firmly in place by sutures 70 snagged into the slots 229 (Figure 6) of the suture retention means 225 and sewn into the adjacent tissue. Note that relatively large organs can be removed from the abdominal space 72 when the port 200 is removed from the umbilicus entrance site following completion of surgery. For example, a 30mm diameter gall bladder may be removed from the umbilicus incision. Larger organs can be cut or morsellated and then removed through the opening. It should be appreciated that surgery through the umbilicus is less painful than surgery through other parts of the abdomen as there are fewer pain receptors as well as less muscle to cut through. Accordingly it also heals faster with less chance of complication.

[0054] Other features can be added to the flexible surgical port device. For example, the flexible surgical port device can include a built-in light on the inside of the device to illuminate the cavity. Luer fittings can be added to the ports; especially the insufflation port. In addition, the flexible nature of each individual working port allows each working port to be clamped with a hemostat to prevent deflation of the abdominal cavity if necessary. If required, each working port can be fitted with a tethered stopper to enable plugging the working port when not in use.

Further the working ports can be fabricated as bellows to facilitate movement of the instruments and port stems. While the working ports 113, 213, 313, 413, 513 have heights (lengths) of preferably between 8 and 12mm, it will be appreciated that the working ports may be extended to be even longer to prevent interference of the laparoscopic tools. Alternatively, the ports can shorter or can be flush with the top wall of the device. In addition, the entire upper part of the device, can be made from a material different from the frustoconical section and attached to the plate 480 by mechanical means of by chemical adhesives and the like. The device can also have attachment means on the port entrances to allow attachment of caps that contain valves or blanks. Still further, a section of material 441 (Figure 17) in the center of the plate between the working channels 413, can be removed to expose the plate 480. If a clear material, such as polycarbonate, is used to form the plate 480, then removing the material enables a clear window to be formed through the top of the port to enable direct visualization of the abdominal cavity.

[0055] The flexible disposable port devices described herein can be made from any flexible elastomeric material, for example, silicone rubber, polyurethane, polyolefin (such as SIBS, SEBS, butyl rubber, polyisoprene, polybutadiene, etc.), polyvinylchloride, natural rubber, blends of two or more of listed material, and the like. SIBS is a block copolymer of styrene-*block*-isobutylene-*block*-styrene. SEBS is a block copolymer of styrene-*block*-ethylene-butylene-*block*-styrene.

[0056] The flexible elastomeric material preferably has a Durometer less than Shore 80A and greater than Shore 20A, and most preferably in a range between Shore 65A and Shore 30A; preferably Shore 45A. The flexible elastomeric material also preferably has a modulus of elasticity at 100% elongation (referred to herein as "Modulus@100%" greater than 0.5Mpa and less than 2MPa such that port device seals around umbilical entrance site and the laparoscopic tools inserted therethrough as well as provide for innocuous operation of the tool when it touches the distal end of the tapered sidewall (Figure 18). If the Modulus@100% is less than 0.5Mpa, the tapered sidewall would buckle in the umbilical entrance site. If the Modulus@100% is greater than 2Mpa, the ports of the device will not easily and quickly seal around the tool(s) inserted therethrough. The flexible elastomeric material also preferably has a tensile strength of greater than 3MPa, a percent of elongation at break greater than 600%, and a tear strength greater than 20kN/m so as not to tear after prolonged use in the body.

[0057] In the embodiments of Figs. 1-4 and Figs. 5-9, it is preferable that the entire device be made from one polymer and as one piece, either by injection molding or compression molding. A filler (such as titanium dioxide) can be added to the elastomeric material as needed to dictate the color and transparency of the device.

[0058] In one embodiment, the flexible disposable port devices described herein are made from SIBS. SIBS is realized from a triblock of polyisobutylene and polystyrene (a block copolymer of poly(styrene-*block*-isobutylene-*block*-styrene)). Polyisobutylene (PIB) is a soft elastomeric material with a Shore hardness of approximately 10A to 30A. When copolymerized with polystyrene, it can be made at hardnesses ranging up to that of polystyrene having a Shore hardness of 100D. Thus, depending on the relative amounts of polystyrene and polyisobutylene, the SIBS material can have a range of hardnesses from as soft as Shore 10A to as hard as Shore 100D. In this manner, the SIBS material can be adapted to have elastomeric and hardness qualities desirable for the flexible port devices as described herein. Details of the SIBS material is set forth in U.S. Patent Nos. 5,741,331; 6,102,939; 6,197,240; 6,545,097, which are hereby incorporated by reference in their entireties. The SIBS material may be polymerized in a controlled manner using carbocationic polymerization techniques such as those described in U.S. Patent Nos. 4,276,394; 4,316,973; 4,342,849; 4,910,321; 4,929,683; 4,946,899; 5,066,730; 5,122,572; and Re 34,640, each herein incorporated by reference in their entireties. The amount of styrene in the copolymer material is preferably between 10 mole % and 25 mole % and most preferably between 17 mole % and 22 mole %. The polystyrene and polyisobutylene copolymer materials are preferably copolymerized in solvents.

[0059] Alternative polymeric materials can be used for the device. Such alternative polymeric materials may include polyisobutylene-based material capped with a glassy segment. The glassy segment provides a hardener component for the elastomeric polyisobutylene. The glassy segment can be a vinyl aromatic polymer (such as styrene, α-methylstyrene, or a mixture thereof), or a methacrylate polymer (such as methylmethacrylate, ethylmethacrylate, hydroxymethalcrylate, or a mixture thereof). Such materials preferably have a general block structure with a central elastomeric polyolefinic block and thermoplastic end blocks. Such materials may have a general structure:

BAB or ABA (linear triblock),

$B(AB)_n$ or $a(BA)_n$ (linear alternating block), or

$X-(AB)_n$ or $X-(BA)_n$ (includes diblock, triblock and other radial block copolymers), where A is an elastomeric polyolefinic block, B is a thermoplastic block, n is a positive whole number and X is a starting seed molecule.

[0060] Such materials may be star-shaped block copolymers (where n=3 or more) or multi-dendrite-shaped block copolymers. These materials collectively belong to the polymeric material referred to herein as SIBS.

[0061] Forming the port devices as described herein from SIBS affords the advantages of superb biocompatibility and biostability characteristics, ease of injection molding, ease of insert molding (particularly for insert molding the reinforcement band or reinforcement plate as described herein), ease of solvent bonding (for example, bonding valves to the ports of the device), accurate control over the Durometer of the material over the required range of Durometer (e.g., between Shore 80A and Shore 20A), providing a Modulus@100% within the preferred range between 0.5Mpa and 2MPa, and providing tensile characteristics (tensile strength, percent of elongation at break, and tear strength) that minimizes tearing of the port device after prolonged use in the body.

[0062] A presently preferred thermoplastic elastomeric material for use in making the port body is a polyurethane blended with a polyolefin (e.g., polybutadiene) which is available from RTP Co., Winona, MN under the tradename RTP-6003-45A. A similar material (polyurethane blended with polybutadiene) is available from New England Urethane, Inc., North Haven, CT under the tradename Neusoft 596-50. The presently preferred materials have the distinct advantage that in addition to their strength, softness, and elongation characteristics, they surprisingly do not readily absorb body fat so that they resist softening and tearing in the body and can be used with mineral oil-based lubricants. They also provide ease of injection molding, ease of insert molding (particularly for insert molding the reinforcement band or reinforcement plate as described herein), ease of bonding (for example, bonding valves to the ports of the device or bonding port caps to the ports), accurate control over the Durometer of the material over the required range of Durometer (e.g., between Shore 80A and Shore 20A), providing a Modulus@100% within the preferred range between 0.5Mpa and 2MPa, and providing tensile

characteristics (tensile strength, percent of elongation at break, and tear strength) that minimizes tearing of the port device after prolonged use in the body.

[0063] For purposes of the presently preferred embodiment, a presently preferred material for the port cap is polyisoprene or a platinum catalyzed liquid silicone rubber (LSR), which is preferably bonded to the port body by a silicone adhesive. A presently preferred material for the compression band around the port cap is platinum catalyzed liquid silicone rubber which is bonded to the port cap with a silicone adhesive. A presently preferred material for the heat shrink tubing is one that has minimal extractables in mineral oil and will pass biocompatibility testing required by the FDA, such as fluorocarbons, crosslinked polyolefins, Nylon and the like.

[0064] Table 1 below illustrates the properties of RTP 6003-45A and three different grade SIBS as compared to other flexible elastomeric materials for the port body, with the silicone (NuSil MED 4940) being the LSR which is presently preferably for the port cap.

TABLE 1

Property		Material							
Property Name	Unit	RTP 6003 Blend of poly-urethane and poly-olefin	SIBS (073T) 20 mole % styrene, molecular weight of ~70,000 Dalton	SIBS (103T) 20 mole % styrene, molecular weight of ~100,000 Dalton	SIBS (102T) 8 mole % styrene, molecular weight of ~100,000 Dalton	Silicone (4940)	SEPS (styrene ethylene-propylene styrene)	SBS (styrene butadiene styrene)	SEBS (styrene ethylene-butylene styrene)
Hardness	Shore A	45	45-47	46-50	25-30	40	80	70	77
Modulus at 100%	MPa	1.3	0.9	1.0	0.5-0.7	2	3.7	2.0	2.4
Tensile Strength at	MPa	4	14	18	16	7.6	42	31	34

break									
% Elongation at break	%	900	650	620	870	550	480	860	500
Tear Strength	KN/m	21	26	38	25	44	46	47	44

[0065] According to one aspect of the invention, it was determined that SIBS does not require lubrication of the ports (or of the instruments extending through the ports) to enable better sliding of the instrumentation in the respective ports. More particularly, as shown in Figure 21, upon initial tool insertion into SIBS ports without lubrication, a relatively large force is required, but thereafter the required insertion force of the non-lubricated SIBS port is similar to a lubricated port. By avoiding the need for such lubrication, the risk of infection stemming from such lubrication is avoided. This feature was unexpected and provides significant advantages. Moreover, it is contemplated that an instrument can be inserted into the non-lubricated SIBS port one or more times at the time of manufacture (or at the time of distribution or prior to use) such the surgeon does not experience the large initial insertion force of the non-lubricated SIBS port. Those well versed in the art will understand that the sliding forces of the instrument through the port are a function of the material, the lubricity and the design of the port. For example, if the port is a simple slit, the length of the slit will contribute to the overall force required to insert a tool. For example if the slit is long, e.g., 0.25" (6.35mm) long, the force required to insert a 5mm diameter tool will be low, but the leakage rate of gas around the tool may be too high. Alternatively, if the slit is 0.125" long (3.15mm) , the leakage rate will be zero but the tool will not slide as easily. With a slit length of 0.1875" (4.8mm), the leakage rate is approximately zero with easy slidability. It is desirable during laparoscopic surgery that the flow rate of carbon dioxide be set at 9 - 15 L/min which provides a pressure in the abdominal cavity of approximately 12-15mmHg. The port construction should be such that the pressure drop during a procedure should be less than 3mmHg.

[0066] In yet other embodiments, the flexible elastomeric material from which the port devices as described herein are formed can contain fillers such as Teflon particles or oils to lubricate the ports to enable better sliding of the instrumentation in the respective ports. The device can also be made with slippery surfaces (hydrophilic or hydrophobic) to facilitate sliding

of the instrument in the ports. Also, although sutures and suture snaggers, both rigid and flexible, are shown to hold the port in place, a belt placed around the abdomen of the patient that contains the port device of the invention will accomplish the same. In addition, the tapered outer surface can be made sticky to decrease sliding, or a flange can be added to the proximal end with an adhesive on the inner surface to further aid in maintaining the port in place.

[0067] In accordance with another aspect of the invention, the side wall could be stepped so that it is generally frustoconical (e.g., it has several frustoconical sections). The side wall could also be stepped or threaded with a helical interface to enable the sidewall to be screwed into the incision. In accord with a further aspect of the invention, the thickness of the frustoconical side wall could change in steps or gradually over the length of the port device. In accordance with an additional aspect of the invention, rather than having ports extending outward from the top wall, no outwardly extending ports are provided, and the ports consist of holes in the top wall of the port device. Alternatively, the ports can extend slightly inside the frustoconical outer wall. Finally, instead of three working ports and an optional insufflation port, a different number of working ports (e.g., four) can be provided. Those skilled in the art will understand that other modifications to this device can be made without deterring from the scope of this invention.

[0068] There have been described and illustrated herein several embodiments of a flexible elastomeric surgical port device and surgical method of using same. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. Thus, while particular flexible elastomeric materials have been disclosed, it will be appreciated that other elastomeric materials can be used as well. In addition, while particular port and valve configurations have been disclosed, it will be understood that other suitable port and valve configurations can be used. Moreover, while particular configurations have been disclosed in reference to integrated reinforcement of the port body, it will be appreciated that other configurations could be used as well. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as claimed.

WHAT IS CLAIMED IS:

1. A surgical apparatus for introduction of laparoscopic instruments into an anatomical cavity through tissue at an entry site, said apparatus comprising:

a one-piece molded body with a frustoconical-shaped wall with an exterior sealing surface for sealable contact with the tissue at the entrance site, the body defining an interior cavity, an open bottom, and a substantially closed top wall with openings from which a plurality of ports extend upward therefrom, the plurality of ports for receiving the laparoscopic instruments for introduction through the interior cavity and open bottom of the body into the anatomical cavity.

2. A surgical apparatus according to claim 1, further comprising:

suture retention means for suturing the body to tissue adjacent the entry site.

3. A surgical apparatus according to claim 2, wherein:

the suture retention means are disposed within the radial periphery of the top wall of the body.

4. A surgical apparatus according to claim 2, wherein:

the suture retention means is integrally formed on a top surface of the top wall of the body about the perimeter of the top wall of the body.

5. A surgical apparatus according to claim 2, wherein:

the suture retention means is integrally formed as part of a plate that covers the top wall of the body and is disposed about the perimeter of the top wall of the body, the plate having thru-holes for accommodating the plurality of ports that extend therethrough.

6. A surgical apparatus according to claim 2, wherein:

the suture retention means is integrally formed as part of a plate that is disposed under the top wall of the body and that extends radially outward beyond the frustoconical-shaped wall of the body.

7. A surgical apparatus according to claim 1, further comprising:

reinforcement means for reinforcing the body such that the frustoconical-shaped wall maintain its shape when inserted through tissue at the entry site.

8. A surgical apparatus according to claim 7, wherein:

the reinforcement means comprises a member that is integrally formed with the molded body by insert molding.

9. A surgical apparatus according to claim 7, wherein:

the reinforcement means comprises a band that extends about the frustoconical-shaped wall.

10. A surgical apparatus according to claim 7, wherein:

the reinforcement means comprising a plate that is integrally formed with top wall of the body.

11. A surgical apparatus according to claim 10, wherein:

the plate includes integrally formed suture retention means that extend radially outward beyond the frustoconical-shaped wall of the body, the suture retention means for suturing the body to tissue adjacent the entry site.

12. A surgical apparatus according to claim 10, wherein:

the plate includes a plurality of thru-holes corresponding to the ports of the body, each thru-hole sized to match the corresponding port.

13. A surgical apparatus according to claim 12, wherein:

the plate provides a pivot point for pivoting movement of the laparoscopic instruments extending therethrough.

14. A surgical apparatus according to claim 12, wherein:

the plate includes at least one thru-hole that allows for inflow of material during insert molding of the body.

15. A surgical apparatus according to claim 10, wherein:

the plate comprises a material selected from the group including a metal, polyoxymethylene, polycarbonate, polyurethane, and poly(acrylonitrile-butadiene-styrene).

16. A surgical apparatus according to claim 1, wherein:

the body is formed from a material having a Hardness of between 30A and 65A, a tensile strength of greater than 3MPa, a tear strength of greater than 20 KN/m, and an elongation percentage at break of greater than 600%.

17. A surgical apparatus according to claim 1, wherein:

the frustoconical-shaped wall of the body has spaced circumferential grooves for assisting cutting or trimming to a desired length.

18. A surgical apparatus according to claim 1, wherein:

the interior cavity of the body is adapted to receive an organ for removal from the anatomical cavity without contacting the tissue at the entry site.

19. A surgical apparatus according to claim 1, further comprising:

a plurality of port caps, respective of said plurality of port caps extending over respective of said plurality of ports.

20. A surgical apparatus according to claim 19, wherein:

said port caps include a cylindrical wall and a top septum.

21. A surgical apparatus according to claim 20, wherein:

said top septum defines a central well where said septum has a reduced thickness.

22. A surgical apparatus according to claim 21, wherein:

said top septum has a slit extending entirely through said septum at said location of said central well.

23. A surgical apparatus according to claim 20, further comprising:

a compressive band located about said top septum.

24. A surgical apparatus according to claim 23, wherein:

said top septum has a slit therein, and said compressive band acts to keep said slit closed.

25. A surgical apparatus according to claim 20, wherein:

each of said plurality of ports has a base section adjacent said top wall having a first thickness and an upper section having a reduced thickness relative to said first thickness, and said cylindrical wall of each of said plurality of port caps extends about said upper section.

26. A surgical apparatus according to claim 25, wherein:

said cylindrical wall for a respective port cap is bonded to said upper section of a respective port.

27. A surgical apparatus according to claim 26, further comprising:

a heat shrink tube extending over each said cylindrical wall and at least a portion of each port base section.

28. A surgical apparatus according to claim 19, wherein:

said plurality of port caps are formed from silicone rubber, and said molded body is formed from a polyurethane blended with a polyolefin and having a Hardness of between 30A and 65A, a tensile strength of greater than 3MPa, a tear strength of greater than 20 KN/m, and an elongation percentage at break of greater than 600%.

29. A surgical apparatus for introduction of laparoscopic instruments into an anatomical cavity through tissue at an entry site, said apparatus comprising:

a body with a frustoconical-shaped wall with an exterior sealing surface for sealable contact with the tissue at the entrance site, the body defining an interior cavity, an open bottom, and a substantially closed top wall with openings from which a plurality of ports extend upward therefrom, the plurality of ports for receiving the laparoscopic instruments for introduction through the interior cavity and open bottom of the body into the anatomical cavity, wherein the body is formed from a material having a Hardness of between 30A and 65A, a tensile strength of greater than 3MPa, a tear strength of greater than 20 KN/m, and an elongation percentage at break of greater than 600%.

30. A surgical apparatus according to claim 29, wherein:

the body is unitary one-piece molded structure.

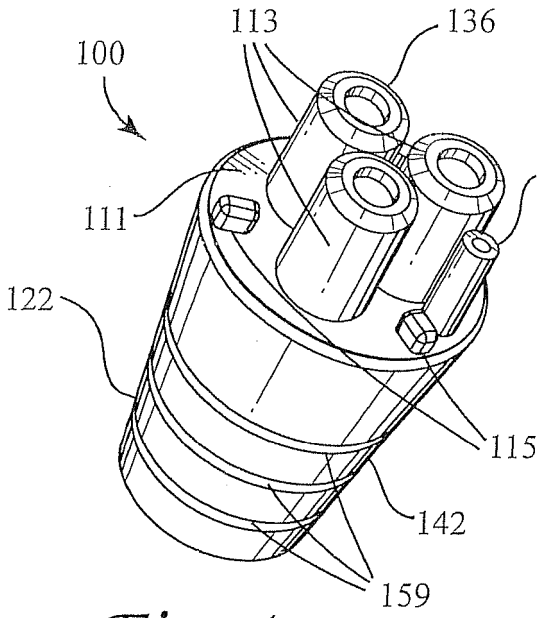

Fig. 1

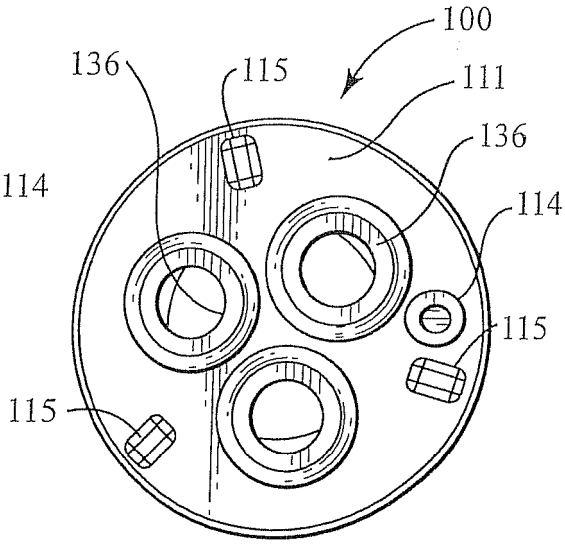

Fig. 2

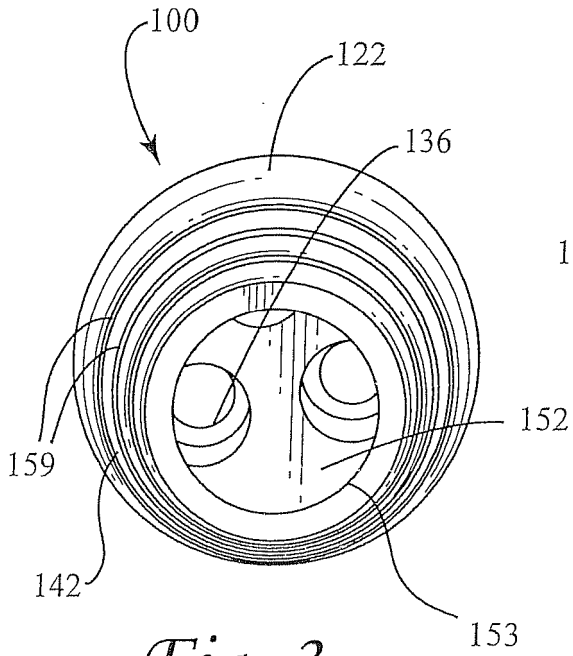

Fig. 3

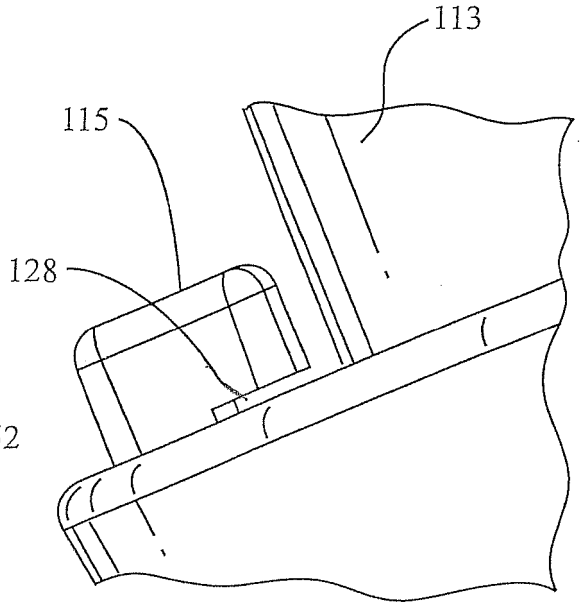

Fig. 4

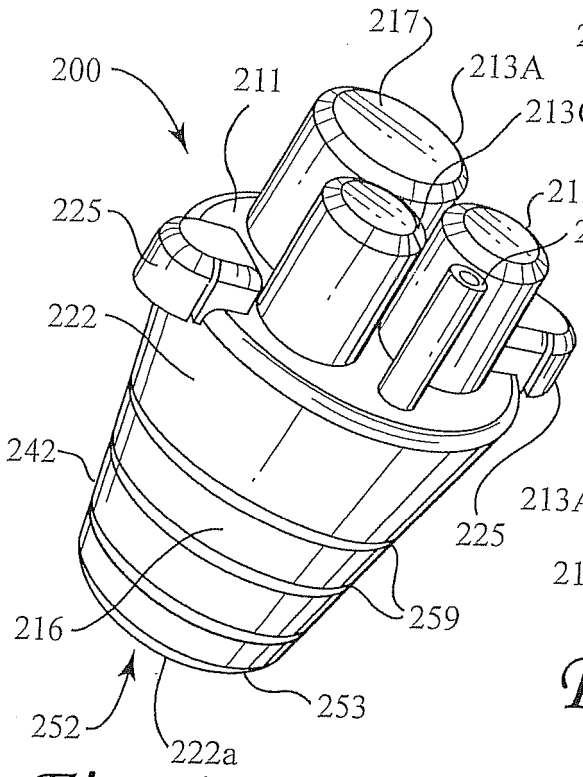

Fig. 5

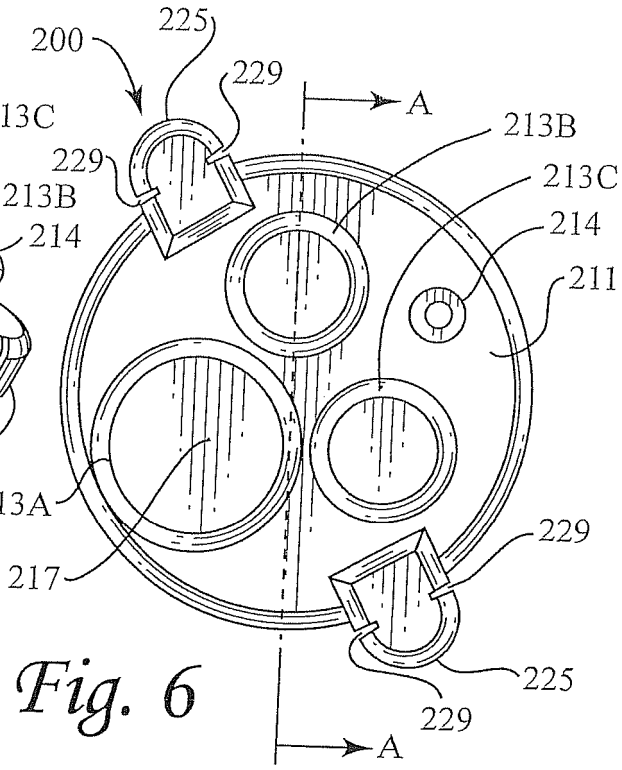

Fig. 6

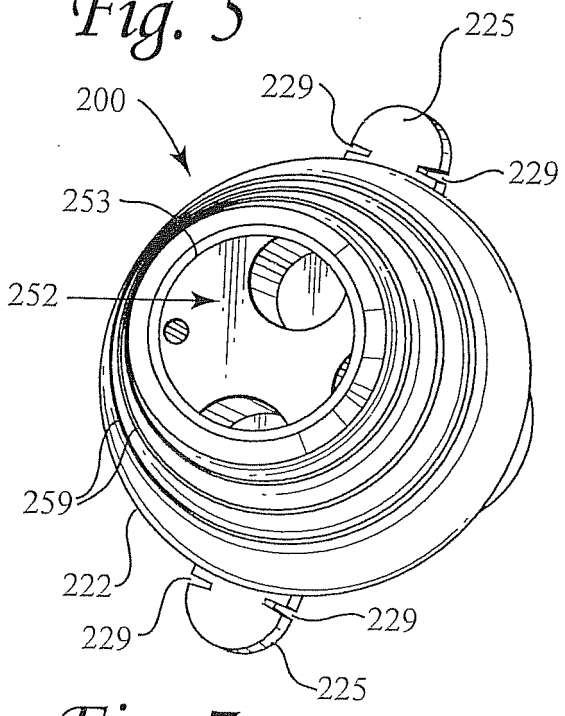

Fig. 7

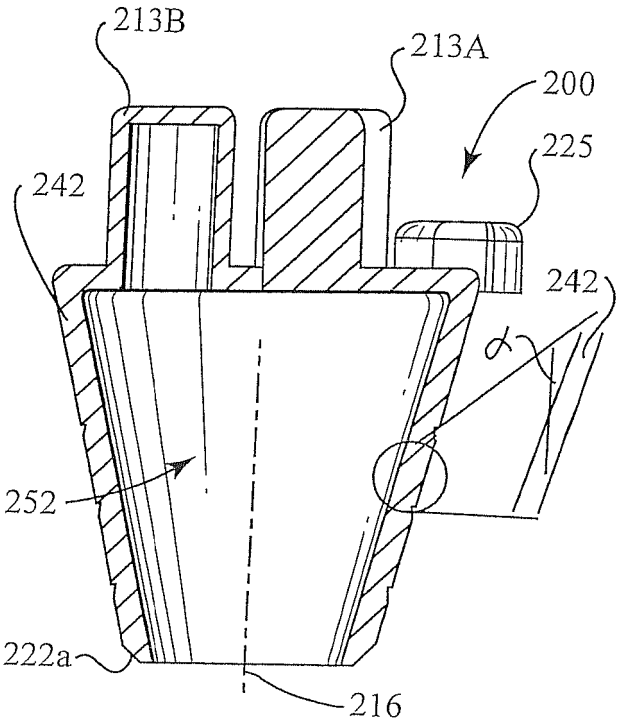

Fig. 8

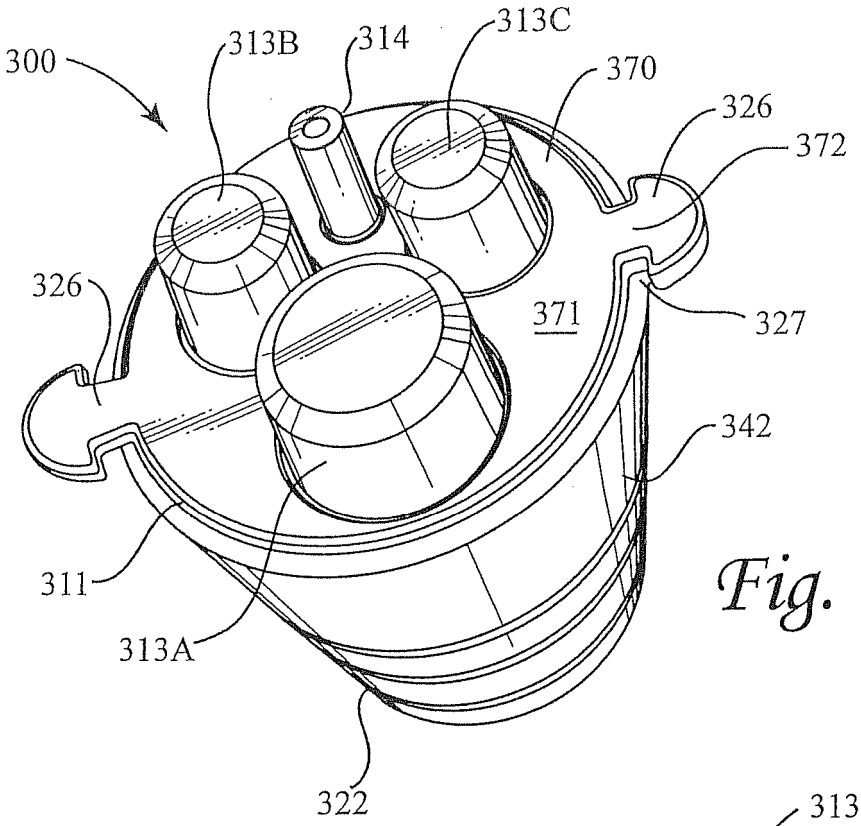
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Fig. 9

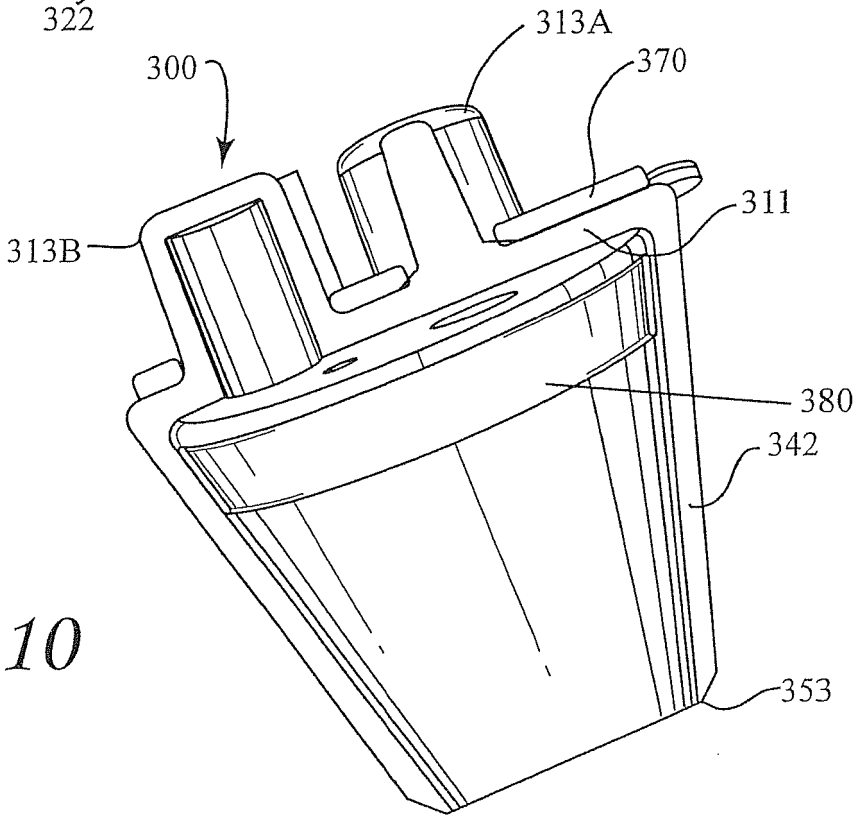
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Fig. 10

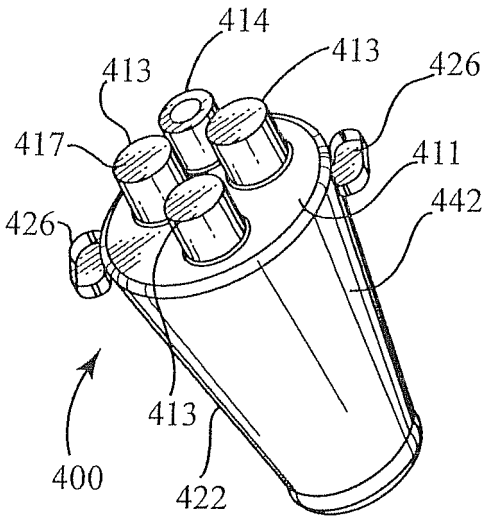

Fig. 11

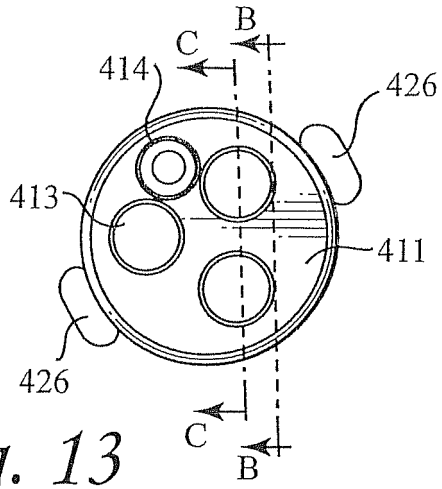

Fig. 13

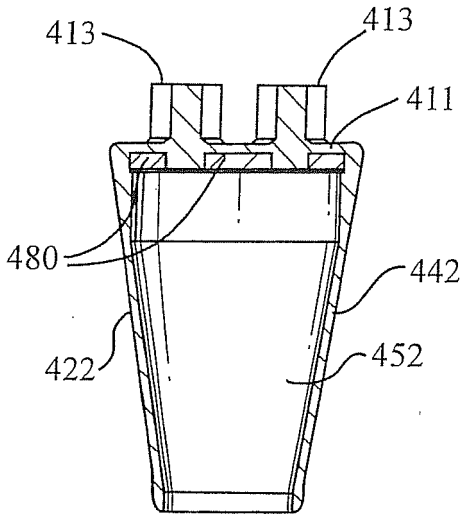

Fig. 16

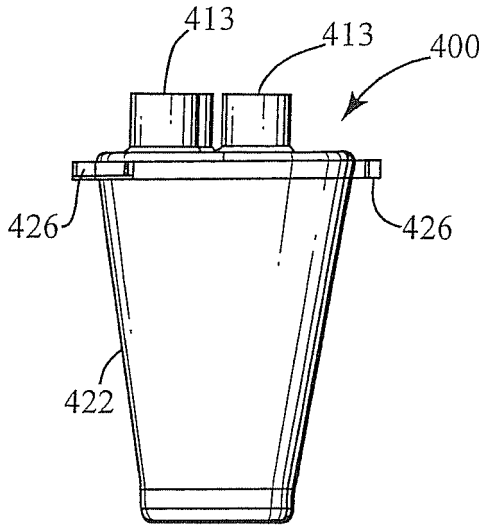

Fig. 12

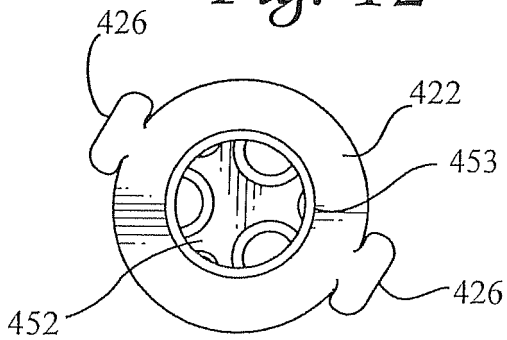

Fig. 14

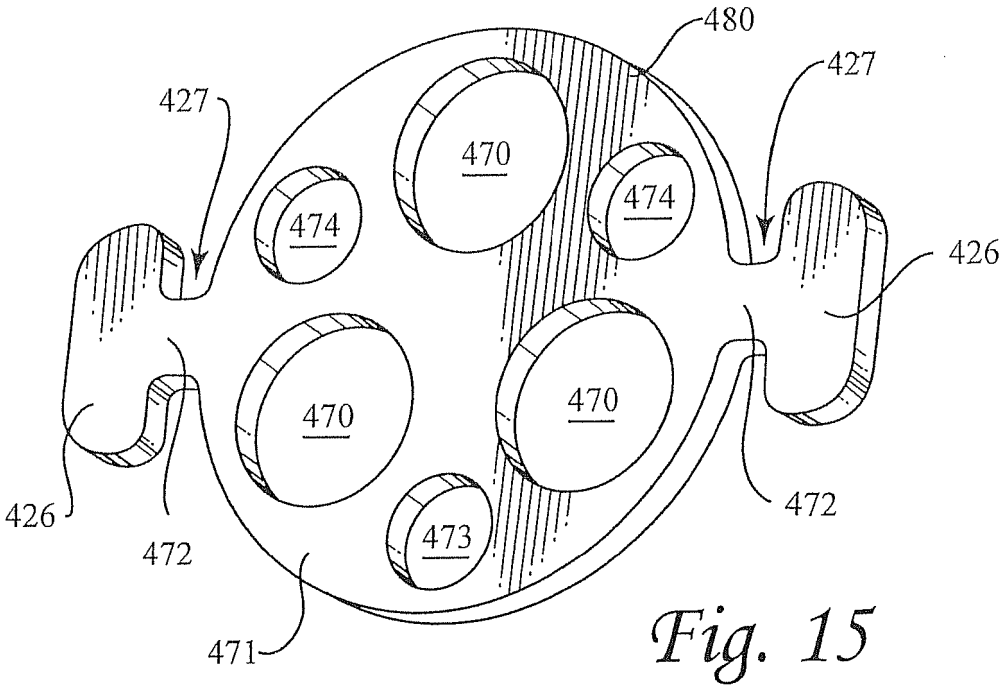
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Fig. 15

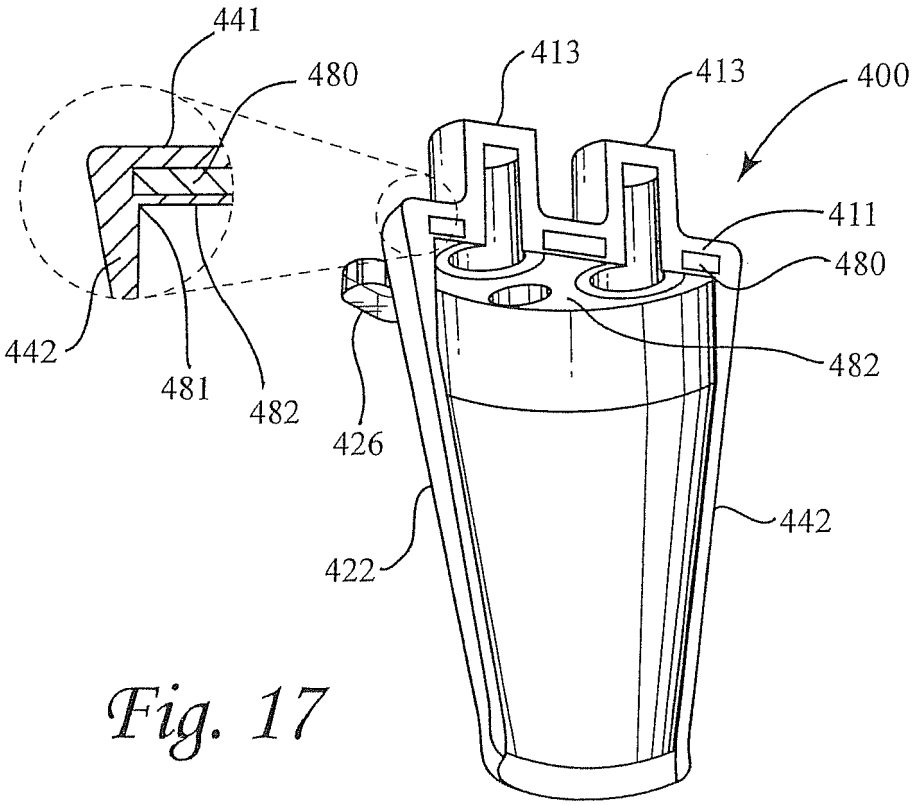
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Fig. 17

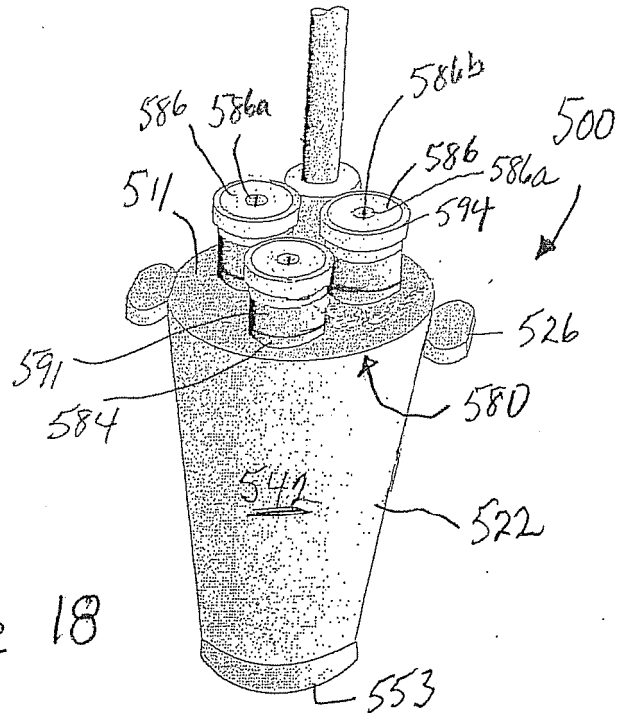

Figure 18

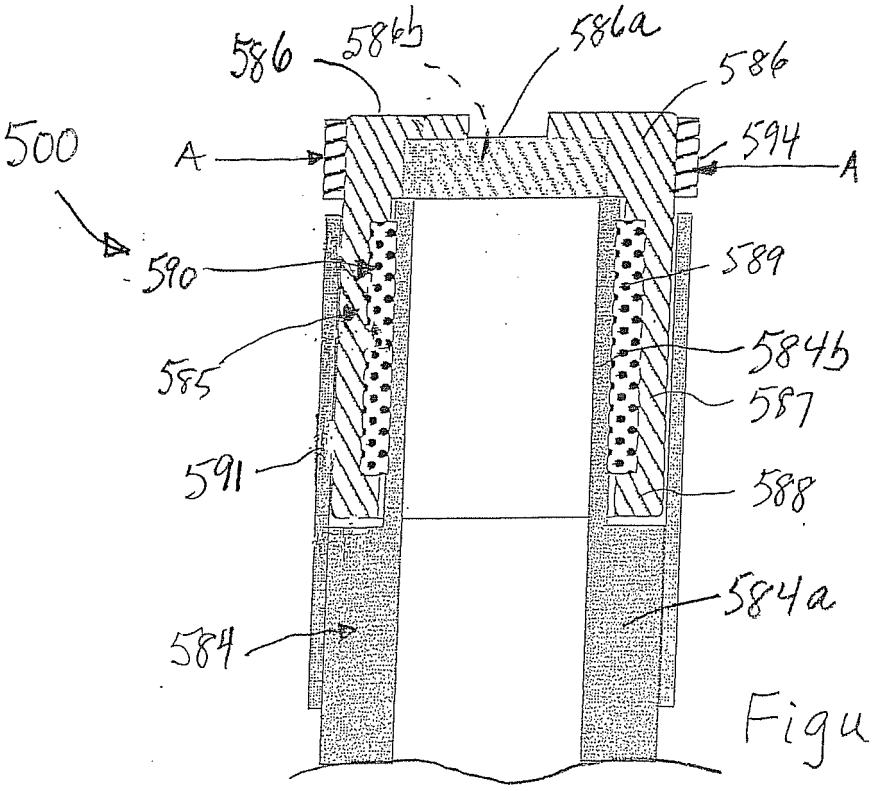

Figure 19

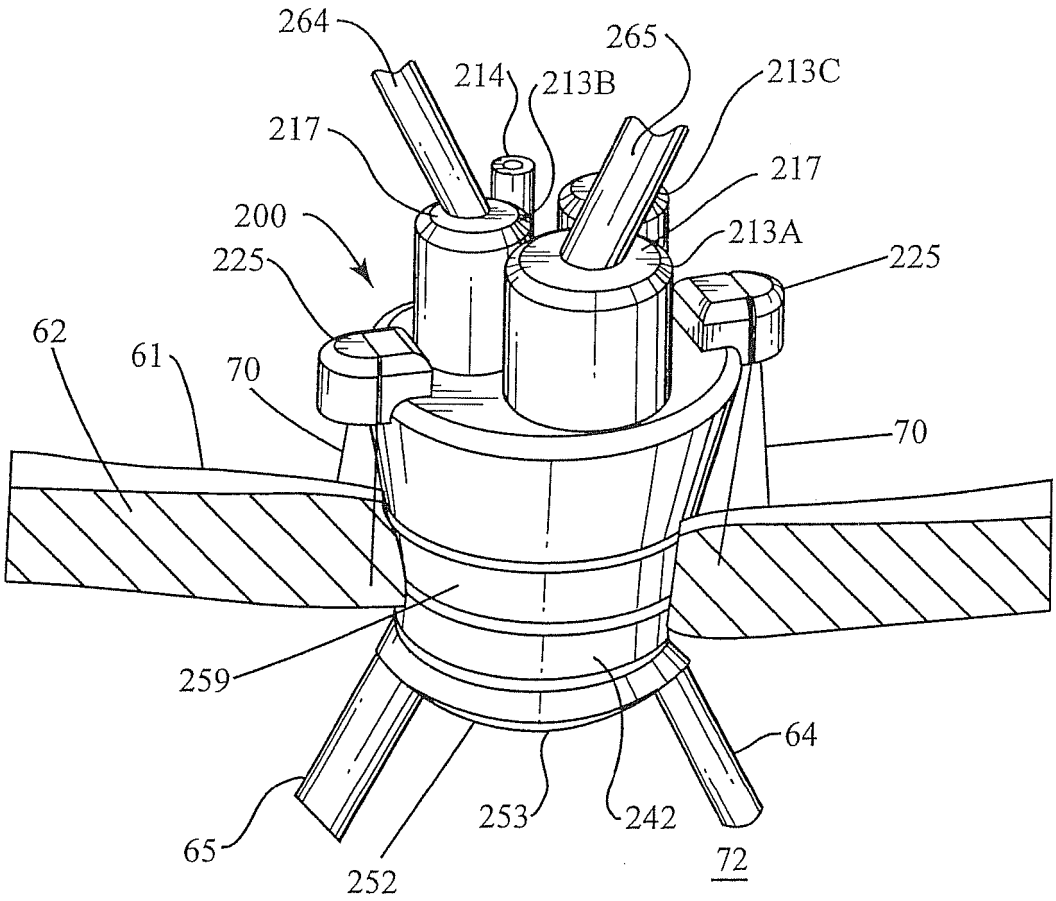
264
265
214
213B
213C
217
217
200
213A
225
225
62
61
70
70
259
64
65
253
242
252
72

Fig. 20

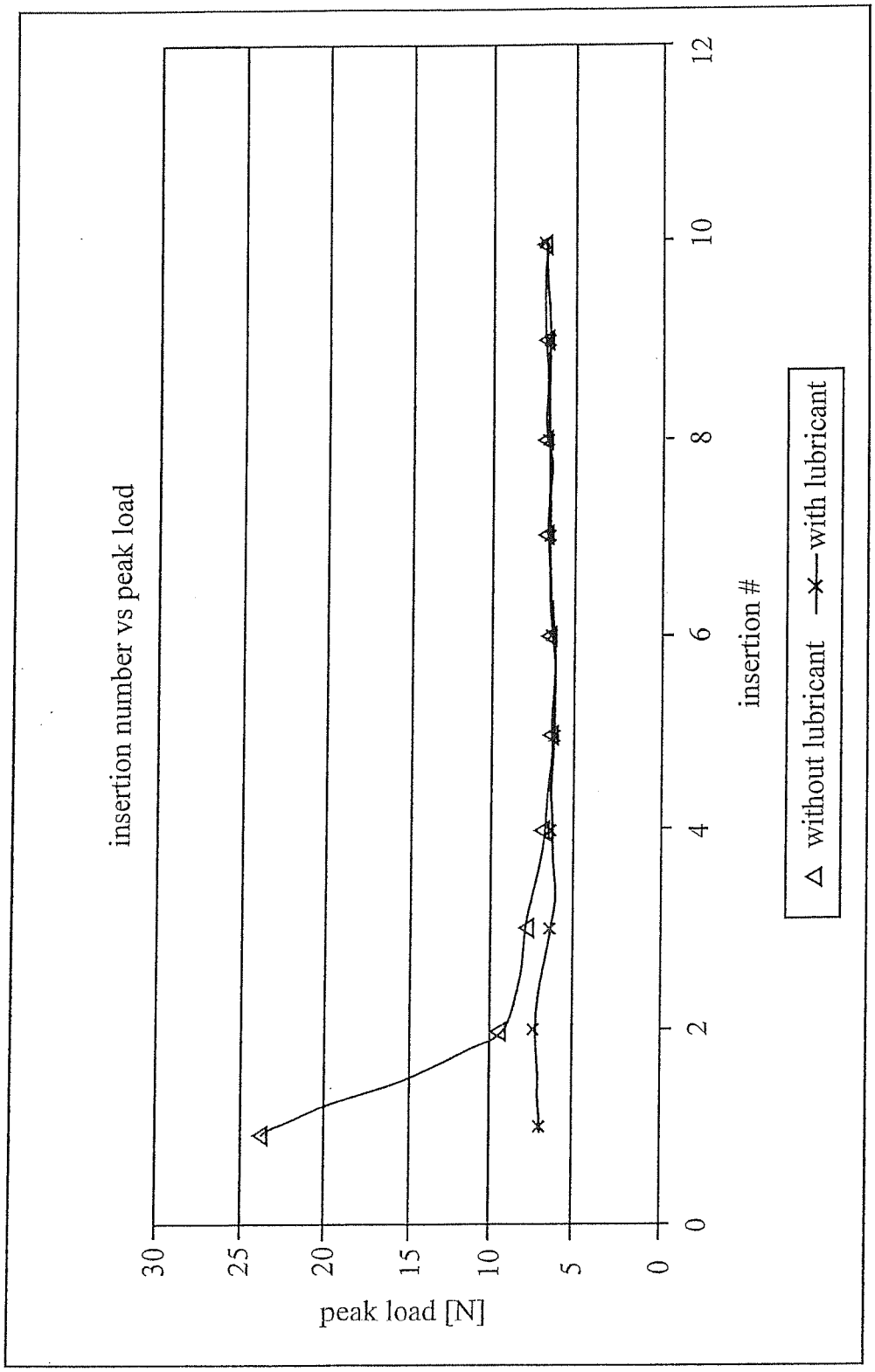
insertion number vs peak load
peak load [N]
30
25
20
15
10
5
0
0
2
4
6
8
10
12
insertion #
without lubricant
with lubricant

Fig.21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/056008

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/34 (2009.01)
USPC - 604/264
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(8) - A61B 17/00, 17/34; A61M 25/00, 31/00 (2009.01)
USPC - 600/184, 201; 604/19, 48, 93.01, 164.01, 167.01, 264

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0171713 A1 (MCFARLANE) 11 September 2003 (11.09.2003) entire document	1-13, 15-26, 28-30
Y	US 6,551,270 B1 (BIMBO et al) 22 April 2003 (22.04.2003) entire document	1-13, 15-26, 28-30
Y	US 5,628,732 A (ANTOON JR et al) 13 May 1997 (13.05.1997) entire document	8, 16, 28-30
Y	US 5,514,133 A (GOLUB et al) 07 May 1996 (07.05.1996) entire document	15
Y	US 5,342,316 A (WALLACE) 30 August 1994 (30.08.1994) entire document	20-26
Y	US 2007/0225650 A1 (HART et al) 27 September 2007 (27.09.2007) entire document	28
A	US 2005/0004592 A1 (CRISCUOLO) 06 January 2005 (06.01.2005) entire document	27

☐ Further documents are listed in the continuation of Box C. ☐

* 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
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"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
15 October 2009	22 OCT 2009

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

专利名称(译)	灵活的一次性手术口		
公开(公告)号	EP2330989A1	公开(公告)日	2011-06-15
申请号	EP2009812268	申请日	2009-09-04
[标]申请(专利权)人(译)	因诺维亚有限责任公司		
申请(专利权)人(译)	INNOVIA LLC		
当前申请(专利权)人(译)	INNOVIA LLC		
[标]发明人	EDELMAN DAVID S PINCHUK LEONARD MARTIN JOHN B PINCHUK BRYAN M RAMER MARC		
发明人	EDELMAN, DAVID, S. PINCHUK, LEONARD MARTIN, JOHN, B. PINCHUK, BRYAN, M. RAMER, MARC		
IPC分类号	A61B17/34		
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优先权	12/468219 2009-05-19 US 61/094706 2008-09-05 US		
其他公开文献	EP2330989A4		
外部链接	Espacenet		

摘要(译)

一种外科设备，用于通过入口处的组织将腹腔镜器械引入解剖腔。该装置包括具有截头圆锥形壁的主体。主体限定内腔，开口底部和基本上封闭的顶壁，顶壁具有开口，多个端口从开口向上延伸。端口适于接收腹腔镜器械，用于通过内腔和开放的身体底部引入解剖腔。在优选实施例中，主体的截头圆锥形壁通过脐管中的切口放置。在本发明的一个方面，主体是整体的单件模制结构。由相对硬的材料形成的加强带或板可以与主体成一体，并且每个具有隔膜的单独形成的端口盖可以结合到端口。