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Shipp et al.

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(54) **INSTRUMENTS AND METHODS FOR USE IN LAPAROSCOPIC SURGERY**

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(51) **Int. Cl.**[7] **A61B 17/22**

(52) **U.S. Cl.** **606/127**; 606/207

(58) **Field of Search** 606/113, 114, 606/115, 127, 128, 205, 206, 207; 604/167.02, 167.04, 164.1, 164.03

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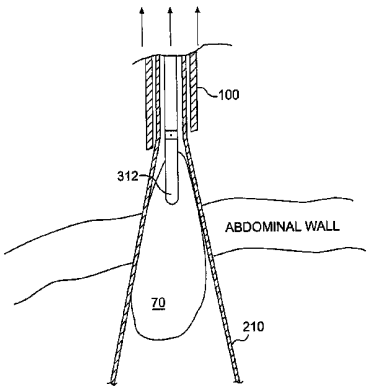
(57) **ABSTRACT**

A surgical dilator extractor is introduced into the abdominal cavity through a trocar cannula and expanded, forming a tissue receiving space, at the distal end. The tissue that is to be extracted is then manipulated into the space with a grasper inserted through a lumen in the dilator extractor. The tissue is then removed from the cavity by the surgeon applying a force onto the dilator extractor that insures the elongation of the tissue and temporarily dilates the entry wound to the extent necessary for the tissue to be removed. Alternative embodiments of the surgical dilator extractor and related instrument tool sets and methods for the use thereof also are disclosed.

84 Claims, 10 Drawing Sheets



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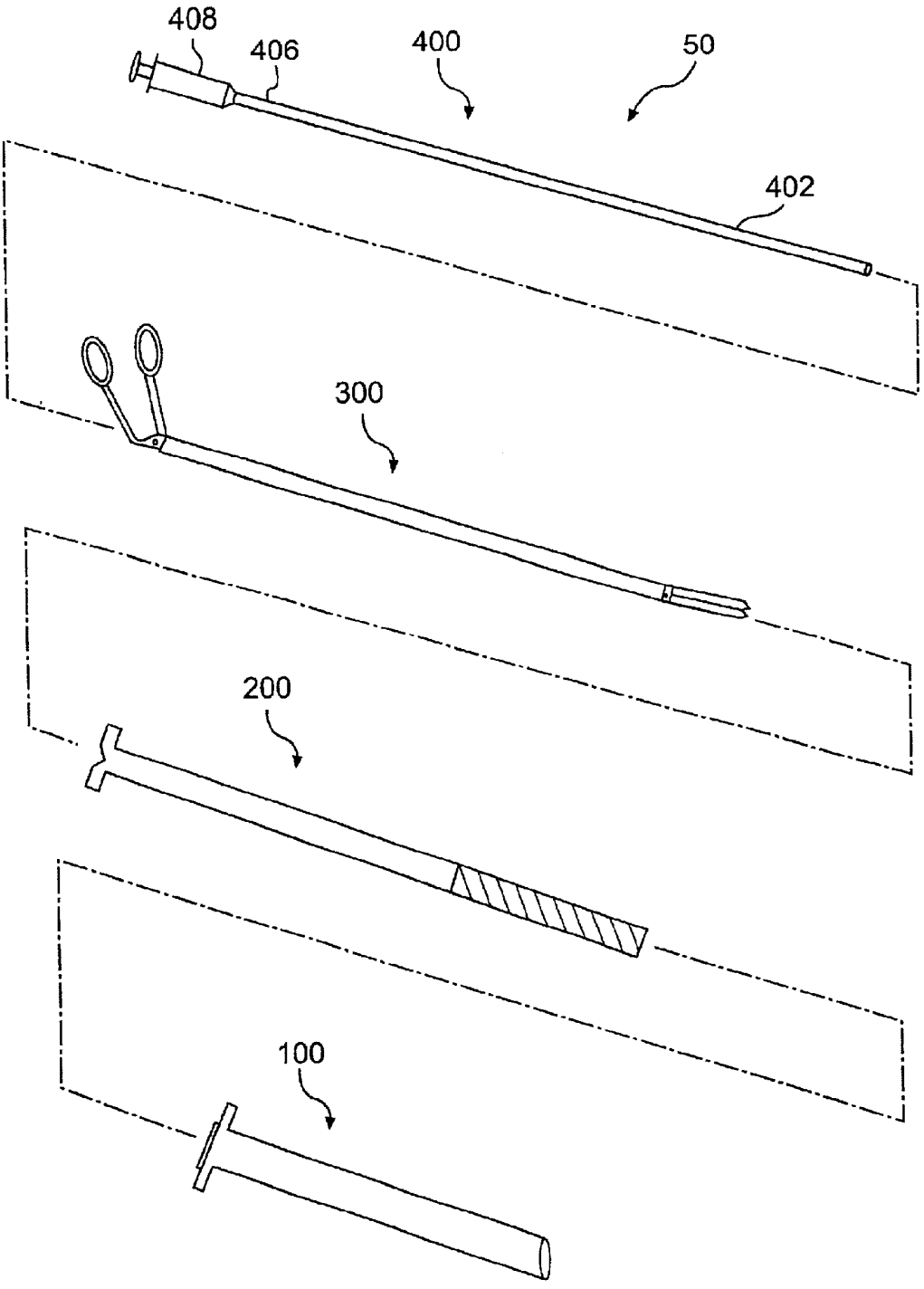


FIG. 1

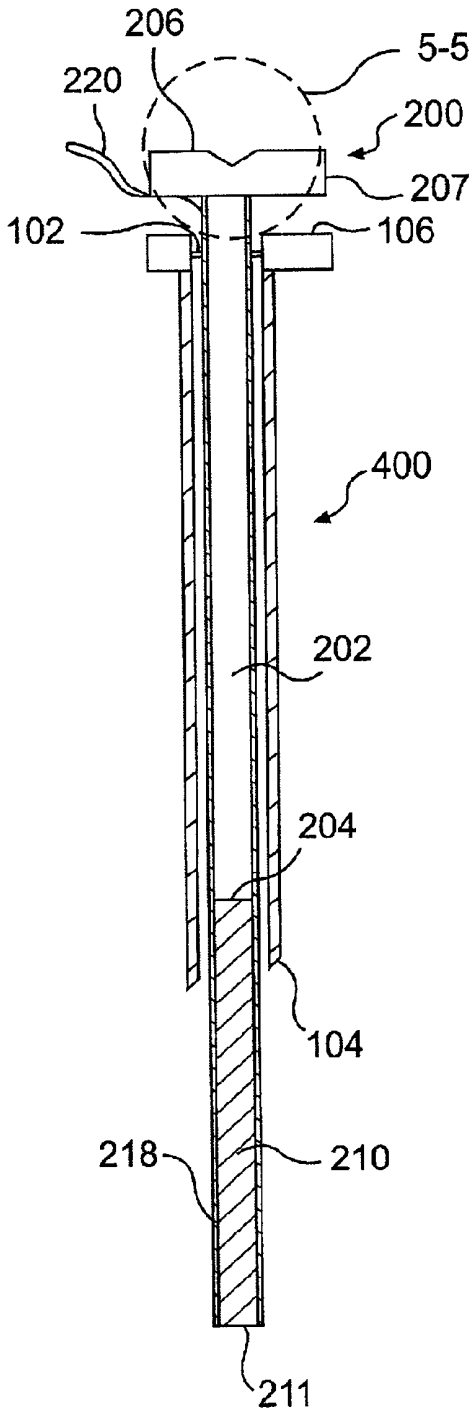


FIG. 2

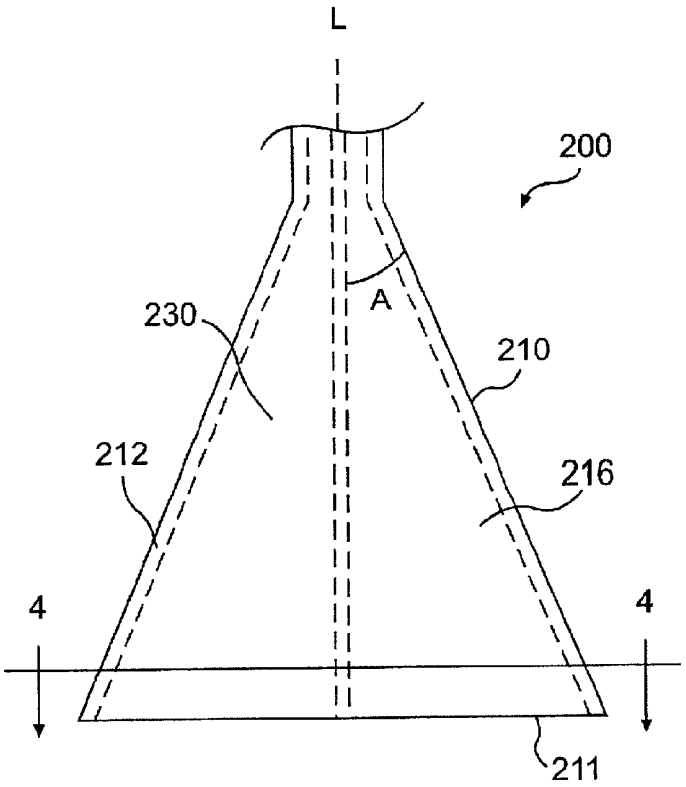


FIG. 3

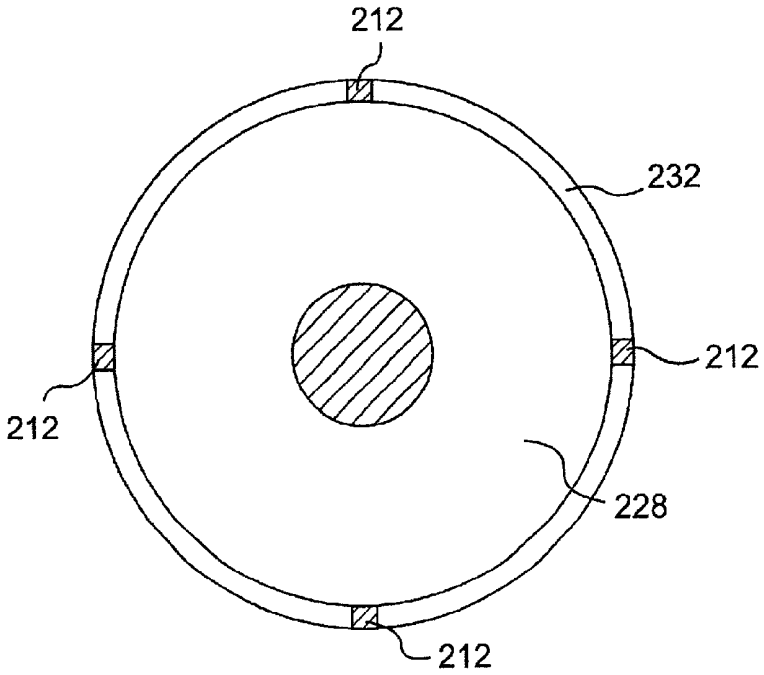


FIG. 4

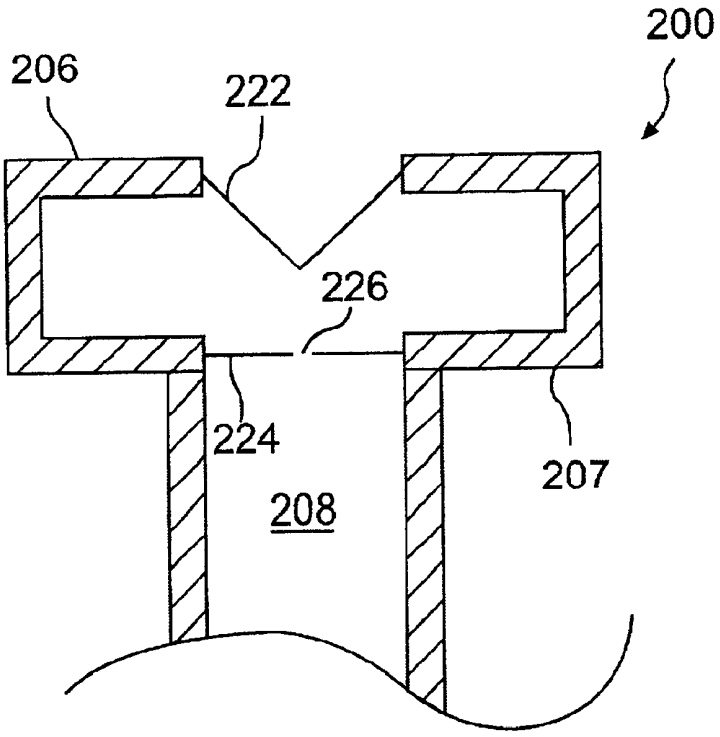


FIG. 5

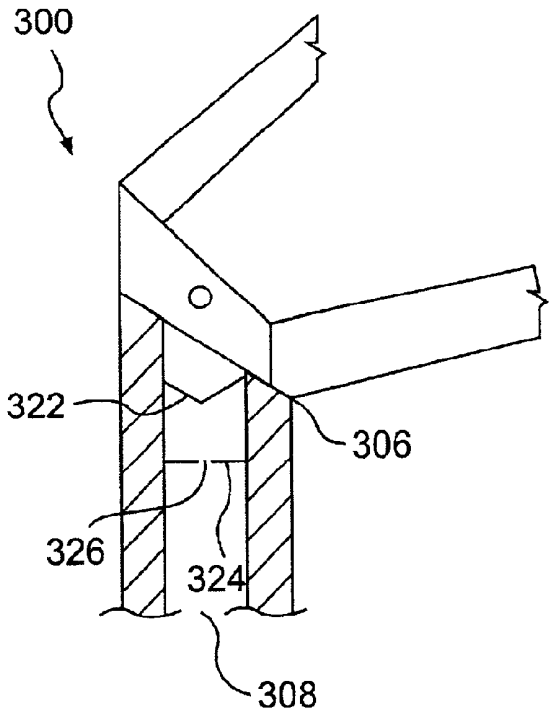


FIG. 6

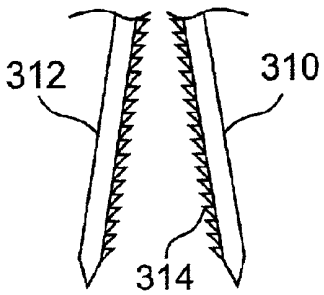


FIG. 7

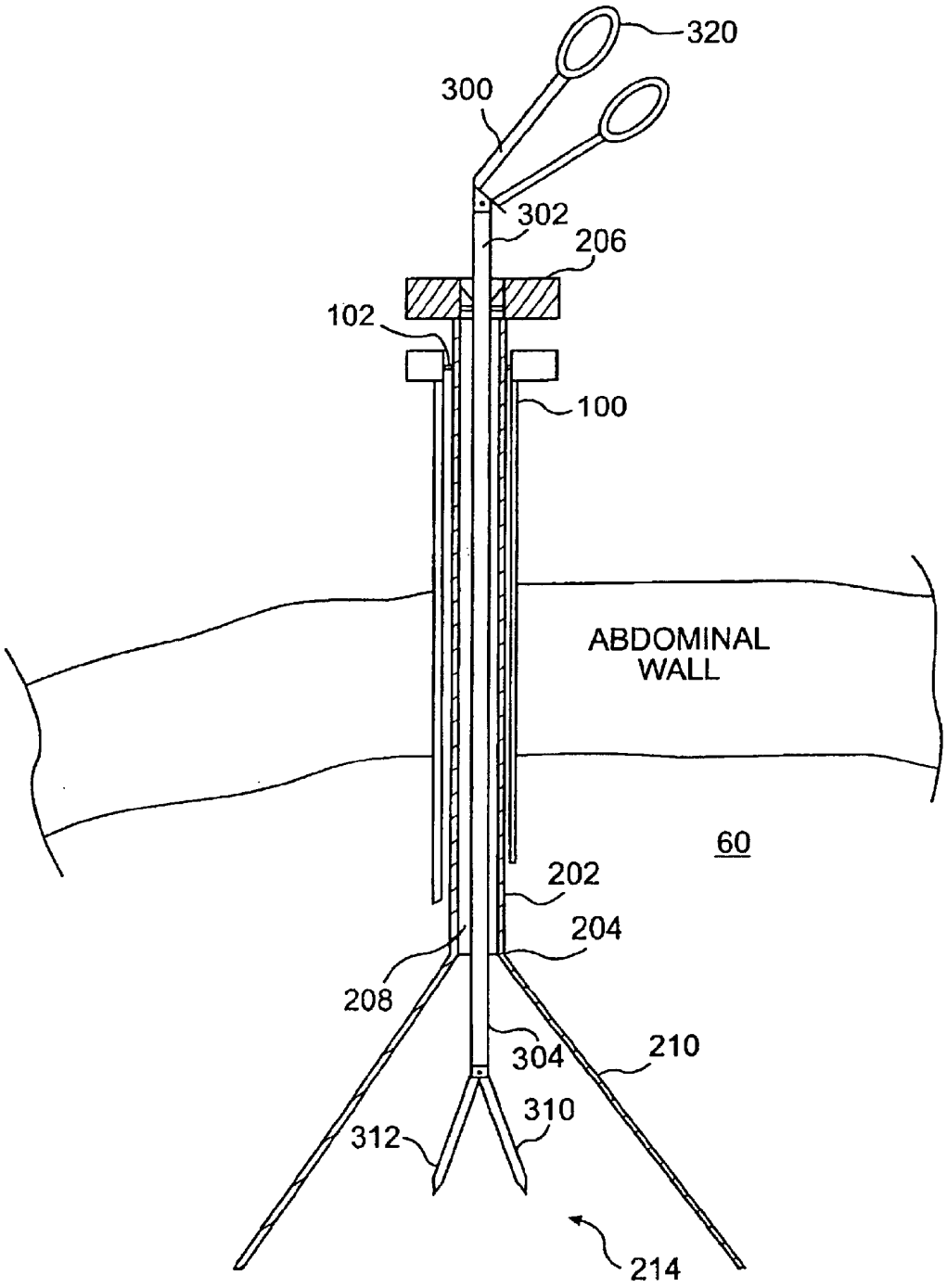

320
300
302
206
102
100
ABDOMINAL WALL
60
202
204
208
304
210
310
312
214

FIG. 8

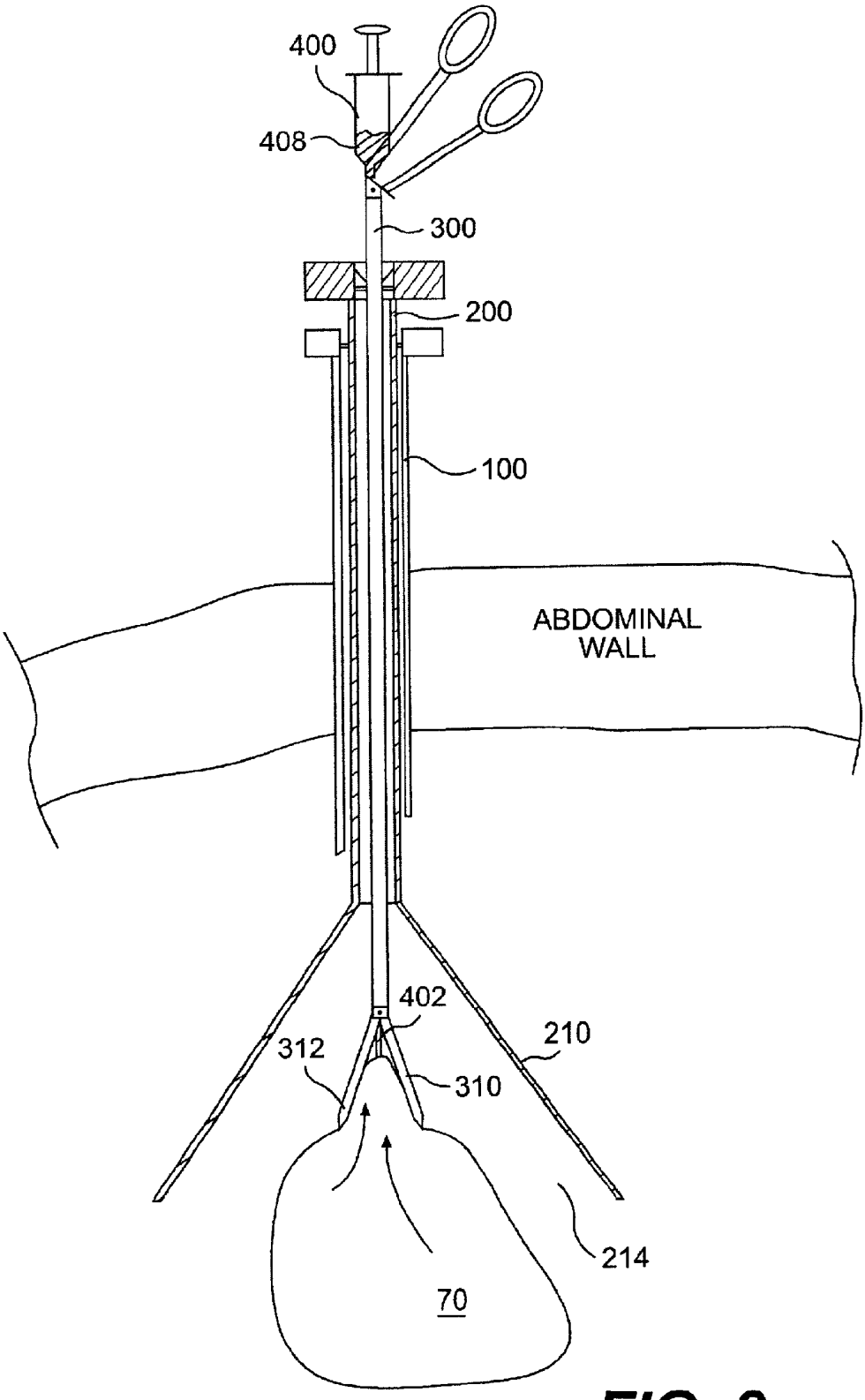


FIG. 9

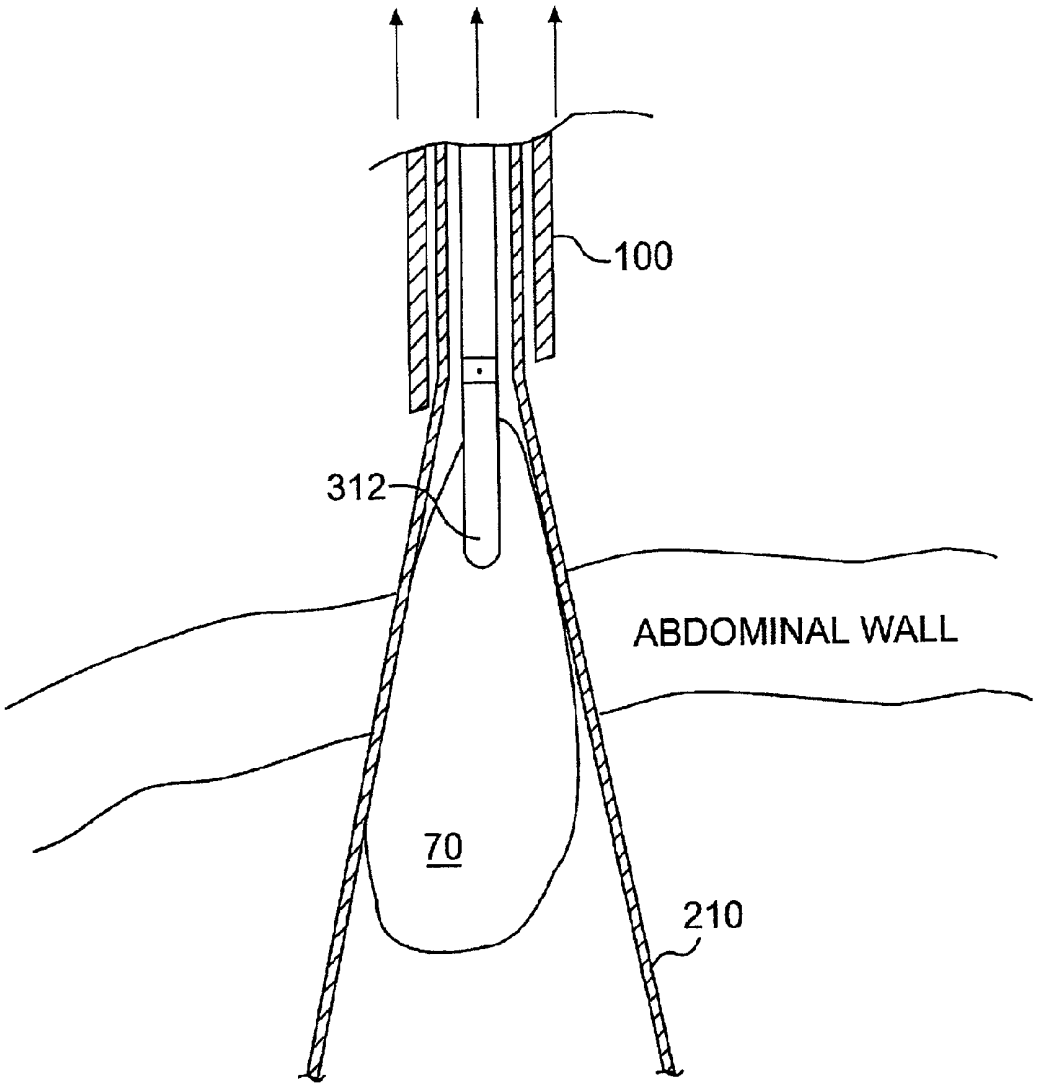


FIG. 10

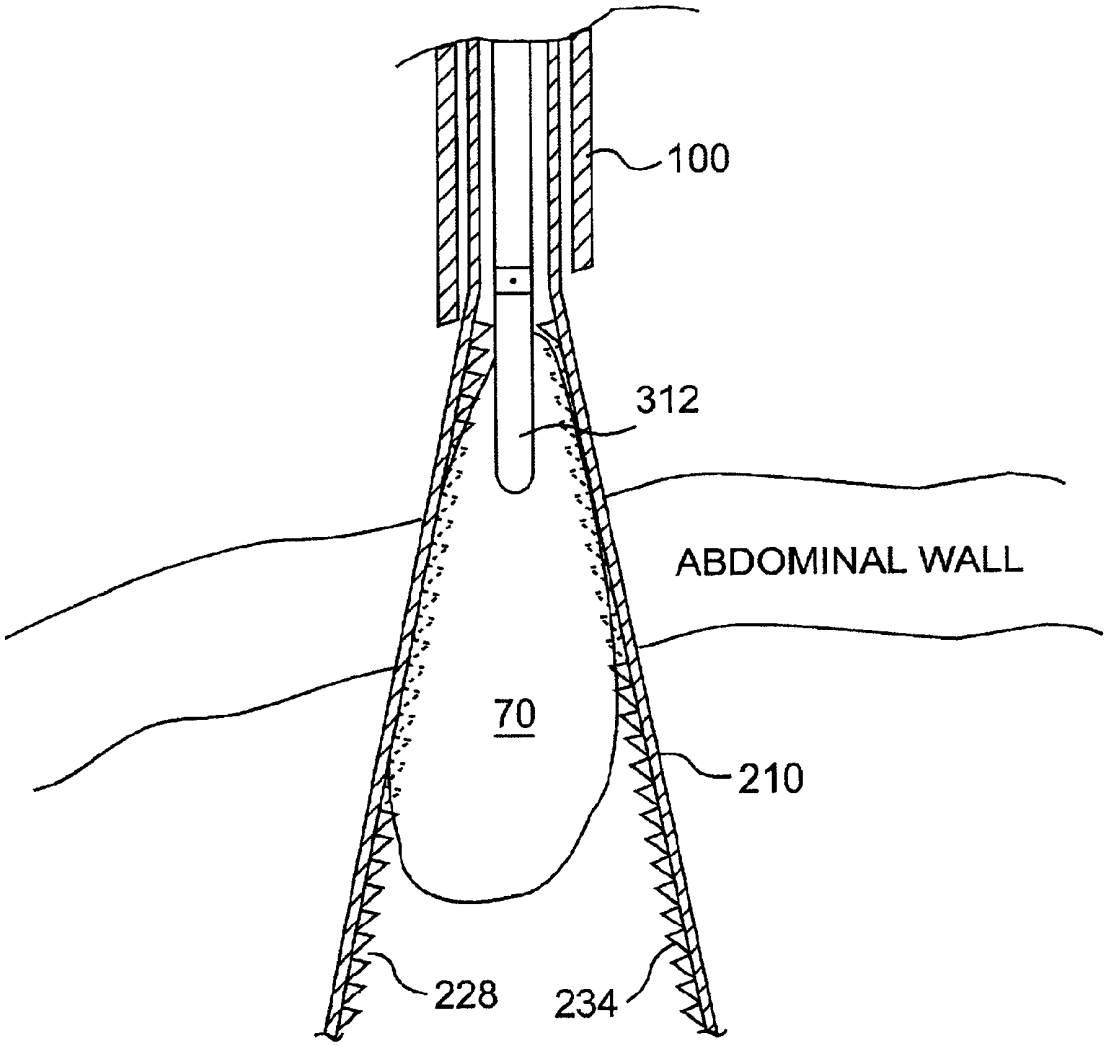


FIG. 11

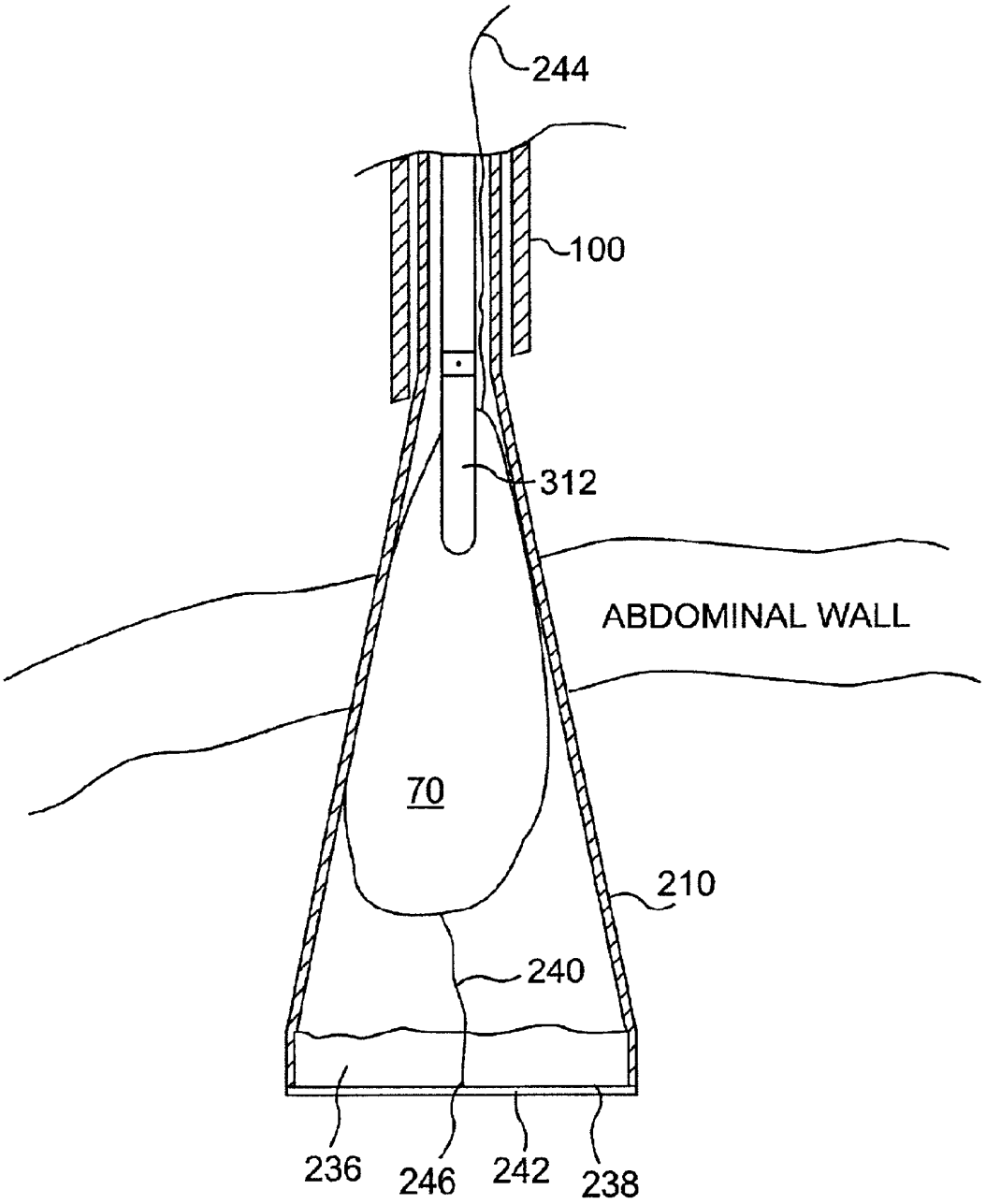


FIG. 12

INSTRUMENTS AND METHODS FOR USE IN LAPAROSCOPIC SURGERY

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/261,798, filed Jan. 17, 2001, incorporated by reference herein.

BACKGROUND

The present invention relates generally to mechanical devices and methods used in laparoscopic surgical procedures to remove organs and excised tissue from internal body cavities.

It will be appreciated by those skilled in the art that the use of bags or pouches to remove organs and large tissue specimen during laparoscopic surgical procedures is well known. As described, for example, in U.S. Pat. No. 5,147,371 a pouch is introduced into the abdominal cavity for retrieving gallstones and tissue. The bag is opened and closed using a wire loop as a drawstring. In U.S. Pat. No. 5,192,284 an expandable bag is inserted into the abdominal cavity through a trocar cannula. The bag described in the '284 patent is made of a memory material that is rigid enough to support itself. The bag expands and remains open when it is inserted into the abdominal cavity through the cannula. U.S. Pat. No. 5,480,404 describes a pouch for extracting tissue that is opened and closed by a ratchet mechanism. U.S. Pat. No. 5,341,815 employs shape memory effect metal to open the bag upon insertion through a trocar. U.S. Pat. Nos. 5,681,324 and 5,971,995 describe similar bags and pouches.

The pouches described in these patents are useful in containing any bile or gallstones that might otherwise spill into the abdominal cavity during extraction of a torn gallbladder. These type of devices, however, suffer from at least two problems. Since such devices are closed on the distal end, air inside the enclosure tends to balloon the pouches or bags during the extraction process thereby increasing the size or not allowing a full collapse of a bag as it is removed from the wound. Additionally, when the tissue is larger than the wound size it is forced to the bottom of the bag as the radial force of the wound acts on the tissue during extraction. This also increases the size to which the wound must be dilated for removal of the tissue. Tapering the bags toward the distal end helps somewhat to lessen this effect, but the result is not optimal and does not fully address the problem of air trapped in the bag.

Since the goal of laparoscopic surgery is to become less invasive by using smaller entry wounds the prior art is of limited value for removing large specimens through, for example 5 mm wounds. When the user pulls on the bag in an attempt to remove it through a small trocar entry wound the specimen is forced to the bottom of the bag by the radial forces exerted by the abdominal tissue or by the forces exerted on the bag from the cannula thus creating a large lump that is often incapable of passing through the wound. The use of this type of extraction bag in these cases often requires de-bulking of the specimen so that the bagged specimen pieces are of such a size that the bag can be extracted through the trocar entry wound, typically 10–12 mm. This is a time consuming process that is not always successful since, for example, large stones may be inside a gallbladder and it also compromises the pathologic examination of the tissue specimen. Alternately the wound size is increased with a scalpel to allow the extraction, thereby lessoning the advantage of the laparoscopic surgery.

Additionally, these types of extraction bags add undue complexity to the procedure since they require the use of two ports, one for the bag and the second for a grasper to retrieve the tissue and put it into the bag.

U.S. Pat. Nos. 5,190,561 and 5,370,647 to Graber disclose several embodiments of laparoscopic extraction devices that allow a grasper to be inserted into the center of an extractor device so that tissue can be more easily manipulated into the inside of the extractor. In each of the embodiments the extractor is introduced into the abdominal cavity through a specially designed trocar cannula equipped with setscrews to lock the extractor to the trocar cannula. Upon exiting the distal end of the cannula, the distal end of the extractor expands, much like an umbrella. A grasper is then introduced into the abdominal cavity through a lumen in the extractor. The specimen is grasped and pulled into the expanded open distal end of the extractor, a cone shaped device. The grasper is then locked to the cannula using the setscrews. The proximal end of the extractor is equipped with a handle, which is used to pull the extractor and the tissue through the cannula. As the handle is pulled upward " . . . the enveloping means collapses around the tissue and returns to its pre-deployment." Thus the enveloping means of Graber '647 is relied on to compress the tissue to a size that allows it to be drawn into the shroud **610**, as shown in FIG. **13**. Thus, the device is not optimally designed to deal with a tissue specimen that will not compress to a point so that it can be drawn through the shroud.

The extractor of Graber '647 also has several other disadvantages. The Graber '647 device cannot be used with standard trocars since it utilizes setscrews, not generally available on trocars in current use, to lock it to the trocar, and it utilizes an expensive locking mechanism to lock the grasper to the extractor. In addition, most abdominal laparoscopic procedures are performed with the abdominal cavity insufflated with carbon dioxide. The lumen in the extractor of Graber '647 has no provision for sealing and thus when the extractor is placed through the trocar cannula's seal, the abdomen would loose its carbon dioxide pressure. The Graber '647 device is removed from the body cavity by an exertion force on the handle of the device. This unduly places rotational and shear forces on the extractor-grasper lever lock and the extractor-trocar setscrews in the case of a trocar cannula that employ screw threads to insure anchorage in the abdominal wall, since these cannula require rather vigorous rotational manipulation to remove them from the abdominal wall.

The extractor cover disclosed in the Graber '647 patent is made from "a sturdy waterproof, stain resistant fabric such as treated sailcloth or duck cloth." These materials are thick and bulky and therefore, are not useful for extractors for less invasive trocar cannula such as 5 mm and smaller devices, since multi-folds of the cover is required for the extractor to pass through small-bore cannula. FIG. **24** of the '647 patent discloses a thin "baggie," however, it requires thick leaves **608** and a plunger rod **606** to compress the tissue. The thickness of these unduly complicating features makes the Graber device ill-suited for small cannulas.

The embodiment disclosed in FIG. **12** of the '647 patent teaches the use of a flexible, waterproof web material with an opening mouth so that tissue can enter the rib portion **510**. While this embodiment partially solves the spillage problem it unduly complicates manipulating the tissue inside the extractor and is overly complex in that the extractor cover and the spillage compartment are made of two separate pieces and must be joined by sewing, heat treating, or welding.

Laparoscopic removal of the gallbladder has, heretofore, entailed the use of four entry cannula, typically two of which are 10/12 mm in diameter and two of which are 5 mm in diameter. The two 5 mm ports are used to accept instruments such as scissors, graspers, electro-surgery probes, and suction/irrigation devices. The 10/12 mm ports are employed to allow the use of 10 mm endoscopes attached to a camera for viewing the surgical field, to allow a clip applier for ligating vessels and ducts, and to allow the removing of the gallbladder following its excision.

In an effort to make the procedure less invasive, 5 mm clip appliers have been developed, such as the one described by Shipp et al. in U.S. Pat. No. 5,858,018. The 5 mm clip applier allows the conversion of one of the two 10/12 mm ports to a third 5 mm port. The remaining 10/12 mm port prior to this invention has been required to accept 10 mm endoscopes and to allow for the removal of the gallbladder, usually through the umbilicus port site. New bright 5 mm endoscopes coupled with more sensitive cameras have been developed that are quite acceptable substitutes for the prior art camera systems. These new developments leave the gallbladder removal through a 5 mm or smaller port as the last obstacle to the full conversion of the process to four much less invasive 5 mm ports. The conversion from two 10 mm and two 5 mm trocars to all 5 mm trocars lowers the entry wounds area by 50 percent, which greatly reduces bleeding and post surgery incisional herniation at the wound sites.

What is needed then is a simple, inexpensive device and a simple, easy to use method for rapid removal of tissue, such as a gallbladder, from a wound site that is smaller than the specimen and one that does not require a substantial secondary operation such as grinding the specimen into smaller pieces, or require that the wound be significantly enlarged.

SUMMARY OF THE INVENTION

The present invention in one embodiment is directed to an expandable dilator extractor that expands upon entry into the abdominal cavity for acceptance of a tissue specimen using a grasper to pull the specimen into the interior of the dilator extractor. The construction of the dilator is such that when a surgeon places an upward force, away from the surface of the abdomen on the deployed dilator, it first causes features inside the tissue space of the dilator extractor to minimize the cross section of the tissue, and thus minimize the wound dilation requirement. This in turn decreases the force required to remove the tissue. The features inside the tissue space of the dilator extractor also preferably grip the tissue so as to keep the tissue in the elongated state and to prevent its motion downward towards the abdominal cavity as the radial forces of the trocar puncture wound act upon it during extraction. Finally, the resulting elongated conical shape forces the trocar puncture wound to expand to allow the larger specimen to be extracted with a minimum of tearing or otherwise permanently enlarging the wound.

The present invention also is directed to a method and describes an apparatus for easily removing fluid from tissue, such as bile from a gallbladder, to further reduce the tissue size prior to extraction.

In another embodiment, the tissue may be treated to partially dissolve the tissue and thus reduce the extraction force. To reduce yet even further the extraction force, the current invention in another preferred embodiment utilizes a very thin, low friction material in contact with the wound.

In another preferred embodiment, the distal end of the cover is open so that no ballooning occurs. Alternatively, the distal end of the cover is drawn up in a drawstring purse fashion. The pursed section is drawn somewhat proximally so that the bottom formed by the purse will serve to retain gallstones and small amounts of bile yet still allows the escape of entrapped gas, thus avoiding ballooning.

In another preferred embodiment the cover is allowed to vent by virtue of being constructed of breathable material such as GoreTeX™, or by virtue of appropriately placed venting holes. The dilator extractor of the present invention preferably employs a seal in the form of a valve at the proximal end to insure against loss of peritoneal pressure when a grasper or other tool is inserted or removed through its cannula into the abdominal cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic view of a syringe with a needle, a grasper, a dilator extractor, and a cannula in accordance with one embodiment of the present invention.

FIG. **2** is a partial side sectional view of the dilator extractor of FIG. **1** inserted in the cannula of FIG. **1**.

FIG. **3** is a partial side elevation view of the leading end of the dilator extractor of FIG. **1** in an expanded position.

FIG. **4** is a bottom plan view along line **4**—**4** of FIG. **3**.

FIG. **5** is an enlarged fragmentary cross sectional view along line **5**—**5** of FIG. **2**.

FIG. **6** is a partial side sectional view of the trailing end of a shaft of the grasper of FIG. **1** with a valve and a seal.

FIG. **7** is a partial side elevation view of a pair of jaws at the leading end of a grasper.

FIG. **8** is a side elevation view of a grasper, dilator extractor, and cannula inserted in the abdominal wall of a patient, the grasper being inserted in the dilator extractor, the dilator extractor being inserted in the cannula, the dilator extractor and cannula being shown in cross section with the dilator extractor in the expanded position.

FIG. **9** is a side elevation view of a syringe, grasper, dilator extractor, and cannula inserted in the abdominal wall of a patient, the grasper being inserted in the dilator extractor, the dilator extractor being inserted in the cannula, the dilator extractor and cannula being shown in cross section with a tissue specimen being aspirated in accordance with the instrumentation and method of the present invention.

FIG. **10** is a partial side elevation view of the grasper, dilator extractor, and cannula of FIG. **9** being withdrawn from the abdominal cavity with the tissue specimen in accordance with the instrumentation and method of the present invention.

FIG. **11** is a side elevation view of a grasper and cannula with another embodiment of a dilator extractor of the present invention having tissue engaging protrusions being withdrawn from the abdominal cavity with the tissue specimen.

FIG. **12** is a side partial cross sectional elevation view of a grasper and cannula with another embodiment of a dilator extractor of the present invention having a draw cable prior to being drawn in and withdrawn from the abdominal cavity with the tissue specimen.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference will now be made in detail to the present preferred embodiments (exemplary embodiments) of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference

numbers will be used throughout the drawings to refer to the same or like parts.

FIG. **1** shows a tool set **50** having a cannula **100**, a dilator extractor **200**, a grasper **300**, and syringe device **400**. As shown in FIGS. **1** and **9**, syringe **400** is insertable in grasper **300**, which is in turn insertable in dilator extractor **200**, which in turn is insertable in cannula **100** to form a multi-coaxial assembly for use in laparoscopic surgery.

Referring to FIGS. **2–4** and **8**, dilator extractor **200** is inserted into a pressurized abdominal cavity **60** through the abdominal wall of a patient. Dilator extractor **200** enters through valve **102** at trailing end **106** of cannula **100**.

Dilator extractor **200** includes a body **202** having a leading end **204**, a trailing end **206**, a longitudinal axis L, and a lumen **208**. Body **202** includes a dilator **210** at leading end **204** that is movable between an unexpanded position, shown in FIG. **2**, and an expanded position, shown in FIG. **8**. Trailing end **206** preferably includes a depth-limiting protrusion in the form of shoulder **207**. Shoulder **207** is adapted to limit the depth of insertion of dilator extractor **200** into cavity **60** of the patient.

When the trailing end portion of dilator **210** clears leading end **104** of cannula **100**, dilator **210** expands to the expanded position owing to memory elements **212**, thus forming a truncated conical-shaped tissue receiving space **214**, enclosed by a dilator cover **216**.

FIG. **2** shows dilator extractor **200** before dilator **210** clears leading end **104** of cannula **100**. Dilator **210** may be preserved in the unexpanded position because of the restraints of a later described retainer **218** or the inner diameter of cannula **100**. In the unexpanded position memory elements **212** are elastically bent inward to permit dilator **210** to have a maximum lateral dimension preferably in the range of 3 mm to 5 mm. Dilator cover **216** is preferably wrapped around memory elements **212** to allow the passage of dilator extractor **200** in the unexpanded position through cannula **100**.

In a preferred embodiment, retainer **218** maintains dilator extractor **200** in the unexpanded state. One suitable retainer is straw-shaped and encircles dilator **210**. Retainer **218** extends toward trailing end **206** of dilator extractor **200** terminating into a graspable surface grip **220** proximate trailing end **206**. The composition of retainer **218** is such that it is strong enough to restrain the spring forces of dilator **210**, yet an upward force on graspable surface grip **220** will cause retainer **218** to peel open allowing dilator **210** to expand. By way of example, a suitable strength welded seam in a polyurethane film can accomplish such a peeling feature.

FIGS. **3** and **4** show dilator **210** in the expanded position. In a preferred embodiment, flat steel wire is formed to an appropriate expansion angle to form memory elements **212**. Preferably, four such wires are attached to body **202** of dilator extractor **200** using appropriate fasteners or by welding them to body **202**. In alternate embodiments, memory elements **212** may include alternate memory materials such as certain types of polymers and may be integral extensions of dilator extractor **200**. Stamped and rolled stainless steel also would provide a dilator such that the memory elements are integral to the body of the device.

Memory elements **212** are preferably parallel to the longitudinal axis of dilator extractor **200** when dilator extractor is in the unexpanded position. As shown in FIG. **3**, when dilator extractor **200** is in the expanded position, memory elements **212** preferably expand dilator **210** to form an angle A between cover **216** of dilator **210** and the longitudinal axis of dilator extractor **200** of at least 10 degrees, more preferably 20 degrees.

Although four longitudinal memory elements **212** are preferred, other forms of memory elements are sufficient for the purpose of expanding dilator **210**. For example, a single memory element may be positioned at leading end **211** of dilator **210** and adapted to run along the circumference of leading end **211**. Other circumferential memory elements may be concentrically included between leading end **211** and leading end **204** of body **202** along dilator **210**. As a further example, a single memory element may form a conical coil adapted to expand dilator **210** in both a longitudinal and axially transverse direction.

Once dilator **210** of dilator extractor **200** is in the expanded position as depicted in FIG. **8**, grasper **300**, in a preferred embodiment, is inserted through channel or lumen **208**, into tissue space **214**, and into cavity **60**.

As shown in FIG. **5**, trailing end **206** preferably includes first and second seals **222**, **224**, respectively. First seal **222** preferably forms a duckbill "V" shaped valve made of a resilient material that forms a seal when no instrument is inserted into lumen **208**. Second seal **224** is preferably formed of a resilient material containing a through hole **226** in its center. Through hole **226** is preferably smaller than the maximum cross sectional dimension of the instrument that the through hole is adapted to receive and forms a seal when the instrument is inserted into lumen **208**. For example, both seals may preferably be configured to permit the passage of grasper **300** therethrough while inhibiting a loss of pressure from within the patient. It is appreciated that more than or less than two seals may be used without departing from the scope of the present invention.

As shown in FIG. **9**, excised tissue **70** is grasped by jaws **310**, **312** of grasper **300** and pulled inside conical tissue space **214**. First and second seals **222**, **224** seal around the outside diameter of grasper **300** so that pressure inside cavity **60** is maintained as grasper **300** and tissue **70** are manipulated. Once tissue **70** is inside conical tissue space **214**, the entire assembly (grasper **300**, dilator extractor **200**, trocar cannula **100**, and tissue **70**) is ready for extraction.

In instances where the tissue specimen is larger than the inside diameter of cannula **100**, such as would usually be the case for a gallbladder specimen with a 5 mm cannula for example, dilator **210** will close somewhat under the influence of the upward force of the surgeon until memory elements **212** and the tissue resilient forces offset the radial forces asserted by the abdominal wall. At this point conical tissue space **214** of dilator extractor **200** will no longer contract and grasper **300**, dilator extractor **200**, and cannula **100** will be locked together in a more or less rigid fashion. This condition is depicted in FIG. **10**. Dilator extractor **200** is constructed in such a manner that application of additional force causes the wedge shape of dilator **210** to begin to increase or dilate the trocar wound in the abdominal wall as the surgeon applies more and more upward force. The larger the specimen, the larger the force necessary to dilate the abdominal wall wound to a size large enough to allow the entire assembly to be removed. The tensile strength of dilator **210** must be adequate to withstand the extraction force. The shape of the trocar puncture wound is important to insure against tearing of the entry wound. A slit entry wound rather than star-shaped entry wound is preferred.

Grasper **300**, as shown in FIGS. **1** and **6–8**, has a shaft **302** having a leading end **304**, a trailing end **306**, and a lumen **308** through the center of shaft **302** that can be occupied by a hollow needle **402** of syringe device **400**. Shaft **302** includes jaws **310**, **312** at leading end **304** for grasping tissue therebetween. As shown in FIG. **7**, jaws **310**, **312** preferably

include surface roughenings such as ridges **314** on the grasping surface of each jaw. As will be appreciated by those of skill in the art, grasper **300** may be adapted to have more than two jaws. For example, a third jaw maybe used to provide a third grasping surface for grasping the tissue. It will be further appreciated that other jaw configurations are possible and within the scope of the present invention. Jaws **310, 312** may have a smooth grasping surface, or may have ridges **314**.

Shaft **302** preferably has a length in the range of 15 cm to 35 cm and an outside maximum cross sectional dimension of less than 5 mm. Lumen **308** of shaft **302** preferably has an inside maximum cross sectional dimension in the range of 1 mm to 4 mm.

As shown in FIGS. **6** and **8**, trailing end **306** of grasper **300** includes a pair of handles **320** for moving jaws **310, 312** relative to one another. Trailing end **306** also preferably includes first and second seals **322, 324**, respectively. First seal **322** preferably forms a duckbill "V" shaped valve made of a resilient material that forms a seal when no instrument is inserted into lumen **308**. Second seal **324** is preferably formed of a resilient material containing a through hole **326** in its center. Through hole **326** is preferably smaller than the maximum cross sectional dimension of the instrument that the through hole is adapted to receive and forms a seal when the instrument is inserted into lumen **308**. For example, both seals may preferably be configured to permit the passage of needle **402** therethrough while inhibiting a loss of pressure from within the patient. It is appreciated that more than or less than two seals may be used without departing from the scope of the present invention.

Trailing end **306** preferably includes a depth-limiting protrusion for limiting the depth of insertion of grasper **300** into the cavity. The depth-limiting protrusion may be formed as a shoulder, or may form a part of handles **320**.

As shown in FIGS. **1** and **9**, trailing end **406** of needle **402** extends beyond grasper handles **320**, and is fitted with a hypodermic syringe **408**. Needle **402** is movable distally so that it punctures the grasped tissue, for example, a gallbladder. Gallbladders that are distended with bile can thus be drained before extraction by aspirating the bile up through needle **402** and into syringe **408**. Alternately, suction for removing the bile can be supplied from any vacuum source such as an aspirator.

This embodiment allows for grasping, tissue manipulation, removal of bile, and extraction all through a single port site. Significantly, one embodiment of needle **402** and grasper **300** allows for the tissue to be firmly grasped by grasper **300** yet needle **402** can still pass through leading end **304** of grasper **300** into the tissue such as a gallbladder where it performs evacuation of the bile.

In one preferred embodiment cover **216**, as best shown in FIGS. **3** and **4**, is preferably made of a laminated, flexible, material that will allow it to be folded and contained in cannula **100** prior to expansion of dilator **210** of dilator extractor **200**. Cover **216** includes an inner surface **228** and an outer surface **230**.

Outer surface **230** of cover **216** preferably is made of a material having a low coefficient of friction, such as a low porosity PTFE (polytetrafluoroethylene). Inner surface **228** is preferably made of a material having a high coefficient of friction, such as coarse weave polyester or nylon. It will be appreciated by those skilled in the art that other materials are suitable for providing a coefficient of friction that is higher on inner surface **228** than outer surface **230** and are within the scope of the present invention. Preferably, the coefficient of friction of inner surface **228** is in the range of 0.5 to 1.0. The two materials are preferably laminated together to form a cell migration barrier **232** to avoid viable cancer cells that might be contained in the excised tissue from coming into contact with the trocar site wound. The low friction outer surface **230** of cover **216** minimizes the force required for extraction while the high friction inner surface **228** provides a gripping force on the tissue surface area and thereby minimizes the force transferred to the grasper/tissue interface during the dilation extraction process. The dilation forces acting on the dilator require that the tensile strength of cover **216** is adequate to withstand the friction force exerted by the tissue on inner surface **228**. Bifurcated PTFE and coarse woven polyester with a total thickness of the lamination of approximately 0.005 inches exhibits a tensile strength of about 10,000 PSI. This will accommodate a friction force between the tissue and cover **216** of about 30 pounds without the material of the cover tearing. The upward force placed on the apparatus by the surgeon is divided between cover **216** and the grasper-tissue interface, thus without significant friction between the inside of cover **216** and the tissue, all the extraction force is transmitted to the grasper-tissue interface.

FIG. **11** shows an alternate embodiment inner surface **228** of cover **216**. Memory elements **212** are equipped with tissue retaining protrusions such as teeth **234**. Preferably, teeth **234** are generally pointed toward trailing end **206** when dilator **210** is in the expanded position so that as dilator **210** closes around the tissue as shown in FIG. **11**, teeth **234** bite into the tissue, thus supplying the dominance of the counter acting force to the extraction force rather than the friction of the tissue against inner surface **228** of cover **216**.

It will be appreciated by those skilled in the art that other forms of tissue retaining protrusions are suitable for gripping the tissue, for example, tabs, ridges, and knurling. Additionally, the tissue retaining protrusions are preferably uniformly spaced around the longitudinal axis of dilator extractor **200** to provide an even distribution of retaining force against the tissue. Tissue retaining protrusions may also be spaced substantially about the entire area of inner surface **228** of cover **216**. Tissue retaining protrusions may be formed on cover **216**, memory elements **212**, or a combination thereof. Forming tissue retaining protrusions on memory elements **212** provides additional stability when withdrawing the assembly from the wound site. Preferably, the tissue retaining protrusions are adapted to grab the tissue without penetrating it in order to reduce the risk of content spillage from the tissue.

FIG. **12** shows another alternate embodiment of the present invention. Dilator **210** preferably includes an elongated cover portion **236** beyond the distal end of memory elements **212**. Elongated cover portion **236** preferably has a hem **238** that at least partially encloses a draw cable **240** at its leading end **242**. Draw cable **240** has a proximal end **244** adapted to lie beyond trailing end **306** of dilator extractor **200** and a distal end **246** adapted to close leading end **242** of elongated cover portion **236**. Distal end **246** of draw cable **240** is fed proximally through dilator extractor lumen **208** and out through seals **222, 224**. Preferably, distal end **246** of cable **240** is adapted to circumscribe the perimeter of cover **216** to form at least one loop around the longitudinal axis of dilator extractor **200**, preferably at hem **238**. More than one loop may be formed to provide greater strength for drawing in leading end **211** of dilator **210**.

In using draw cable **240**, the tissue is manipulated into tissue space **214**. The surgeon then pulls draw cable **240** proximally, thus drawing in leading end **242** of elongated

cover portion **236** like a drawstring purse. The pursed section is drawn somewhat proximally so that the bottom formed by the purse will serve to retain tissue and contents therein such as gallstones and small amounts of bile, yet still allow the escape of entrapped gas, thus avoiding ballooning.

Cover **216** of dilator **210** may be breathable or vented to avoid ballooning. Alternatively, vents with valves may be incorporated in the side of body **202** to vent off gases as the tissue is being extracted.

Having described the apparatus, methods for its use will now be described. It should be understood that the order disclosed is only preferred and that the steps may be performed in other orders while still being within the scope of the present invention. Additionally, some steps may be repeated as necessary.

A preferred method of removing tissue from the abdominal cavity is shown in FIGS. **8–10**. Cannula **100** is inserted through the abdominal wall and into cavity **60**, which is preferably pressurized. Preferably a cannula having a maximum diameter in the range of 3 mm to 5 mm is used in order to make the procedure less invasive. Dilator extractor **200** is inserted into cannula **100** through seal **102** to a position where leading end **211** of dilator **210** extends beyond leading end **104** of cannula **100**. Dilator **210** is expanded to form tissue extraction space **214**. Grasper **300** is inserted into dilator extractor **200** through seals **222**, **224** and through lumen **208**. The tissue is grasped by grasper **300** and manipulated into tissue space **214**. If desired, grasper **300** may be locked to dilator extractor **200** to provide more stability. If dilator extractor **210** includes elongated cover portion **236**, the surgeon may pull draw cord **240** at proximal end **244** to draw in elongated cover portion **236**, thus substantially trapping the tissue and any of its contents in tissue receiving space **214**. Next, an upward force is exerted on dilator extractor **200**, dilating the trocar wound such that the tissue is removed from the cavity under the influence of the upward force.

Alternately, for tissue containing a fluid such as bile in a gallbladder, additional steps may be included such as suctioning out the fluid prior to the extraction step. For example, needle **402** of syringe device **400** is inserted into grasper **300** through seals **322**, **324** and through lumen **308** to a position where leading end **404** of needle **402** extends beyond leading end **204** of body **202** of dilator extractor **200**. Fluid is then suctioned from the tissue through needle **402** by syringe **408**. It will be appreciated that vacuum sources other than syringe **408** may be used to aspirate the tissue, for example, an aspirator. It will be further appreciated that aspiration may occur during other phases of the operation prior to the extraction of the tissue from the wound site. For example, needle **402** may be inserted through lumen **208** of dilator extractor **200** and fluid suctioned from the tissue before grasper **300** is inserted or used.

To further reduce the extraction force needed to withdraw the assembly with the tissue, the tissue may be treated to at least partially dissolve the tissue or its contents, for example, gallstones of a gallbladder. A syringe may be used to inject a composition capable of dissolving tissue. One example of such a composition is methyl tert-butyl ether. The tissue is treated preferably after fluid is suctioned. It will be appreciated that the tissue may be treated irrespective of any fluid suction.

Simulated dilator extractors were built and tested in the abdominal cavity of a swine. Aluminum cones of varying base diameters representing varying tissue sizes simulated the dilator section. Abdominal access for the cones was gained through a 100 mm incision along the midline of the animal. A 5 mm trocar with a single sided cutting tip obturator (rather than the more common three side pyramidal tip) was used to entry the cavity through a circular 5 mm wound located approximately 30 mm to the left of the midline. Each of four simulators consisting of 5 mm cylinders, 100 mm long transitioning into truncated cones with 5 mm diameter tops tapering to bases of 15, 20, 25, 30 mm diameters respectively, were separately tested by inserting them through the access incision. The 5 mm trocar was then inserted into the abdominal cavity, the obturator removed, and the 5 mm simulator tops were then inserted from the distal of the cannula so that they were exposed above the cannula valve. A force gage was then attached to the exposed section. The vertical pull force required to dilate the 5 mm puncture wound so that the cone was total extracted from the animal was then measured with a calibrated force gage. A new 5 mm trocar site was used for each of the four cones. The extraction force is shown in the table below:

Cone Base Diameter, mm	Upward Extraction Force, lbs
15	12
20	21
25	37
30	50

Each measurement was repeated using the same puncture wound to test the extent to which the wound had been torn or permanently stretched. The data indicated that dilation of 2 to 3 times is possible. Up to 20–25 mm the forces are of reasonable magnitude to make the device practical. The minimizing wound size is important to minimizing postoperative hernias and other complications.

Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

We claim:

1. A method for aspirating material from an animal or human body cavity, the method comprising the steps of:

inserting an instrument adapted to manipulate the tissue through the body cavity, the instrument having a passage therein;

suctioning fluid from the tissue through the passage of the instrument; and

dilating the cavity to remove tissue that is unable to fit completely within a cannula without substantial compression of the tissue.

2. The method of claim **1**, further comprising the step of grasping the tissue with the instrument to remove the tissue from the cavity.

3. The method of claim **1**, further comprising the step of treating the tissue to at least partially dissolve the tissue or any contents in the tissue.

4. The method of claim **3**, wherein the treating step includes the sub-step of treating the tissue with methyl tert-butyl ether.

5. The method of claim **3**, wherein the treating step is performed through the passage of the instrument.

6. The method of claim **1**, further comprising the steps of inserting a cannula into the cavity, the cannula having a lumen adapted to accept the instrument.

7. The method of claim 1, wherein the dilating step is performed by the instrument.

8. The method of claim 7, wherein the instrument is a surgical extractor having a dilator.

9. The method of claim 1, wherein the suctioning step includes the step of suctioning bile from a gall bladder.

10. The method of claim 1, wherein the inserting step includes the step of inserting a cannula having a maximum diameter in the range of 3 mm to 5 mm.

11. The method of claim 1, further comprising the step of removing the tissue from the cavity.

12. A method for removing tissue from an animal or human body cavity that is unable to fit completely within a cannula without substantial compression, the method comprising the steps of:

inserting the cannula into the cavity;

inserting a dilator having a leading end through the cannula;

expanding the leading end of the dilator to an expanded position;

inserting a grasper through the dilator;

grasping the tissue with the grasper;

moving the tissue with the grasper into the dilator; and

removing the cannula and the dilator together with the dilator remaining substantially in the expanded position.

13. The method of claim 12, further comprising step of retaining the tissue within the expanded leading end of the dilator.

14. The method of claim 12, wherein the step of removing includes removing the dilator having a generally conical shape in the expanded position.

15. The method of claim 12, further comprising the step of suctioning fluid or other material from the tissue.

16. The method of claim 15, wherein the suctioning step includes the step of suctioning bile or other material from a gall bladder.

17. The method of claim 12, wherein the leading end of the dilator includes a draw cable for drawing in the leading end of the dilator, further comprising the step of pulling the draw cable to draw in the leading end of the dilator.

18. The method of claim 12, wherein the step of inserting the cannula includes inserting a cannula having a maximum diameter in the range of 3 mm to 5 mm.

19. A surgical tool set for removing tissue from an animal or human body cavity, said tool set comprising:

a surgical extractor dilator having a leading end, a trailing end, a length therebetween, and a lumen between the leading and trailing ends, said leading end having a dilator movable between an unexpanded position and an expanded position;

a grasper insertable within said lumen of said surgical extractor dilator, said grasper having a leading end with grasping surfaces, a trailing end with a handle, and a lumen between the leading and trailing ends, said lumen of said grasper adapted to permit the passage of a surgical instrument therethrough, said grasper having a length greater than the length of said surgical extractor dilator; and

an elongated needle adapted to insert within said lumen of said grasper, said needle having a length sufficient to extend beyond a distal end of said grasper.

20. The surgical tool set of claim 19, wherein said needle is adapted to be connected to a syringe.

21. The surgical tool set of claim 19, wherein said needle is adapted to be connected to an aspirator.

22. The surgical tool set of claim 19, further comprising a cannula for providing protected access to a surgical site, said cannula having a leading end, a trailing end, a length therebetween, and a lumen between the leading and trailing ends adapted to permit passage of said surgical extractor dilator therethrough.

23. The surgical tool set of claim 22, wherein said cannula has a maximum outer diameter less than 10 mm.

24. The surgical tool set of claim 23, wherein said cannula has a maximum outer diameter in the range of 3 mm to 5 mm.

25. The surgical tool set of claim 19, further comprising at least one seal oriented within said lumen of said surgical extractor dilator configured to permit the passage of said grasper therethrough while inhibiting a loss of pressure from within the body cavity after said surgical extractor dilator is inserted in the patient.

26. The surgical tool set of claim 25, wherein said at least one seal has a through-hole smaller than the maximum cross sectional dimension of said grasper.

27. A surgical extractor for moving tissue from an animal or human body cavity, the extractor comprising:

a body having a leading end, a trailing end, a longitudinal axis, and a lumen between said leading and trailing ends;

a dilator at the leading end of said body being movable between an unexpanded position and an expanded position, said dilator having an inner surface; and

tissue retaining protrusions on said inner surface of said dilator, said tissue retaining protrusions being uniformly spaced around the longitudinal axis of said body and being configured to generally point towards said trailing end of said body when said dilator is in the expanded position.

28. The surgical extractor of claim 27, wherein said tissue retaining protrusions are teeth.

29. The surgical extractor of claim 27, wherein said tissue retaining protrusions are spaced substantially about the entire area of said inner surface.

30. The surgical extractor of claim 27, wherein said dilator includes a memory element configured to expand said dilator from the unexpanded position to the expanded position.

31. The surgical a extractor of claim 30, wherein said dilator includes memory elements parallel to the longitudinal axis when said dilator is in the unexpanded position.

32. The surgical extractor of claim 30, wherein said memory element is adapted to expand said leading end of said dilator to an angle of at least 10 degrees from the longitudinal axis of said surgical extractor.

33. The surgical extractor of claim 30, wherein said memory element is adapted to expand said leading end of said dilator to an angle of at least 20 degrees from the longitudinal axis of said body.

34. The surgical extractor of claim 27, further comprising a retainer around at least a portion of said dilator for maintaining said dilator in the unexpanded position, said retainer being adapted to be removed from said dilator, thereby allowing said dilator to move to the expanded position.

35. The surgical extractor of claim 27, wherein said dilator has a maximum diameter in the range of 3 mm to 5 mm in the unexpanded position.

36. The surgical extractor of claim 27, wherein said tissue retaining protrusions are formed from a memory element.

37. A surgical extractor for removing tissue from an animal or human body cavity, the extractor comprising: a body having a leading end, a trailing end, a longitudinal axis, and a lumen between said leading and trailing ends;

a dilator at the leading end of said body being movable between an unexpanded position and an expanded position, said dilator having an inner surface, said dilator including a cell migration barrier formed between at least two different materials; and

tissue retaining protrusions on said inner surface of said dilator, said tissue retaining protrusions being uniformly spaced around the longitudinal axis of said body.

38. The surgical extractor of claim 37, wherein one of said materials is PTFE.

39. The surgical extractor of claim 37, wherein one of said materials is polyester.

40. The surgical extractor of claim 37, wherein said tissue retaining protrusions are teeth.

41. The surgical extractor of claim 37, wherein said tissue retaining protrusions are spaced substantially about the entire area of said inner surface.

42. The surgical extractor of claim 37, wherein said dilator includes a memory element configured to expand said dilator from the unexpanded position to the expanded position.

43. The surgical extractor of claim 42, wherein said dilator includes memory elements parallel to the longitudinal axis when said dilator is in the unexpanded position.

44. The surgical extractor of claim 42, wherein said memory element is adapted to expand said leading end of said dilator to an angle of at least 10 degrees from the longitudinal axis of said surgical extractor.

45. The surgical extractor of claim 42, wherein said memory element is adapted to expand said leading end of said dilator to an angle of at least 20 degrees from longitudinal axis of said body.

46. The surgical extractor of claim 37, further comprising a retainer around at least a portion of said dilator for maintaining said dilator in the unexpanded position, said retainer being adapted to be removed from said dilator, thereby allowing said dilator to the expanded position.

47. The surgical extractor of claim 37, wherein said dilator has a maximum diameter in the range of 3 mm 5 mm in the unexpanded position.

48. The surgical extractor of claim 37, wherein said tissue retaining protrusions are formed from a memory element.

49. A surgical extractor for removing tissue from an animal or human body cavity, the extractor comprising:

a body having a leading end, a trailing end, a longitudinal axis, and a lumen between said leading and trailing ends;

a dilator at the leading end of said body being movable between an unexpanded position and an expanded position said dilator having an inner surface and a memory element configured to expand said dilator from the unexpanded position to a expanded position, said memory element being along a circumference of said dilator; and

tissue retaining protrusions on said inner surface of said dilator, said tissue retaining protrusions being uniformly spaced around the longitudinal axis of said body.

50. The surgical extractor of claim 49, wherein said memory element is positioned at a leading end of said dilator.

51. The surgical extractor of claim 49, wherein said tissue retaining protrusions are teeth.

52. The surgical extractor of claim 49, wherein said tissue retaining protrusions are spaced substantially about the entire area of said inner surface.

53. The surgical extractor of claim 49, wherein said memory element is adapted to expand and said leading end of said dilator to an angle of at least 10 degrees from the longitudinal axis of said surgical extractor.

54. The surgical extractor of claim 49, wherein said memory element is adapted to expand said leading end said dilator to an angle of at least 20 degrees from the longitudinal axis of said body.

55. The surgical extractor of claim 49, further comprising a retainer around at least a portion of said dilator for maintaining said dilator in the unexpanded position, a said retainer being adapted to be removed from said dilator, thereby allowing said dilator to move to the expanded position.

56. The surgical extractor of claim 49, wherein said dilator has a maximum diameter in the range of 3 mm to 5 mm in the unexpanded position.

57. The surgical extractor of claim 49, wherein said tissue retaining protrusions are formed from a memory element.

58. A surgical extractor for removing tissue from an animal or human body cavity, the extractor comprising:

a body having a leading end, a trailing end, a longitudinal axis, and a lumen between said leading and trailing ends; and

a dilator at the leading end of said body being movable between an unexpanded position and an expanded position, said dilator having an inner surface made substantially of a first material and an outer surface made substantially of a second material, said first material of said inner surface having a coefficient of friction greater than a coefficient of friction of said second material of said outer surface.

59. The surgical extractor of claim 58, wherein the coefficient of friction of said inner surface of said dilator is in a range from 0.5 to 0.9.

60. The surgical extractor of claim 58, wherein said dilator includes a cell migration barrier formed between at said first and second materials.

61. The surgical extractor of claim 58, wherein one of said materials is PTFE.

62. The surgical extractor of claim 58, wherein one of said materials is polyester.

63. The surgical extractor of claim 58, further comprising surface roughenings along said inner surface.

64. The surgical extractor of claim 58, further comprising protrusions adapted to grab tissue without penetrating the tissue.

65. A surgical extractor for removing tissue from an animal or human body cavity, the extractor comprising:

a body having a leading end, a trailing end, a longitudinal axis, and a lumen between said leading and trailing ends;

a dilator at the leading end of said body being movable between an unexpanded position and an expanded position; and

a retainer for restricting said dilator in the unexpanded position, said retainer being adapted to be removed from said dilator, thereby allowing said dilator to move to the expanded position, said retainer including a grip proximate said trailing end of said body for peeling open said retainer.

66. The surgical extractor of claim 65, wherein said retainer comprises a polyurethane film.

67. A surgical extractor for removing tissue from an animal or human body cavity of a patient, the extractor comprising:

a body having a leading end, a trailing end, a longitudinal axis, and a lumen between said leading and trailing ends;

a dilator at the leading end of said body being movable between an unexpanded position and an expanded position, said dilator having a leading end;

a cover at the leading end of said dilator adapted to capture the tissue prior to the extraction thereof from the patient; and

a draw cable running through said lumen of said body, and having at least one loop at the leading end of said cover, said draw cable being adapted to draw in said cover upon moving said draw cable away from the trailing end of said body.

68. The surgical extractor of claim 67, wherein said cover includes a hem enclosing at least a portion of said draw cable.

69. The surgical extractor of claim 67, wherein said draw cable is adapted to run from said cover through said lumen of said body and lie beyond said trailing end of said body.

70. The surgical extractor of claim 67, wherein said cover has a perimeter and a distal end of said draw cable is adapted to circumscribe the perimeter of said cover to form said a least one loop.

71. The surgical extractor of claim 70, wherein said draw cable is adapted to form a plurality of loops around the perimeter of said cover.

72. The surgical extractor of claim 67, wherein said cover is made from a breathable material.

73. The surgical extractor of claim 67, wherein said cover is watertight.

74. A method for removing tissue from an animal or human body cavity, the method comprising the steps of:

inserting a cannula into the cavity;

inserting a dilator into the cannula, the dilator having a leading end with a cover attached thereto, the cover having draw cable adapted to draw in the cover;

expanding the leading end of the dilator to an expended position;

moving the tissue into the dilator; and

drawing the draw cable.

75. The method of claim 74, wherein the drawing step includes the step of drawing the draw cable to draw in the cover while the tissue is within the cavity.

76. The method of claim 74, further comprising the step of dilating the cavity to remove the tissue.

77. The method of claim 74, further comprising the steps of inserting a grasper through the cannula and grasping the tissue with the grasper to remove the tissue from the cavity.

78. The method of claim 74, wherein the draw cable has a distal end attached to the cover an a proximal end lying outside the cannula, the pulling step including the sub-step of pulling the proximal end of the draw cable to draw in the cover.

79. A method of removing tissue from an animal or human body cavity, the method comprising the steps of:

inserting a cannula into the body cavity;

inserting a dilator having a leading end through the cannula;

expanding the leading end of the dilator to an expanded position;

inserting a grasper having a passage into the body cavity;

suctioning fluid from the cavity through the passage of the grasper; and

grasping the tissue to remove the tissue from the cavity.

80. The method of claim 79, further comprising the step of removing the cannula with the dilator remaining substantially in the expanded position.

81. The method of claim 79, wherein the leading end of the dilator includes a draw cable for drawing in the leading end, further comprising the step of pulling the draw cable to draw in the leading end of the dilator.

82. The method of claim 79, further comprising the step of removing the cannula with the dilator remaining substantially in the expanded position.

83. The method of claim 79, wherein the step of inserting the cannula includes inserting a cannula having a maximum diameter in the range of 3 mm to 5 mm.

84. The method of claim 79, wherein the step of suctioning includes the step of suctioning bite or other material from a gall bladder.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,958,069 B2
DATED : October 25, 2005
INVENTOR(S) : John I. Shipp et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 10,
Line 65, change “steps” to -- step --.

Column 11,
Line 60, change “to insert” to -- to be inserted --.

Column 12,
Line 21, change “moving” to -- removing --.

Column 13,
Lines 2 and 3, rewrite as follows:
-- animal or human body cavity, the extractor comprising:
a body having a leading end, a trailing end, a longitudinal axis, --.
Line 42, after “dilator” add -- to move --.
Line 55, change “position” to -- position, --.
Line 57, change “a” to -- the --.

Column 14,
Line 5, delete “and”.
Line 9, after “end” insert -- of --.
Line 14, delete “a”.

Column 15,
Line 26, change “a” to -- at --.
Line 40, after “having” insert -- a --.
Line 41, change “expended” to -- expanded --.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

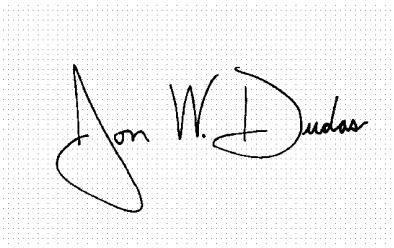
PATENT NO. : 6,958,069 B2
DATED : October 25, 2005
INVENTOR(S) : John I. Shipp et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 16,
Line 10, change "an" to -- and --.
Line 39, change "bite" to -- blle --.

Signed and Sealed this

Thirty-first Day of January, 2006



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Director of the United States Patent and Trademark Office

专利名称(译)	用于腹腔镜手术的器械和方法		
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摘要(译)

手术扩张器抽取器通过套管针套管引入腹腔并在远端处扩张，形成组织接收空间。然后通过插入穿过扩张器提取器中的内腔的抓紧器将待提取的组织操纵到该空间中。然后，外科医生通过向扩张器提取器施加力来从组织中取出组织，该力确保组织的伸长并使入口伤口暂时扩张到组织被移除所需的程度。还公开了手术扩张器提取器和相关器械工具组的替代实施例及其使用方法。