The invention provides an exemplary system, and method for interfacing with the hollow body cavity. The system comprises a manipulable sleeve (10) have a proximal end, a distal end, and a handle (16) at the proximal end. An internal lumen (18) extends between the proximal, the distal ends, and a manipulation mechanism (48) is included at the handle to manipulate the distal end of the sleeve. A flexible fiberscope (54) is provided which is inserted into the internal lumen (18) to allow the fiberscope (54) to be manipulated by operation of the manipulation mechanism (48).
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FLEXIBLE ENDOSCOPIC SYSTEM AND METHODS

BACKGROUND OF THE INVENTION

This invention relates generally to the field of scopes for imaging hollow body cavities. More specifically, the invention relates to the use of a flexible endoscopic system for visualizing the interior of a hollow body cavity. The invention also provides for an operative system that is useful in connection with the diagnostic scope.

The development of fiberscopes has greatly facilitated the visualization of the interior of a hollow body cavity in a non-intrusive manner. Traditional fiberscopes are constructed of fiber optic bundles, a light cable and a lens system. The proximal end of the fiberscope also includes an eye piece so that when the fiberscope is inserted into a body cavity, an image of the body cavity can be visualized from outside the patient by looking through the eye piece.

Fiberscopes are typically encased in a rigid tube or sheath to form an endoscope, also referred to as hysteroscopes, cavitoscopes, cystoscopes, urethroscopes, borescopes, and the like. However, construction of the endoscope to include a rigid sheath limits the field of vision within the body cavity. In view of such limitations, some have proposed creating a permanent bend in the endoscope. Although such a bend may facilitate the visualization of a different region of the hollow body cavity, the field of vision is still restricted to a single location as dictated by the angle of the bend.

Hence, it would be desirable to provide an improved endoscopic system having improved visualization capabilities. It would be desirable if such an endoscopic system were easy to use while providing a wide range of vision within a body cavity. It would be particularly desirable if such an endoscopic system worked in combination with various other systems of an operative kit. For example, it would be desirable if such a kit provided various options including introducing and removing various fluids to and from the hollow body cavity, providing a seal between the body cavity and the endoscope, providing electrosurgical features, and providing the option of performing directed biopsies.

SUBSTITUTE SHEET (RULE 26)
SUMMARY OF THE INVENTION

The invention provides exemplary systems and methods for interfacing with a hollow body cavity. In one exemplary embodiment, a system is provided which comprises a manipulatable sleeve having a proximal end, a distal end, and a handle at the proximal end. An internal lumen extends between the proximal end and the distal end, and a manipulation mechanism is included at the handle to manipulate the distal end of the sleeve. The sleeve is configured such that a flexible fiberscope may be inserted into the internal lumen to allow the fiberscope to be manipulated by operation of the manipulation mechanism.

In this way, a flexible fiberscopic system is provided having sufficient pushability and protection to allow the combined fiberscope and sleeve to be inserted into the hollow body cavity. Once within the hollow body cavity, the manipulation mechanism may be operated to manipulate the distal end of the fiberscope while within the body cavity.

In a particular aspect, the manipulation mechanism comprises a pull wire having a distal end which is attached to the distal end of the manipulatable sleeve and a lever to move the pull rod. Preferably, the manipulatable sleeve includes a plurality of outer lumens, and the pull wire is disposed in one of the outer lumens. Optionally, one or more stationary wires may be disposed in some of the outer lumens to bias the sleeve in a generally straight orientation and to provide a degree of rigidity to the sleeve to facilitate its introduction into the hollow body cavity. In one particularly preferable aspect, the sleeve is constructed of a flexible material, such as a flexible polymer, to facilitate its manipulation when within the body cavity.

In yet another aspect, the handle includes an irrigation port and an aspiration port. The irrigation and aspiration ports are each in communication with one of the outer lumens. In this way, fluids may be introduced into and withdrawn from the hollow body cavity through the sleeve.

In still another aspect, the system includes a sheath having an expansible cuff. The sheath is configured to receive the sleeve. In this way, the sheath may be introduced into the hollow body cavity and the cuff expanded to provide a seal with the body cavity. In this manner, when the sleeve is inserted into the sheath and the body cavity is distended with a fluid, the fluid will not escape out.
of the body cavity. Preferably, the expansible cuff comprises a balloon or other expansible member. The sheath may be inserted into the body cavity with the assistance of an atraumatic obturator which is insertable into the sheath. Preferably, the obturator comprises a rod which is constructed of a flexible polymer. Instead of using the obturator, the fiberscope and sleeve may be inserted into the sheath and the combined sleeve and sheath inserted directly into the body cavity.

In one particular aspect, an electrosurgical element is disposed at the distal end of the sleeve. In this way, various electrosurgical procedures may be performed using the sleeve (which will be connected to an electrosurgical power supply). A variety of electrosurgical elements may be attached to the distal end of the sleeve, including wire loops, snares, cauterizing tips and the like. A return electrode may also be disposed in the sleeve.

The system of the invention is also useful in providing other operative features. For example, the fiberscope may be removed from the sleeve and a biopsy tool inserted through the internal lumen. By using the fiberscope, the sleeve may be manipulated to a particular region in the body cavity where it is desired to perform a biopsy procedure. The sleeve can then be maintained in this orientation while the fiberscope is removed and the biopsy tool is inserted. In this way, a method is provided for performing directed biopsies.

The invention further provides an exemplary method for diagnosing and/or treating a hollow body cavity. According to the method, a manipulatable sleeve is provided having a proximal end, a distal end and a handle at the proximal end. An internal lumen extends between the proximal end and the distal end, and a manipulation mechanism is included at the handle to manipulate the distal end of the sleeve. The distal end of the sleeve is inserted into the body cavity, and a flexible fiberscope is introduced into the internal lumen until the distal end of the fiberscope is within the body cavity. The manipulation mechanism is then operated to manipulate the fiberscope while within the body cavity. A portion of the interior of the body cavity is then viewed with the fiberscope.

Optionally, the sleeve may be rotated to facilitate the viewing of another portion of the interior of the body cavity. To facilitate introduction of the sleeve
into the body cavity, a sheath may be inserted into the body cavity, and the sleeve inserted into the sheath. The sleeve (in combination with the fiberscope) may be introduced into the sheath prior to inserting the sheath into the body cavity. Alternatively, an obturator may be inserted into the sheath prior to introducing the sheath into the body cavity.

In another aspect of the method, a cuff on the sheath is expanded to provide a seal between the body cavity and the sheath. In still another aspect, the sleeve includes a plurality of outer lumens so that a fluid may be introduced into the cavity through one of the outer lumens. In this way, fluids may be introduced into the body cavity to distend the body cavity. Conveniently, fluid may be withdrawn from the body cavity through another one of the lumens. In this manner, fluids may be circulated through the body cavity to clear the field of vision. In one particular aspect, the distal end of the fiberscope may be positioned near the distal end of the sleeve so that as a fluid is introduced through one of the outer lumens, the lens on the fiberscope is cleaned.

In one particularly preferable aspect, the sleeve may be provided with an electrosurgical element at the distal end. In this way, various electrosurgical procedures may be performed on at least a portion of the interior of the body cavity. For example, the electrosurgical element may be employed to perform cauterization, polyp removal, cutting, snaring, vaporizing, fulgurating, desiccating, and the like. Advantageously, the fiberscope may be maintained within the sleeve while performing the electrosurgical procedure so that the region of interest may be viewed with the fiberscope while performing the treatment. Similarly, the sleeve may be manipulated with the manipulation mechanism while performing the electrosurgical procedure.

In another particularly preferable aspect, the body cavity comprises the uterus, and the sleeve is introduced through the cervical canal. In still another aspect, the fiberscope may be removed from the sleeve after a region of interest has been located. A biopsy tool is then inserted through the internal lumen to perform a directed biopsy.

While being particularly useful in treating the uterus, the invention will also find use in treating other hollow body cavities. For example, the invention is
useful in a wide variety of both gynecologic and laparoscopic procedures, including procedures for treating ailments such as endometriosis, adhesions, myomas, and the like. In laparoscopic applications, the invention functions as a low profile directional viewing system having micro electrosurgical and intraluminal tool passage capabilities. More specifically, the sleeve may be used to provide a pneumoperitoneal seal while also providing for multiple-pass access into the body cavity. Some of the lumens may be used to provide irrigation and suction commonly used in laparoscopy procedures. Some of the lumens may also be used to facilitate introduction of various micro-instruments, e.g. graspers, biopsy needles, and the like.

The invention is particularly useful in laparoscopic procedures because it provides a close range visualization system using a relatively small percutaneous port. In this way, minor abnormalities requiring minimal intervention may be treated using small tools (including those with electrosurgical function) which are used in a clear working environment.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of an exemplary manipulatable sleeve according to the invention.

Fig. 1A is a cross-sectional view of the sleeve of Fig. 1 taken along lines A-A.

Fig. 1B is a cross-sectional end view of an alternative sleeve design according to the invention.

Fig. 2A is a side view of a handle of the sleeve of Fig. 1.

Fig. 2B is a cross-sectional end view of the handle of Fig. 2A.

Fig. 3 is a side view of a flexible fiberscope that is insertable into the sleeve of Fig. 1 according to the invention.

Fig. 3A is an end view of the fiberscope of Fig. 3.

Fig. 4 is a side view of an exemplary sheath having an expansible cuff according to the invention.

Fig. 5 is a side view of an atraumatic obturator that is insertable into the sheath of Fig. 4 according to the invention.
Figs. 6-12 illustrate an exemplary method for visualizing the interior of a hollow body cavity using the components illustrated in Figs. 1-5.

Fig. 13 is a side view of an exemplary wire loop that may be incorporated into the sleeve of Fig. 1.

Fig. 13A is an end view of the wire loop of Fig. 13.

Fig. 13B illustrates the wire loop of Fig. 13 included within a sleeve according to the invention.

Fig. 13C is an end view of the wire loop and sleeve of Fig. 13B.

Fig. 13D illustrates deployment of the wire loop of Fig. 13B according to the invention.

Fig. 14 illustrates a biopsy tool that is insertable through the sleeve of Fig. 1.

Figs. 15A-15C illustrate view of a sleeve having electrodes for use in myolysis procedures according to the invention.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The invention provides exemplary systems, devices and methods for visualizing and/or treating a hollow body cavity in a non-intrusive manner. One exemplary system provides various components in kit form. In this way, the components may be used in combination to perform the various diagnostic and/or operative procedures. The versatility of the system allows it to be used in diagnosing or treating a wide variety of hollow body cavities, including the uterus, prostate, ureter, urethra, bladder, urinary outflow tract organs and ducts, cervix, and the like. Central to the system is a sleeve having a distal end that may be manipulated from the proximal end. Such a sleeve allows various components to be introduced through the sleeve and then manipulated from outside of the patient. As one example, a flexible fiberscope may be inserted into the sleeve so that the sleeve may be manipulated to in turn manipulate the distal end of the fiberscope. When properly positioned, the fiberscope may optionally be removed from the sleeve and other instruments or devices inserted through the sleeve as described hereinafter.

Use of the manipulatable sleeve is further advantageous in that a variety of deployable tip types may be used in combination with the sleeve to provide a
wide variety of diagnostic and/or operative features. For example, various
electrosurgical elements may be provided at the distal end of the sleeve,
including electrocautery loops, electrocautery and biopsy snare tips, cautery
spheres/tips, and the like. Such electrosurgical elements may be utilized while
the fiberscope remains in the sleeve so that the procedures may be performed
under direct visualization.

A further advantage of the sleeve is that it includes a variety of lumens
through which various diagnostic and/or operative elements may be introduced.
For example, in addition to receiving the fiberscope, various instruments
including baskets, snare, scissors, biopsy pipelles, grasping forceps, and the
like could be introduced into the body cavity through the various lumens of the
sleeve. The lumens may also be employed to perform directed biopsy
procedures, to house deployable RF current conductors and/or tools, to deliver
distention media into the hollow body cavity, to introduce needles for drug
therapy, and the like.

The sleeve of the invention may be manipulated in a variety of ways. For
example, the distal end may be provided with a shaped distal tip that may be
straightened by introducing a fiberscope or telescope through the sleeve. The
distal tip may alternatively be manipulated using eccentric tensioning wires that
are operated from the proximal end or handle. As another alternative, the distal
end may be shaped with a shaping wire or memory material that may be
straightened with a straightening mandrel disposed adjacent to the shaping
wires.

A variety of scope types may be introduced through the sleeve to
visualize the interior of the body cavity. For example, endoscopes, telescopes,
fiberscopes, cavitoscopes, and the like may be introduced through the sleeve.
These may either be rigid, semi-rigid, or flexible, and will preferably have an
outer diameter in the range from about 0.3 mm to about 2 mm.

As previously described, the sleeve of the invention is preferably
constructed of a multi-lumen body. Such a construction provides for a number of
advantages including, allowing for inflow and outflow of irrigation/distension
media, the housing of articulating and stiffening wires, and the delivery of
surgical and diagnostic instruments. Optionally, an inflow lumen of the sleeve
may be thermo formed to produce a hydro-deflection which cleans the lens of
the scope and clears its field of vision. Some of the lumens may also be used to
support various combinations of deployable electrosurgical tools as previously
described. Further, the actuating and stiffening wires may also be used to pass

5 electrical RF current to the distal tip. The sleeve preferably includes at least one
working lumen passing the length of the sleeve which allows the passage of the
scope and larger sized surgical instruments. The working lumen preferably has a
diameter that is in the range from about 0.3 mm to about 3 mm.

Other features of the system include the ability to deflect the distal end of

10 the sleeve at least 900 so that acute angulation may be provided. Further, a
highly distensible sheath is provided having a balloon that is able to autoposition
and anchor the sheath within the cervical canal. In this way, the sleeve may be
introduced into the uterus through the sheath.

The system of the invention provides a variety of clinical advantages.

15 Such advantages include, for example, the ability to use the working lumen of
the sleeve to perform a directed biopsy. This is best accomplished by employing
the scope to properly position the distal end of the sleeve. The distal end is then
held in place while the scope is removed and a biopsy device is inserted through
the working lumen. For example, a pipelle or biopsy needle may be inserted

20 through the working lumen. Alternatively, a hollowed grasper type instrument
may be employed. As another alternative, a biopsy snare may be introduced
through the working lumen.

By providing both inflow and outflow capabilities, irrigation and/or
distension media may be introduced into the body cavity to optimize visibility and
distension. In another advantage, the introduction and delivery of the sleeve
under direct visualization using a flexible or semi-rigid scope optimizes the
orientation and navigation of the scope while minimizing or eliminating the risk of
perforation. Another advantage is that the use of the highly distensible sheath
balloon allows for cervical voids to be filled while occluding outflow. In this way,
interuterine pressure, and therefore distension, is maintained more easily and
visibility is optimized.

Still a further clinical advantage is that steerability of the sleeve permits
access and visualization to extreme, e.g., deep lateral, regions of the body
cavity. Steerability and tool deployability also allows for manipulation of surgical tools under direct visualization. Still another advantage is that the flexible distal tip and body of the sleeve allows the body to remain atraumatic during introduction and manipulation within the body cavity.

The sleeve of the invention will preferably be introduced into a body cavity through a sheath. In turn, the sheath may be inserted with the assistance of an obturator. One particular clinical advantage of such an arrangement is that the sheath/obturator diameters may be sized to emulate the natural diameter of the cervical canal so that dilation is not needed. Further, only a single pass of the sheath is required through the cervical canal to place the sheath. Once placed, numerous atraumatic passes of the sleeve and other surgical instruments may occur through the sheath.

Referring now to the drawings, an exemplary system for interfacing with a hollow body cavity will be described. The system described with reference to the figures will find its greatest use in interfacing with the uterine cavity. However, it will be appreciated that the principles described herein will be useful in connection with other body cavities as previously described. As illustrated in Fig. 1, the system comprises a manipulatable sleeve 10 having a proximal end 12 and a distal end 14. Sleeve 10 is constructed of a tubular body 15 and a handle 16. As illustrated in Fig. 1A, a central working lumen 18 extends between proximal end 12 and distal end 14. Distributed about working lumen 18 are a plurality of outer lumens or channels that are formed in body 15, i.e., by extrusion. The larger diameter lumens or channels are used for passage of large diameter instruments or fluids. The smaller lumens or channels are preferably used for passage of electrical current or for movement (either rotary or linear) of wires to deploy surgical instruments.

Disposed in an outer lumen 20 is a pull wire 22 which may be pulled from outside the patient to articulate or manipulate distal end 14. In particular, pull wire 22 is attached at its distal end to distal end 14 so that as wire 22 is pulled, distal end 14 will bend. Disposed in outer lumens 24 and 26 are a pair of wires 30 and 32, respectively. Wires 30 and 32 provide a degree of rigidity to sleeve 10 and also serve to straighten distal end 14 after releasing pull wire 22. In some cases, wires 30 and 32 may be replaced with tubes to provide lumens to
hold moveable instruments, such as snares, electrodes, and the like. Such tubes preferably have a stiffness and tensile properties sufficient to provide the desired degree of rigidity to sleeve 10.

Preferably, body 15 of sleeve 10 will be constructed of a generally flexible material which will facilitate manipulation of distal end 14. Exemplary materials for constructing body 15 of sleeve 10 comprise flexible polymers, such as nylon or polyethylene, polyolefins, urethanes, ionomers, low durometer thermoplastic materials, and the like. As previously mentioned, other mechanisms may be provided to manipulate the distal end, including a memory-shaped tip and a straightening device. For example, the tip may be constructed of a memory material and pre-shaped into a desired configuration. One or more mandrels may then be inserted through the sleeve to straighten the distal end. As the mandrels are withdrawn, the tip resumes its initial configuration.

Sleeve 10 further includes an inflow or irrigation lumen 34 and a pair of outflow or aspiration lumens 36. Inflow lumen 34 is in communication with an inflow tube 38 while outflow lumens 36 are in communication with an outflow tube 40. In this way, various fluids may be introduced into or withdrawn from the body cavity by connecting tubes 38 and 40 to appropriate aspiration and vacuum sources. In this way, fluids may be introduced through sleeve 10 to distend the uterus or other body cavity, to enhance tissue visualization, particularly during a hysteroscopy procedure, to facilitate drug therapy, and the like.

It will be appreciated that the number and particular arrangement of lumens may be varied depending on the particular use. One such arrangement is illustrated in Fig. 1B where pull wire 22 and stationary wires 30 and 32 are integrally formed within the wall of the sleeve. The particular geometry and size of each lumen may also be varied depending the types of diagnostic or operative instruments that are to be inserted through the sleeve.

Referring now to Figs. 1, 2A and 2B, construction and of operation of handle 16 will be described in greater detail. Handle 16 is configured to slidably accept imaging systems, drug delivery systems, or other components that are placed through working lumen 18. Conveniently, proximal end 12 includes a lock 42 for anchoring an endoscope to handle 16. Handle 16 further includes an electrical conductor (not shown) for connection of sleeve 10 to a RF generator.
In this way, electrical current may be supplied to any electrosurgical elements disposed at distal end 14 of sleeve 10 as described in greater detail hereinafter.

Handle 16 further includes an inflow port 44 and outflow port 46 into which inflow lumen 38 and outflow lumen 40, respectively, are inserted. A knob 48 is disposed on the exterior of handle 16 and is employed to transfer a force from a user's hand to pull wire 22. More specifically, knob 48 is attached to a shaft 50 which in turn is attached to a connecting element 52. Pull wire 22 is attached to connecting element 52 so that as knob 48 is rotated, pull wire 22 will be moved in the proximal direction. In turn, distal end 14 of sleeve 10 will bend toward handle 16. To straighten distal end 14, knob 48 is rotated in the opposite direction, with wires 30 and 32 (see Fig. 1A) serving to straighten distal end 14. Although shown as a knob, it will be appreciated that a variety of mechanisms may be employed to transfer a force to wire 22, including screws, triggers, levers, buttons, detented linear actuators and the like.

Referring to Figs. 3 and 3A, an exemplary fiberscope 54 will be described. For convenience of description, fiberscope 54 may be divided into a flexible distal portion 56 and a proximal housing portion 58. Distal portion 56 has a proximal end 60 and a distal end 62. At distal end 62 is a series of lenses. Extending between proximal end 60 and distal end 62 are a plurality of fiber optic bundles. In one preferable embodiment, fiberscope 54 includes a 30K bundle of fibers. Also extending between proximal end 60 and distal end 62 is a light cable for supplying light to distal end 62. The fiber optic bundles are preferable coated with a protecting covering which is preferably flexible. one exemplary type of covering is a polyamide sheath. Such a material serves to protect the fiber optic bundles as well as providing a degree of flexibility to distal portion 56. Optionally, the inner diameter of the polyamide sheath may be coated black to minimize diffraction and maximize contrast. Connecting distal portion 56 to proximal housing portion 58 is a strain relief 64. Proximal to strain relief 64 is a mount 66 which is received into lock 42 of handle 16 (see Fig. 2A) when fiberscope 54 is inserted into sleeve 10 as described in greater detail hereinafter.
Proximal to mount 66 is a light post 68 to which a conventional light cable may be attached to provide light to the cable extending through distal portion 56. Housing portion 58 further includes a lens housing 70 and an eye cup 72. Eye cup 72 includes a lens 74 which allows a viewer to visualize an image disposed in the vicinity of distal end 62. Disposed within lens housing 70 are series of lenses to enhance visualization of the image viewed through lens 74.

Distal portion 56 has an outer diameter which is smaller than the diameter of working lumen 18 so that distal portion 56 may be inserted through lumen 18. Further, distal portion 56 is sufficiently flexible so that distal end 62 may be bent by an angle of at least 900 when knob 48 of sleeve 10 (see Fig. 1) is operated. In this way, fiberscope 54 in combination with sleeve 10 may be used to visualize a significant area within the interior of a hollow body cavity simply by inserting fiberscope 54 into sleeve 10 and manipulating knob 48.

Referring now to Fig. 4, an exemplary embodiment of a sheath 76 will be described. Sheath 76 comprises a tubular body 78 through which sleeve 10 or other instruments may be inserted. In this way, sheath 76 provides a convenient pathway for the introduction of various instruments, such as an obturator, a pipelle, a manipulatable sleeve and the like.

Tubular body 78 is preferably constructed of a semi-rigid or flexible polymeric tubing having an inside diameter which will slidably accept an obturator 80 (see Fig. 5) or sleeve 10. The proximal end 82 of body 78 includes a collar or supporting ring which provides the user with a convenient way to grasp and manipulate tubular body 78 and to prevent the collapse of the thin-walled tubing of which body 78 is constructed. Further, the collar at proximal end 82 is tapered inward to allow for easy insertion of the obturator 80 or other device into tubular body 78.

Along an outer cylindrical surface of tubular body 78 is a distensible cuff 84 (see also, Fig. 9). Cuff 84 is preferably constructed of a concentric sleeve of a highly distensible material, such as polyurethane (a thermo plastic elastomer), silicone, latex rubber or the like. Cuff 84 is assembled onto tubular body 78 under a slight axial and radial tension so that any surface friction or movement on cuff 84 will not cause movement of cuff 84. Cuff 84 is attached on each of its ends and sealed with an airtight seal to the outer surface of body 78 using an
interference fit and/or an adhesive bond. A conduit 86 is placed in communication with cuff 84, and a luer lock 88 is attached to conduit 86 so that a fluid pressurization/injection device, such as a syringe, may be connected to luer lock 88 to inflate cuff 84. After being placed transcervically, cuff 84 is pressurized causing cuff 84 to expand outwardly and fill any voids and cavities between the exterior of sheath 76 and the cervix. Axial distension of cuff 84 causes the formation of proximal and distal lobes (see Fig. 9) which provide a three axis auto-positioning motion and anchoring feature. The lobe formation and radial distension of cuff 84 causes an occlusion of the cervix and thereby, optimizes intrauterine distension and visibility.

As previously mentioned, Fig. 5 illustrates obturator 80 which is insertable into sheath 76. Obturator 80 comprises an elongate member 90 which is preferably constructed from a flexible polymer, such as nylon or polyethylene. Elongate member 90 includes a tip 92 which is preferably formed in an elliptical or bullet shape. Once placed within sheath 76 (see Figs. 6, 7 and 8) and then in the cervical orifice, the combined obturator 80 and sheath 76 may easily and atraumatically translate and navigate within the cervix. Hence, one purpose of obturator 80 is to stiffen and atraumatically guide sheath 76 to its proper cervical/uterine position. Once appropriately positioned, a handle 94 may be grasped to remove obturator 80 from sheath 76.

Referring now to Figs. 6-12, an exemplary method for visualizing the interior of the uterine cavity employing sleeve 10, fiberscope 54, sheath 76 and obturator 80 will be described. As shown in Fig. 6, obturator 80 is initially inserted into sheath 76. Handle 90 is pushed until tip 92 exits tubular body 84 of sheath 76 as illustrated in Fig. 7. The combined obturator 80 and sheath 76 are then introduced into the cervical canal as shown in Fig. 8. Sheath 76 preferably has an outer diameter which can pass through the cervical opening in an atraumatic manner. Sheath 76 and obturator 80 are introduced through the cervical canal until tip 92 is within the uterine cavity U as illustrated in Fig. 8.

When appropriately positioned, an incompressible fluid is introduced into luer fitting 88 where it passes through conduit 86 and inflates cuff 84 as illustrated in Fig. 9. As previously described, cuff 84 fills any voids or cavities within the cervical canal and provides a seal both at the external and internal os.
of the cervix. Further, when cuff 84 is distended, sheath 76 is anchored within the cervix. At this point, obturator 80 is removed by pulling on handle 90 so that only sheath 76 remains within the cervix as illustrated in Fig. 10.

As illustrated in Fig. 11, fiberscope 54 is inserted into sleeve 10 until mount 66 is locked within lock 42. The combined fiberscope 54 and sleeve 10 are then inserted into sheath 76. Sleeve 10 is slid through sheath 76 until distal end 62 of fiberscope 54 is within the uterine cavity U. Knob 48 may then be operated to manipulate distal end 62 as previously described. Further, sleeve 10 may be rotated within sheath 76 so that virtually all of the interior of uterine cavity U may be visualized through eye piece 72.

Prior to visualization, a distension fluid is preferably introduced into inflow lumen 38 to distend the uterine cavity U as illustrated in Fig. 12. Further, fluids may be circulated through uterine cavity U by withdrawing fluid through outflow lumen 40 to clear any blood or debris existing within the uterine cavity U. In this way, visualization within uterine cavity U is improved. Further, as fluids are introduced through inflow lumen 38, they will spray out of inflow lumen 34 (see Fig. 1A) to clean the lens on distal end 62.

As an alternative to introducing sheath 76 with obturator 80, sleeve 10 in combination with fiberscope 54 may be inserted directly into sheath 76 and the combined assembly inserted through the cervix using direct vision. In this way, obturator 80 is not needed and insertion may be performed under visualization.

Referring now to Figs. 13 and 13A, an electrocautery loop 96 will be described. Electrocautery loop 96 may be included within a sleeve which is similar to sleeve 10 as previously described so that an electrosurgical procedure may be performed within a body cavity under direct visualization. For example, as shown in Figs. 13B-D, loop 96 is coupled to a sleeve 10, which is similar to sleeve 10 as previously described. In this way, loop 96 may be translated in and out of sleeve 10, when performing a procedure as shown in Fig. 13D. Electrocautery loop 96 is in communication with an ESU electrical conductor in the handle (not shown) so that electrical current may be supplied to loop 96. Conveniently, one or more of wires which are similar to wires 30 and 32 (see Fig. 1A) may also be connected to the ESU and provide a return conductive path.
Optionally, sleeve 10 (see Fig. 1) may be configured so that tubular body 15 is removable to allow a variety of tubular bodies having different electrosurgical elements to be attached to handle 16. For example, sleeve 10 may be provided with electrocautery snares, biopsy snares, cauterization spheres or tips, and the like.

In one embodiment, wires 30 and 32 may be replaced with sufficiently rigid tubes as previously described. Deployable surgical tips may then coupled to the tubes. For example, a deployable resector loop may be movably received within the two tubes to allow the resector loop to be slid forward (into the operating field of view) when performing a procedure. As another alternative, a deployable snare may be coupled to the tubes. The snare is preferably constructed of a wire having a pre-shaped loop that is constructed of a memory material. One end of the wire is preferably fixedly mounted within one of the tubes while the other end is moveable within the other tube. In this way, when the wire is distally moved, a loop is formed at the distal end having the pre-formed shape. Preferably, the loop extends into the field of view of the scope to allow the loop to be visualized. To remove a fibroid, the loop is employed to grasp the fibroid, current is supplied to the loop to resect the fibroid, and then the fibroid is removed from the body cavity. Optionally, the wire loop may be employed to mechanically remove the fibroid without supplying current to the loop. Further, the wire loop may be employed to collect tissue within a body cavity. As a further alternative, the tubes may receive myolysis needles.

Another advantage of the system of the invention is that it may be employed to perform directed biopsies. As illustrated in Fig. 14, a biopsy needle system 98 may be inserted into sleeve 10 after distal end 14 has been positioned at a desired location and fiberscope 54 has been removed. System 98 comprises a cannula 100 and a needle 102 which is inserted into cannula 100. In use, system 98 is passed through distal end 14 and positioned at the target location where the biopsy is to be performed. Needle 102 is rotated within cannula 100 to remove a section of tissue. System 98 is then removed from sleeve 10. It will further be appreciated that a variety of other biopsy tools may be employed to remove the sample of tissue including, pipeline, grasping forceps, snares, and the like as in known in the art.
Sleeve 10 may also be employed to deliver other instruments or devices into the body cavity. Such instruments or devices may be inserted through working lumen 18 or through various other lumens that may be included within sleeve 10. For example, in addition to receiving a fiberscope, the lumens of sleeve 10 may receive baskets, snares, scissors, pipelles, grasping forceps, needles for drug therapy and the like. Further, since sleeve 10 may have its distal end 14 manipulated, such tools may be articulated under direct visualization to place a tool at a precise location within the body cavity. Furthermore, if desired, sleeve 10 may be removed from sheath 76 and other instruments inserted into the body cavity through sheath 76.

Referring now to Figs. 15A-15C, a sleeve 1011 is shown which is similar to sleeve 10 as previously described but further includes a pair of deployable electrodes 110 parallel to a scope lumen 112. Electrodes 110 are configured to function in a bipolar manner for use in myolysis procedures. As shown in phantom line, electrodes 110 are translatable relative to sleeve 1011 to assist in performing the procedure.

The invention has now been described in detail for purposes of clarity of understanding. However, it will be appreciated that certain changes and modifications may be made. Therefore, the scope and content of the invention are not limited by the foregoing description. Rather, the scope and content are to be defined by the following claims.
WHAT IS CLAIMED IS:

1. A hysteroscopic device comprising:
   an elongate sleeve having a proximal end, a distal end and a
   handle at the proximal end, wherein an internal lumen extends between the
   proximal end and the distal end; and
   a manipulation mechanism to manipulate the distal end of the
   sleeve, wherein the lumen is adapted to receive a flexible fiberscope which
   may be manipulated by operation of the manipulation mechanism.

2. A device as in claim 1, wherein the manipulation mechanism
   comprises a pull wire having a distal end which is attached to the distal end of
   the sleeve and a lever to move the pull rod.

3. A device as in claim 2, wherein the sleeve includes a plurality of
   outer lumens, and wherein the pull wire is disposed in one of the outer lumens.

4. A device as in claim 3, further comprising at least one stationary
   wire disposed in another one of the outer lumens to bias the sleeve in
   generally straight orientation.

5. A device as in claim 2, wherein the handle includes an irrigation
   port and an aspiration port, wherein the irrigation port and the aspiration port
   are each in communication with one of the outer lumens.

6. A device as in claim 1, wherein the sleeve is constructed of a
   flexible polymer.

7. A device as in claim 1, wherein the manipulation mechanism
   manipulates the distal end at least ninety degrees from the longitudinal axis of
   the sleeve.
8. A system for interfacing with a hollow body cavity, the system comprising:
   a manipulatable sleeve having a proximal end, a distal end and a handle at the proximal end, wherein an internal lumen extends between the proximal end and the distal end, and wherein a manipulation mechanism is included at the handle to manipulate the distal end of the sleeve; and a flexible fiberscope which is insertable into the internal lumen to allow the fiberscope to be manipulated by operation of the manipulation mechanism.

9. A system as in claim 8, wherein the manipulation mechanism comprises a pull wire having a distal end which is attached to the distal end of the manipulatable sleeve and a lever to move the pull wire.

10. A system as in claim 9, wherein the manipulatable sleeve includes a plurality of outer lumens, and wherein the pull wire is disposed in one of the outer lumens.

11. A system as in claim 10, further comprising at least one stationary wire disposed in another one of the outer lumens to bias the sleeve in a generally straight orientation.

12. A system as in claim 10, wherein the handle includes an irrigation port and an aspiration port, wherein the irrigation port and the aspiration port are each in communication with at least one of the outer lumens.

13. A system as in claim 8, wherein the sleeve is constructed of a flexible polymer.

14. A system as in claim 8, further comprising a sheath having an expansible cuff, and wherein the manipulatable sleeve is insertable into the sheath.
15. A system as in claim 14, wherein the distensible cuff comprises a balloon.

16. A system as in claim 14, further comprising an atraumatic obturator which is insertable into the sheath.

17. A system as in claim 16, wherein the obturator comprises a rod which is constructed of a flexible polymer.

18. A system as in claim 8, further comprising an electrosurgical element disposed at the distal end of the sleeve.

19. A system as in claim 18, further comprising a return electrode disposed in the sleeve.

20. A system as in claim 18, wherein the electrosurgical element is selected from the group of elements consisting of wire loops, snares, and cauterization tips.

21. A system as in claim 8, further comprising a biopsy tool which is insertable through the internal lumen of the sleeve.

22. A device to facilitate access to the uterus, the device comprising:
   a sheath having a proximal end, a distal end, and an internal lumen extending between the proximal end and the distal end; and
   an occlusion member near the proximal end, wherein the occlusion member is expansible to occlude the internal and the external os of the cervix.

23. A device as in claim 22, wherein the occlusion member comprises a balloon.
24. A method for diagnosing or treating a hollow body cavity, the method comprising:
   providing a manipulatable sleeve having a proximal end, a distal end, a handle at the proximal end, and an internal lumen extending between the proximal end and the distal end, wherein a manipulation mechanism is included at the handle to manipulate the distal end of the sleeve;
   introducing the distal end of the sleeve into the body cavity;
   introducing a flexible fiberscope into the internal lumen until a distal end of the fiberscope is within the body cavity;
   operating the manipulation mechanism to manipulate the fiberscope while within the body cavity; and
   viewing a portion of the interior of the body cavity with the fiberscope.

25. A method as in claim 24, further comprising rotating the sleeve, and viewing another portion of the interior of the body cavity.

26. A method as in claim 24, further comprising introducing a sheath into the body cavity, and inserting the sleeve into the sheath.

27. A method as in claim 26, further comprising introducing the sleeve into the sheath prior to inserting the sleeve into the body cavity.

28. A method as in claim 26, further comprising inserting an obturator into the sleeve prior to introducing the sheath into the body cavity.

29. A method as in claim 26, further comprising expanding a cuff on the sheath to provide a seal between the body cavity and the sheath.
30. A method as in claim 24, wherein the sleeve includes a plurality of outer lumens, and further comprising introducing a fluid into the body cavity through one of the outer lumens.

31. A method as in claim 30, further comprising withdrawing fluid from the body cavity through another one of the outer lumens.

32. A method as in claim 30, further comprising positioning the distal end of the fiberscope near the distal end of the sleeve, and introducing a fluid through one of the other lumens to clean a lens on the fiberscope.

33. A method as in claim 24, wherein the sleeve includes an electrosurgical element at the distal end, and further comprising performing an electrosurgical treatment on at least a portion of the interior of the body cavity.

34. A method as in claim 33, wherein the electrosurgical treatment is selected from the group of treatments consisting of cauterization, polyp removal, cutting, snaring, vaporizing, fulgurating, and desiccating.

35. A method as in claim 33, further comprising viewing a region of the interior of the body cavity with the fiberscope while performing the electrosurgical treatment.

36. A method as in claim 35, further comprising manipulating the sleeve with the manipulation mechanism while performing the electrosurgical treatment.

37. A method as in claim 24, wherein the body cavity comprises the uterus, and further comprising introducing the sleeve through the cervical canal.
38. A method as in claim 24, further comprising removing the fiberscope, and introducing a biopsy tool through the internal lumen.

39. A method as in claim 38, further comprising maintaining the distal end of the sleeve in substantially the same position during removal and introduction of the tool.

40. A method as in claim 24, wherein the operating step comprising pulling a pull wire to manipulate the distal end of the sleeve.

41. A method as in claim 40, further comprising operating a lever on the handle to pull the pull wire.

42. A method for providing access to the uterus, the method comprising:

providing a sheath having a proximal end, a distal end, and an internal lumen extending between the proximal end and the distal end, and an occlusion member near the proximal end;

inserting the distal end of the sheath through the cervical canal and into the uterus;

expanding the occlusion member to occlude the internal and the external os of the cervix; and

introducing at least one instrument into the uterus through the internal lumen.

43. A method as in claim 42, wherein the occlusion member comprises a balloon, and wherein the instrument comprises an imaging device.

44. A method as in claim 43, further comprising withdrawing the imaging device and inserting another instrument through the internal lumen.

SUBSTITUTE SHEET (RULE 26)
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**
- IPC(6) : A61B 1/303
- US CL : 600/135

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)
  - U.S. : 600/102, 105, 114-116, 135, 153; 604/55; 606/119

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)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
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<th>Relevant to claim No.</th>
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<tr>
<td>X</td>
<td>US 5,325,845 A (ADAIR) 05 July 1994, entire document.</td>
<td>1-4, 7-11, 21, 24, 25, 40, 41</td>
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<tr>
<td>Y</td>
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<td>X</td>
<td>US 3,882,852 A (SINNREICH) 13 May 1975, Fig. 4, and col. 3 lines 15-49.</td>
<td>22, 23</td>
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<tr>
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<td>US 5,368,598 A (HASSEON) 29 November 1994, Fig. 6.</td>
<td>42-44</td>
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</table>

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

- "T" special categories of cited documents: 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 defining the general state of the art which is not considered to be of particular relevance.
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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.
- "&" document member of the same patent family.

Date of the actual completion of the international search: 04 JUNE 1999

Date of mailing of the international search report: 24 JUN 1999

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<td>US 4,984,563 A (RENAUD) 15 January 1991, col. 5 line 38 to col. 6 line 23.</td>
<td>5, 12, 30, 31, 42-44</td>
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