

UTERINE MANIPULATOR**Field of Invention**

The present invention relates to a uterine manipulator which is an apparatus which surgeons use to manipulate the position of a patient's uterus.

Background on Laparoscopy & Laparoscopic Hysterectomy

By way of background, laparoscopy is a procedure that allows a surgeon to look into a female patient's abdomen or pelvis with a small camera. Through a small incision in the umbilicus, a laparoscope provides the surgeon with a direct view of the patient's internal organ structure. The uterus, fallopian tubes, ovaries, intestines, liver and appendix can be viewed, and the surgical procedure can be accomplished through small tiny holes made in the abdomen.

In the operating room, the patient is put under general anesthesia. A uterine manipulator is inserted through the patient's vagina into the uterine cavity. A small incision is made in or near the umbilicus through which a small needle is inserted, and carbon dioxide (CO₂) gas is introduced to raise the abdomen.

The introduction of the CO₂ gas creates a pneumoperitonuem, which is essential in order to safely introduce the instruments into this cavity which are used to visualize the abdomen. When an adequate pneumoperitonuem is created, the laparoscopic camera is inserted. The appropriate operative instruments can then be introduced through other incisions (often two other incisions on the left and right of the original umbilicus incision) to allow the surgeon to perform the surgical procedure. The surgeon sees the entire procedure and the patient's anatomy on a television screen, which also allows photos to be taken and videos to be recorded for reference.

A number of surgical procedures can be conducted laparoscopically, for example, hysterectomies, tubal ligations, treatments for infertility, ectopic pregnancies and endometriosis etc.

A hysterectomy, which involves the removal of a patient's uterus, is one of the most frequently performed of all surgical operations. A number of conditions can affect the uterus, such as fibroids, uterine cancer, adenomyosis, etc. which may require its removal.

Traditionally, the uterus has been removed through an abdominal or vaginal route. The optimum approach to hysterectomy retains the advantages of the abdominal route, which

include clear visualization and ease of manipulation of the adnexal structures, and to combine these features with the advantage of vaginal hysterectomy, namely the avoidance of a large abdominal incision. Laparoscopic hysterectomy, which attempts to combine these techniques, offer a significant reduction in postoperative pain, discomfort and shorter recovery period. Compared to traditional open-abdominal procedure, a laparoscopic hysterectomy reduces hospital stay and cost by 50%. The patient can return to work after around three weeks, versus six weeks for traditional surgery. For these reasons, it is anticipated that laparoscopic hysterectomy will become the standard rather than the exception in future.

There are variations to the procedure, but it usually begins with insufflation of the abdomen with a Veress needle and the insertion of a primary trocar through the umbilicus. A video-laparoscope is introduced into the abdominal cavity through the umbilical trocar. One to four secondary trocars are inserted under direct vision, avoiding abdominal wall vessels. Reusable or disposable instruments such as electrocoagulation, laser, clips, staplers, endoloops, sutures and ultrasonic scalpels have been used to ligate ligaments and for hemostasis.

In the case of Total Laparoscopic Hysterectomy (TLH), complete laparoscopic dissection of the uterus is carried out until the uterus lies free of all attachments in the peritoneal cavity. The uterus may be dissected retroperitoneally. The uterus is morcellated in the abdominal cavity or removed through the vagina. The vagina incision is closed with laparoscopically placed sutures.

Other variations include :

- Laparoscopically Assisted Vaginal Hysterectomy (LAVH)
- Laparoscopic Hysterectomy (LH)
- Laparoscopic Supracervical Hysterectomy (LSH)
- Laparoscopic Classical Intrafascial Supracervical Hysterectomy (CISH)
- Laparoscopically Assisted Doderlein Hysterectomy (LADH)
- Vaginally Assisted Laparoscopic Hysterectomy (VALH)

Laparoscopic hysterectomy is a spectrum of procedures and the phrase "laparoscopic hysterectomy" is used to describe any type of surgery where laparoscopy and hysterectomy are linked together.

The prior art contains known uterine manipulator that attempt to solve the problems encountered.

The Valtchev Uterine Mobilizer, produced by Conkin Surgical Instruments Ltd. of Canada, is a lever-based apparatus. It consists of a cannula that is inserted into the uterus which swivels via a pivoted link mechanism. It is cumbersome to adjust the angle of the cannula because a user must exert a large force to activate the lever mechanism. In addition, locking of the cannula's angle is achieved by a thumb screw which may loosen and cause the angle to shift. Another disadvantage of the Valtchev device is its inability to maintain the pneumoperitoneum. In a hysterectomy operation, once a cut is made, the CO₂ gas tends to leak from the abdominal cavity through the cut, causing the pneumoperitoneum to be lost.

The Lumin device, produced by Utah Medical Products Ltd., is described in United States Patent No. 5,645,561 (Smith). It provides an ergonomic gun/trigger handle which controls the manipulation angles. The major setback of this design is that, in use, the gun/trigger handle is positioned in such a way that the surgeon must leave his operating position (which is usually facing the same direction as the patient and by her side) to access the gun handle to carry out adjustments. Alternatively, an assistant may be required to operate the tool on the surgeon's instructions, leaving the surgeon with less control. In the Smith patent, although the prior art instrument is able to be used with one hand, the surgeon is required to use one hand to hold the handle of the apparatus, as well as to use his or her fingers of that same hand to pivot the actuating lever both forwards and backwards. In other words, the surgeon must exert force to move the lever both forwards as well as backwards.

In addition to the Smith patent, the prior art contains apparatus which are modeled on the configuration of a gun-pistol-trigger handle, for example United States Patent No. 5,409,498 (Braddock). All these apparatus, which have gun-pistol-trigger handles, suffer from the same deficiency of preventing a surgeon from using the apparatus while standing alongside the patient's waist.

Another uterine manipulator, produced by the International Centre for Endoscopic Surgery in France (C.I.C.E.), consists of a conical screw threaded cannula that is inserted into the uterus and swiveled to the desired angle. It has a rubber seal that prevents the pneumoperitoneum from being lost. A problem with this C.I.C.E. uterine manipulator is that it uses a handle that must be rotated in order to pivot the cannula, wherein the handle rotation is roundabout an axis that is perpendicular to the longitudinal axis of the main manipulator apparatus, i.e. the handle has a similar pivoting motion as the screw threaded cannula.

The prior art described above as discussed by way of example, and are not be construed as an admission of the state of common general knowledge in this field of art.

An object of the present invention is to overcome or ameliorate one or more of the problems in the prior art, or to provide an improved alternative to the prior art.

Summary of Invention

According to the present invention, there is provided a hand-operable gynecologic apparatus operatively adapted to translate a user's squeeze and release hand action into a motion capable of manipulating a patient's uterus, the apparatus comprising:

an elongated supporting member adapted to be inserted through the patient's vagina;

a pivotable projection attached to one end of the elongated supporting member, the projection being adapted, in use, to be inserted into the uterus;

a squeezable hand-grip located proximate the other end of the elongated supporting member, the hand-grip being squeezable between a fully-non-squeezed state and a fully-squeezed state; and

a connection mechanism that translates movement of the hand-grip into pivoting motion of the projection.

Preferably, squeezing of the hand-grip translates into pivoting motion of the projection in one direction and wherein releasing of the hand-grip translates into pivoting motion of the projection in an opposite direction.

Preferably, the hand-grip includes a palm-engaging portion and a finger-engaging portion.

Preferably, the palm-engaging portion is positioned closer to the pivotable projection than the finger-engaging portion so as to ensure that, in use, the user activates the mechanism with his forearm positioned generally alongside the elongated supporting member.

Preferably, the palm-engaging portion and the finger-engaging portion are biased with respect to one another by a biasing means.

Preferably, the biasing means of the hand-grip is adapted to bias only against the squeezing of the hand-grip so as to automatically urge the hand-grip towards the fully-non-squeezed state when the hand-grip is released.

Preferably, the biasing means is a spring.

Preferably, the finger-engaging portion is pivotally connected to the palm-engaging portion.

Preferably, the hand-grip is provided with a locking mechanism adapted to releasably lock the hand-grip in a selected state that is between the fully-non-squeezed state and the fully-squeezed state.

Preferably, the locking mechanism is located on the palm-engaging portion so that the user can operate the locking mechanism with his thumb.

Preferably, the hand-grip is shaped and adapted to be grasped by being surrounded by the user's palm and fingers.

Preferably, both the hand-grip and the projection are located upstanding on the same upper surface of the supporting member.

Preferably, the projection is pivotable in a plane which is parallel to and which passes through the longitudinal axis of the elongated supporting member.

Preferably, the projection is also rotatable.

Preferably, the connection mechanism is located substantially within the elongated supporting member.

Preferably, the connection mechanism is formed as an elongated bar that is connected at one end thereof to the pivotable projection and at another end thereof to the squeezable hand-grip.

Preferably, the elongated bar is provided with a release mechanism that releasably connects the elongated bar to the squeezable hand-grip.

Preferably, the projection is a cannula.

Preferably, the hand-grip and the cannula are releasably connected to the elongated supporting member.

Drawings

In order that the invention might be more fully understood, embodiments of the invention will be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is an illustration of an embodiment of a gynecologic apparatus inserted through a patient's vagina into her uterus;

Figure 2 is a cross-sectional side view of the gynecologic apparatus of Figure 1 with the hand-grip illustrated in a fully-non-squeezed state;

Figure 3 is a similar cross-sectional side view of the embodiment of Figure 2 except shown with the hand-grip illustrated in a fully-squeezed state; and

Figure 4 shows a sequence of nine diagrams which illustrate the pivoting motion of the cannula that is attached to the end of the gynecologic apparatus of Figures 1, 2 and 3. The illustration shows the pivoting motion being between 105° and -15° with respect to the longitudinal axis of the supporting member of the apparatus.

Description of Embodiments

Figure 1 illustrates an embodiment of a hand-operable gynecologic apparatus shown in use with the apparatus inserted through a patient's vagina 20. The apparatus is a uterine manipulator which is a surgical hand tool designed for laparoscopic hysterectomies, tubal ligations, infertility investigations and other procedures requiring the uterus to be moved from its natural rest position. It is applied vaginally in order to mobilize the uterus so that all aspects of the internal genitalia can be exposed and examined by the surgeon. The uterine manipulator primarily is used for laparoscopic hysterectomies. It can, however, be used for other gynecological purposes as discussed above, but functions most effectively when it is used in laparoscopic hysterectomies.

In use, a stainless steel cannula 300 is inserted into the uterine cavity through the cervical canal before the insufflation of the abdomen. Preferably, the cannula 300 has a rounded tip to minimize uterine perforation during insertion and use. When sufficient pneumoperitonuem is created, the cannula can be swiveled about a fixed point, which is the cervix, allowing the uterus to be anteverted or pivoted up to 105° in one direction and minus 15° in an opposite direction. Other embodiments can be designed for greater degrees of movement, but this range is suitable for most surgical operations.

The cannula is pivotable in a plane which is parallel to and passes through the axis of the elongated supporting member. For instance, in Figures 2 and 3, that plane would be the plane of the sheet of paper of the drawing.

The apparatus uses a pivotable projection in the form of a cannula 300 to manipulate the orientation of the patient's uterus 30. The cup 302, illustrated as surrounding the cannula 300, is optional in the first embodiment of Figure 1, although highly preferred. The apparatus can be used without this cup, using only the cannula as the projection. The cup acts as a guide for the surgeon to perform the dissection of the uterus, and also provides a form of the traction between the cannula and the uterus so as to prevent any slippage of the uterus. In a sense, the cup serves as a guide and 'cutting board' for the surgeon to perform the dissection. In addition, in further embodiments, the cannula may be modified by having serrations for better traction.

The pivoting motion of the cannula 300 is achieved when the user, usually a surgeon, squeezes or releases the handle 100 of the apparatus. This squeeze and release motion of the handle is translated into the pivoting motion of the cannula 300 which is able to manipulate the position of the patient's uterus 30.

In Figure 1, the surgeon's hand and forearm are illustrated in dotted lines. These dotted lines indicate that the surgeon is able to operate the apparatus while standing alongside the patient's waist and side, rather than having to operate the apparatus while standing in a location between the patient's legs. This also avoids the need for an assistant to operate the apparatus, since the surgeon can operate the apparatus from where he is standing alongside the patient. This is an important feature of the apparatus of the present embodiment, because laparoscopic hysterectomy operations, for example, required the surgeon to operate while standing by the side of the patient. Since the surgeon can operate the apparatus while standing aside the patient, it avoids the need for the surgeon to move away from this operating position simply to operate the apparatus. Thus, the apparatus of the present embodiment allows the surgeon to remain in one position beside the patient throughout the operations procedure.

The gynecologic apparatus is provided with an elongated support member 200 which is adapted to be inserted through the patient's vagina 20, as shown in Figure 1. The pivotable cannula 300 is attached to the left hand end of the elongated support member 200, as illustrated. The cannula is adapted to be inserted into the uterus 30.

As illustrated in Figure 1, the squeezable hand-grip 100 is located proximate the left hand end of the supporting member 200. In Figure 1, the hand-grip 100 is located at the very left hand end of the supporting member, but in other embodiments it is sufficient for the squeezable hand-grip to be proximate or close to the left hand end. It is sufficient merely that, when the apparatus is inserted into the patient's vagina 20, the squeezable hand-grip 100

remains outside the patient's body in a position that is convenient for the surgeon to reach and operate.

Figures 2 and 3 are side cross sectional views of the same apparatus of Figure 1. Figure 2 illustrates the hand-grip 100 in a fully-non-squeezed state, while Figure 3 shows the same hand-grip 100 in a fully-squeezed state. By comparing the orientation of the cannula 300 in Figures 2 and 3, it is appreciated that the squeezing and releasing of the hand-grip causes the cannula 300 to pivot. Thus, in use, the squeezing and releasing of the hand-grip causes the position of the uterus 30 to be manipulated as the cannula pivots about the end of the supporting member 200.

Within the elongated supporting member 200 is an elongated activation bar 205. This activation bar 205 reciprocates within the supporting member 200. As illustrated in Figures 2 and 3, the right hand end of the activation bar 205 is connected an end of the cannula 300. Also, the left hand end of the same activation bar 205 is connected to a finger-engaging portion 120 of the hand-grip 100. The activation bar 205 is located substantially within the elongated supporting member 200.

The hand-grip 100 includes a palm-engaging portion 115. The finger-engaging portion 120 is pivotally connected to the palm-engaging portion 115. The palm-engaging portion 115 and the finger-engaging portion 120 together combine to form the hand-grip 100. The surgeon's hand grasps this hand-grip in his hand such that the surgeon's palm rests against the palm-engaging portion 115, while the surgeon's fingers wrap around the finger-engaging portion 120. The hand-grip is ergonomically shaped and adapted to be grasped by being surrounded by the surgeon's palm and fingers.

The palm-engaging portion 115 is fixed and always remain motionless with respect to the elongated supporting member 200. In contrast, the finger-engaging portion 120 is pivotally connected to the palm-engaging portion 115, and so the finger-engaging portion is able to move with respect to the elongated supporting member 200. The lower end of the finger-engaging portion 120 is connected to the left hand end of the activation bar 205. Thus, the act of squeezing and releasing the finger-engaging portion 120 causes the activation bar 205 to reciprocate in the supporting member 200. Particularly, the squeezing of the hand-grip 100, as shown in Figure 3, causes the cannula to pivot in an anti-clockwise direction (as shown in Figure 3). Releasing of the hand-grip 100 (as shown in Figure 2) causes the cannula 300 to

rotate in an opposite clockwise direction. The expressions "clockwise" and "anti-clockwise" are used conveniently to describe the motion as illustrated in Figures 2 and 3.

The finger-engaging portion 120 and the palm-engaging portion 115 are also connected by a sliding link bar 119 that guides the motion of the finger-engaging portion. The link bar 119 is pivotally connected to the finger-engaging portion 120, and is also pivotally connected to a sliding plate 118 which slides in an elongated groove in the palm-engaging portion 115. The sliding plate 118 has a series of nine v-shaped grooves which can engage the locking button 117, hence providing a means of locking when the sliding plate 118 and locking button 117 are engaged.

As shown in the cross sectional views of Figures 2 and 3, the hand-grip 100 is provided with a biasing means in the form of a spring 101. The finger-engaging portion is biased with respect to the palm-engaging portion. The spring 101 is adapted to urge the finger-engaging portion 120 away from the palm-engaging portion 115. In Figure 3, the spring urges the finger-engaging portion in a clockwise direction. Thus, when the surgeon squeezes the hand-grip 100, he is squeezing against the biasing force of the spring. The spring 101 acts against only the squeezing of the hand-grip 100. When the surgeon releases the hand-grip 100, the spring 101 automatically urges the finger-engaging portion 120 towards its fully-non-squeezed state. In other words, squeezing of the hand-grip 100 causes it to be squeezed as shown in Figure 3, while releasing of the hand-grip 100 causes it to automatically and gradually revert to the fully-non-squeezed state as shown in Figure 2.

The strength of the spring 101 must be such that the components do not spring apart too rapidly. The ideal strength of the spring causes the components to separate gradually, in order to allow the surgeon to monitor the pivoting of the cannula, so that he can arrest the cannula at the appropriate orientation by halting the separation of the finger-engaging portion 120 and the palm-engaging portion 115. Thus, the spring 101 automatically urges the finger-engaging portion of the hand grip towards the fully-non-squeezed state when the hand-grip is released.

In use, the surgeon squeezes and releases the hand-grip 100 until the cannula 300 is positioned to the surgeon's satisfaction. In the process of fine-tuning the position of the cannula 300, the surgeon might slightly squeeze the hand-grip 100.

If he finds that the cannula 300 has pivoted too far anti-clockwise (as shown in Figure 3) the surgeon can release the hand-grip 100 and allow the spring 101 to slowly urge the

finger-engaging portion away from the palm-engaging portion. When the spring 101 has urged the finger-engaging portion sufficiently to correct the orientation of the cannula, the surgeon can use his hand to re-grasp the hand-grip 100. This prevents any further outward movement of the finger-engaging portion.

At this point, the surgeon can use a locking button 117 to lock the components of the hand-grip 100 in this desired position, which corresponds to the desired position of the cannula 300. The hand-grip 100 is provided with a locking mechanism 117 which is adapted to releasably lock the hand-grip 100 in a position between the fully-non-squeezed state and the fully-squeezed state. In the embodiment, the locking button 117 is operated by the surgeon's thumb, since the button 117 is located on an upper region of the palm-engaging portion 115. Since the fine-locking mechanism on the hand-grip is positioned for activation by the surgeon's thumb, the mechanism can be operated and locked using only one hand. To release the lock, the user presses the same button with his thumb to release the lock and cannula. This is an advantage over earlier prior art manipulators because the user does not need to use his other hand to activate or release the lock. This means that the surgeon need not need to leave his operating position beside the patient's side or to stretch out to use the tool (in an operating room scenario).

The releasable locking mechanism of the hand grip works in the following manner. Referring to Figure 3, the surgeon, in use, presses the locking button 117 in order to place the hand-grip in an unlocked state. The surgeon holds the locking button 117 down with his thumb while the angle of the cannula is adjusted. To do this, the surgeon presses on the locking button 117, while simultaneously squeezing or releasing the finger and palm engaging portions of the hand grip 100 until the desired cannula angle is reached. Then, when the desired angle is reached, the surgeon releases his thumb off the locking button 117 which results in the cannula 300 being locked in that position. The locking button 117 is biased by a leaf spring 106 such that removing thumb pressure from the button 117 causes the button 117 to lock into the v-shaped grooves in the sliding plate 118 to immobilize the sliding plate, thus fixing the angle of the cannula. In contrast, pressing the locking button 117 causes the button 117 to disengage from the v-shaped grooves in the sliding plate 118 which allows the angle of the cannula 300 to be adjusted.

The spring causes the hand-grip to act as a self-correcting mechanism. Once the toggle button is activated, the torsion spring 101 in the hinge of the handle forces the components of

the handle apart, hence pulling the link shaft, swiveling the cannula downwards automatically. This is an advantage over known earlier manipulating apparatus as they would require the user to provide an equal amount of force, effort and activation method to change the angle of the cannula in either direction. In the case of the present embodiment of the uterine manipulating apparatus, the surgeon need only to resist the force of the torsion spring and vary his holding force to achieve the desired angle.

In use, the hinged and spring-loaded hand-grip allows fine adjustment of the angular orientation of the cannula 300. The locking mechanism allows the cannula to be locked in any desired position, hence locking the uterine position, allowing clear visualization of the areas of interest and freeing the surgeon's hands during the operation.

Thus, the surgeon is able to use the force of his hand to close his grip on the hand-grip 100, but is able to rely on the resilient force of the spring 101 to expand the hand-grip 100. It can be appreciated, from an ergonomic point of view, that it is easier for a surgeon to tighten his grip on the hand-grip 100, and that it would be more difficult for the surgeon to use the force of his hand to expand the hand-grip components. This feature of the present embodiment thus overcomes a problem in the prior art United States Patent No. 5,645,561 (Smith) which required the surgeon to use the force of his hand to move the hand grip components both backwards and forwards. The present embodiment overcomes a disadvantage of the Smith patent, because in the present embodiment, the surgeon only has to use the force of his hand to tighten his grip on the hand-grip, while the resilient spring 101 allows the hand-grip portions to expand to the required position. In other words, the present embodiment avoids the need for the surgeon to use the force of his hand to expand the hand-grip.

In the embodiment of Figures 1, 2 and 3, the hand-grip and the cannula are releasably connected to the elongated supporting member, and thus can be disconnected for cleaning of the individual parts, preferably by autoclaving. This separability feature also allows different handles and different projections to be attached to the supporting member 200, so that the elongated member 200 of the apparatus can be used for other types of surgical procedures.

Autoclaving is a sterilizing and cleaning process where the instruments are placed in an autoclave oven and subjected to high heat and pressure. Therefore, instruments that are to be cleaned and sterilized in this manner are preferably made of materials that can withstand such high temperatures and pressure, for example, stainless steel. In the exemplary embodiment, the elongated supporting member 200 and cannula 300 are made totally of stainless steel. It is

preferable that any parts of the tool that enter the patient's body to be autoclaved after use. The handle 100, which is made of other light-weight and non-autoclavable materials such as aluminum and rubber, may be detached and cleaned by chemical soaking.

In Figures 2 and 3, the left hand end of the elongated activation bar 205 is provided with a release mechanism. The release mechanism includes a slide bar 211 which slides in a cylindrical channel in the base of the hand-grip 100. The lower base of the finger-engaging portion 120 is connected to the left-most end of the slide bar 211. Thus, the reciprocating movement of the slide bar 211 is governed by the pivoting motion of the finger-engaging portion 120. In Figures 2 and 3, the right hand end of the slide bar 211 is provided with a T-shaped slot which is adapted to engage with a float joint 206. The float joint 206 is itself connected to the activation bar 205. Hence the reciprocation of the slide bar 211 causes the reciprocation of the activation bar 205. In the present embodiment, the release mechanism ensures that there is no permanent connection between the float joint 206 and the slide bar 211. This ensures that when the handle 100 is detached from the elongated supporting member 200, the float joint 206 can be unhooked from the slide bar 211. The handle grip 100 is releasably fastened to the elongated support member 200 by a lock nut 214 which clamps the flange of the elongated support member 200 securely to the handle grip 100.

In Figure 1, when the apparatus is inserted into the patient, the palm-engaging portion 115 of the hand grip is closer to the cannula 300, as compared to the finger-engaging portion 120. In other words, the finger-engaging portion 120 is further away from the cannula 300 than the palm-engaging portion 115. This relative orientation ensure that, in use, the surgeon is able to grasp the hand-grip 100 while he is standing alongside the patient's waist. This is in contrast to the pistol-trigger-grip of the prior art apparatus of U.S. patent 5,645,561 (Smith) where the trigger or finger-engaging portion is closer to the cannula than the palm-engaging handle. This prior art arrangement leads to the deficiency of the surgeon having to stand in a location between the patient's legs in order to operate the prior art uterine manipulating apparatus.

Specifically, embodiments of the present invention seek to avoid the problems inherent in prior art designs that is similar to the handle-grip of a pistol or gun, because the gun-pistol-trigger handle configuration requires the surgeon to stand in a position between the patient's legs to operate the handle of the apparatus.

In Figures 1, 2 and 3, both the hand grip 100 and the cannula 300 are both located upstanding on the same upper surface of the supporting member 200. This is in contrast to the

prior art U.S. patent 5,645,561 (Smith) in which the hand-grip is oriented downwards while the cannula is oriented upwards, using the orientation in Figures 1 to 3 as a reference. This means that the prior art apparatus of the Smith patent cannot be used by the surgeon when he is standing alongside the patient's side. The surgeon or his assistant is forced to operate the prior art apparatus while standing in a position between the patient's legs.

As shown in Figures 2, 3 and 4, the cannula 300 is pivotable in a plane which is parallel to and which passes through the axis of the elongated supporting member 200.

Figure 4 illustrates a sequence of diagrams which show the cannula pivoting from 105° with respect to the longitudinal axis of the supporting member 200, all the way through to -15° with respect to that same axis. Although the diagrams only show a selection of pivoting angles, namely minus 15° , 0° , 15° , 30° , 45° , 60° , 75° , 90° and 105° , it can be appreciated that the pivoting motion of the cannula 300 is smooth and can be pivoted in very small increments, since it is required to position the uterus 30 in the exact position that the surgeon requires it to be in for performing the surgical operation.

The wide range of angles that the cannula, hence the uterus, can be swiveled allows the surgeon better access during examination and dissection. This is especially important in laparoscopic hysterectomies as the uterus has to be completely dissected. Dissection will be hindered if clear access to the cutting area cannot be provided by the apparatus.

In the present embodiment, the apparatus does not have any means of providing a rotatable motion of the cannula around the axis of the supporting member 200 with the handle remaining in the upright position. Thus, in order to rotate the cannula 300 around about the axis of the supporting member 200, the entire apparatus, including the hand-grip, must be axially rotated within the patient's vagina. For the sake of clarity, in Figures 2 and 3, this means that the cannula 300 would be rotated in and out of the page of the drawing. This allows the uterus to be moved in an arc about 45° to the left or right (in and out of the drawing). However, in modifications, the apparatus can be provided with mechanisms that allow such axial rotation of the cannula to be achieved mechanically, rather than having to rotate the entire apparatus within the patient's vagina.

The cannula is made of stainless steel, but may also be made of any inert non-pliable material. The cannula in the present embodiment is not hollow, although the shape and configuration of the pivoting projection can be varied depending on the needs of the particular application. The components of the hand-grip may be made from light-weight metallic

materials for comfortable usage and durability. Apart from the materials used in the construction of specific parts of the tool as mentioned, the rest of the tool is made from stable, high heat resistance and non-reactive materials, allowing the tool to be cleaned, sterilized and lubricated using convention methods such as chemical soaking and autoclaving.

In other embodiments, it is possible for the apparatus to include the optional insulating Guide Cup 302 which assists the surgeon in dissection of the uterus. The cup 302 is made of insulating material. The cup acts as a support ring around the base of the uterus. The cup serves as a guide for the dissection of the uterus from its attachments in the peritoneal cavity. The use of insulating material prevents burns to the patient's tissue when electrical cutting instruments are used. The cup is an optional attachment to the tool and can be removed when the tool is used solely for laparoscopic pelvic examinations. The insulating guide cup provides a clearer dissection path to guide the incisions made by the surgeon. As the tissue is separated, the cup will come into view, and the surgeon uses this as a guide for positioning the next cut, which follows the circumference of the cup. The cup is made of insulating materials so that traditional and electrical cutting tools can be used, since the insulation minimises the risk of burning the patient's tissue.

The apparatus may be provided with a series of cannulas and cups of different lengths and sizes to cater for variations in dimensions of the uterus sizes of different patients.

The shaft or body of the supporting member 200 is preferably provided with one or more flexible elastic seal rings 209 which prevent the gas of the pneumoperitoneum escaping from the patient's body. These are made of natural rubber or other suitable resilient material. These sealing rings 209 enable the pneumoperitoneum to be maintained by stopping or minimising any gas leakage if the fornix is opened at any time during the operation procedure. The adjustable flexible natural rubber sealing ring or rings are placed in the vaginal opening to prevent the pneumoperitoneum from being lost at all times during the procedure. The flexible rubber flaps forms a seal with the patient's tissue to act as a progressive seal that prevents loss of the CO₂ gas. Loss of the pneumoperitoneum is very likely to happen in the case of hysterectomies because as the dissection of the uterus this carried out, the CO₂ gas will escape through the opening created by the cut. Maintaining an effective seal is therefore very important in any laparoscopic procedure as sudden loss of the pneumoperitoneum can cause the cutting and viewing instruments to injure the internal organs of the patient.

During the initial insertion of the apparatus into the patient's vagina, the sealing ring 209 is retracted further along the shaft 200. When insertion is completed, the seal ring is slid along the shaft 200 and is then fixed securely in position in the vaginal opening. The locking collar 210 is used to fasten the sealing rings 209 in position. The locking collar 210 is provided with a locking pin 217 which sits in indentations disposed at regular intervals on the surface of the supporting member 200.

The apparatus of the embodiment of Figures 1 to 3 can be fully disassembled into six major parts for cleaning and sterilization. In the embodiment, no screws and removable fasteners need be used for the parts of the apparatus that enter the patient's body, which avoids the problem of parts detaching from the apparatus while still inside the patient's body. Preferably, all fastening and connecting methods used on the tool are secure and permanent, such as rivets, welding or moulding.

Embodiments of the uterine manipulator can be used in a variety of laparoscopic gynecological procedures. It provides an easy to use adjustment handle that controls the cannula through a wide range of angles. Once the desired angle is achieved, the manipulator feature a quick lock mechanism that will lock the angle securely. When the manipulator apparatus is provided with the seals, it is better able to maintain the pneumoperitonuem throughout the procedure for safety reasons. The manipulator is lightweight yet robust enough for use in the operating room scenario.

The embodiments have been advanced by way of example only, and modifications are possible within the scope of the invention as defined by the appended claims.

For instance, in other embodiments, the hand-grip need not be strictly at the end of the elongated support member, but may also be proximate or close to the end of the supporting member. It is important merely that the hand-grip be positioned so as to remain outside the patient's body when the apparatus is inserted into the patient's vagina.

In other embodiments, the biasing means can be formed as a resilient single component, such as a flexible metallic plate.

In other modifications, the sliding link bar and toggle button mechanism can provides a number of different possible positions for locking of the angle of cannula.

In other embodiments, parts of the connecting mechanism can be outside the supporting mechanism.

In other embodiments, the hand-grip and the cannula may omit a release mechanism so as to be permanently connected to the elongated supporting member 200.



CLAIMS:

1. A hand-operable gynecologic apparatus operatively adapted to translate a user's squeeze and release hand action into a motion capable of manipulating a patient's uterus, the apparatus comprising:
 - an elongated supporting member adapted to be inserted through the patient's vagina;
 - a pivotable projection attached to one end of the elongated supporting member, the projection being adapted, in use, to be inserted into the uterus;
 - a squeezable hand-grip located proximate the other end of the elongated supporting member, the hand-grip being squeezable between a fully-non-squeezed state and a fully-squeezed state; and
 - a connection mechanism that translates movement of the hand-grip into pivoting motion of the projection.
2. An apparatus of claim 1 wherein squeezing of the hand-grip translates into pivoting motion of the projection in one direction and wherein releasing of the hand-grip translates into pivoting motion of the projection in an opposite direction.
3. An apparatus of either claim 1 or 2 wherein the hand-grip includes a palm-engaging portion and a finger-engaging portion.
4. An apparatus of claim 3 wherein the palm-engaging portion is positioned closer to the pivotable projection than the finger-engaging portion so as to ensure that, in use, the user activates the mechanism with his forearm positioned generally alongside the elongated supporting member.
5. An apparatus of claim 3 or 4 wherein the palm-engaging portion and the finger-engaging portion are biased with respect to one another by a biasing means.
6. An apparatus of claim 5 wherein the biasing means of the hand-grip is adapted to bias only against the squeezing of the hand-grip so as to automatically urge the hand-grip towards the fully-non-squeezed state when the hand-grip is released.



7. An apparatus of claim 5 or 6 wherein the biasing means is a spring.
8. An apparatus of any one of claims 3 to 6 wherein the finger-engaging portion is pivotally connected to the palm-engaging portion.
9. An apparatus of any one of the preceding claims wherein the hand-grip is provided with a locking mechanism adapted to releasably lock the hand-grip in a selected state that is between the fully-non-squeezed state and the fully-squeezed state.
10. An apparatus of claim 9 wherein the locking mechanism is located on the palm-engaging portion so that the user can operate the locking mechanism with his thumb.
11. An apparatus of any one of the preceding claims wherein the hand-grip is shaped and adapted to be grasped by being surrounded by the user's palm and fingers.
12. An apparatus of any one of the preceding claims wherein both the hand-grip and the projection are located upstanding on the same upper surface of the supporting member.
13. An apparatus of any one of the preceding claims wherein the projection is pivotable in a plane which is parallel to and which passes through the longitudinal axis of the elongated supporting member.
14. An apparatus of any one of the preceding claims wherein the projection is also rotatable.
15. An apparatus of any one of the preceding claims wherein the connection mechanism is located substantially within the elongated supporting member.
16. An apparatus of any one of the preceding claims wherein the connection mechanism is formed as an elongated bar that is connected at one end thereof to the pivotable projection and at another end thereof to the squeezable hand-grip.



17. An apparatus of claim 16 wherein the elongated bar is provided with a release mechanism that releasably connects the elongated bar to the squeezable hand-grip.
18. An apparatus of any one of the preceding claims wherein the projection is a cannula.
19. An apparatus of any one of the preceding claims wherein the hand-grip and the cannula are releasably connected to the elongated supporting member.