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(54) GYNECOLOGICAL ABLATION SYSTEM USING AN ABLATION NEEDLE

GYNÄKOLOGISCHE ABLATIONSSYSTEM UNTER VERWENDUNG EINER ABLATIONSNADEL

SYSTEME D'ABLATION GYNECOLOGIQUE FAISANT APPEL A UNE AIGUILLE D'ABLATION

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(73) Proprietor: **Lee, Bruce, B.**
Monterey, CA 93940-4522 (US)

(72) Inventor: **Lee, Bruce, B.**
Monterey, CA 93940-4522 (US)

(74) Representative: **Freeman, Jacqueline Carol**
W.P.Thompson & Co.
55 Drury Lane
London WC2B 5SQ (GB)

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to a system for treating gynecological disorders. More particularly, the present invention relates to the treatment of pelvic tumors.

BACKGROUND OF THE INVENTION

[0002] Benign and malignant tumors can occur in the pelvis. For example, uterine leiomyomata, are muscle cell tumors that occur in 77% of women in the reproductive years. Although uterine leiomyomata rarely (0.1 %) progress to cancer, these tumors can cause excessive menstrual bleeding, irregular bleeding, pregnancy loss, infertility, urinary frequency, and pelvic pressure or pain with sexual activity, menses, or daily activities. Women with uterine leiomyomata frequently incur surgical procedures (e.g., hysterectomy, dilatation and curettage, myomectomy, and hysteroscopy), medical and hormonal therapies, office visits, and a variety of radiologic procedures (e.g., ultrasounds, CAT scans, and MRIs), in an effort to treat these tumors. Uterine leiomyomata account for approximately 200,000 hysterectomies per year in the United States alone, at a direct cost of well over $2 billion. Hysterectomies carry a morbidity rate of 1%, with 2,000 deaths per year and 240,000 complications per year in North America.

[0003] Uterine leiomyomata are most often multiple, and may be subserosal (i.e., bulging externally from the uterus), intramural (i.e., growing entirely within the wall of the uterus), submucosal (i.e., hidden within the uterine cavity), or pedunculated (i.e., growing outward with a stalk-like base). Because patients may have multiple uterine leiomyomata at different locations, conservative surgeries may involve both an abdominal and a vagina (hysteroscopic) approach, thereby necessitating two procedures.

[0004] Investigators have utilized a laser or bipolar cautery to perform myolysis or destruction of these tumors, although neither of these methods is performed in significant numbers today. These methods necessarily destroy normal overlying tissue in order to treat the underlying tumor. As a result, the integrity of the uterus is compromised, and harmful scar tissue (e.g., adhesions) may occur. Thus, there is a need for an improved method of treating benign and malignant pelvic tumors that does not damage the overlying tissue. Such an improved method could be used on women who wish to later conceive and subsequently deliver. There is also a need for a single method capable of treating all sizes of subserosal, intramural, submucuosal, and pedunculated tumors in all locations. A single method, which would relieve most or all symptoms of abdominal or pelvic pain/pressure, abnormal uterine bleeding, urinary frequency, infertility, and miscarriage, is also needed. In addition, it would be desirable for the method to be less invasive, cheaper, and safer than conventional methods of treating pelvic tumors, and also to allow for uterine preservation.

[0005] The US 5, 672, 174 discloses an ablation treatment apparatus with a pointed tip and deployable electrodes for deployment in a tissue mass.

SUMMARY OF THE INVENTION

[0006] The present invention is defined in claim 1 and can be used in an outpatient procedure also referred to as "the Halt procedure," that utilizes electromagnetic energy to effectively ablate pelvic tumors. The invention employs an ablation device that uses radio-frequency (RF) energy to treat pelvic tumors, while sparing the surrounding normal tissue. Although the ablation device utilized in the present invention has FDA approval for ablation of soft tissue tumors, no known reports exist in the medical literature of the ablation device's application to uterine leiomyomata or other pelvic tumors. In addition, current results indicate that, compared to other conservative therapies, the present method is very effective. Thus far, the present invention has provided relief from all of the types of symptoms caused by pelvic tumors, such as uterine leiomyomata. Furthermore, the present invention is versatile, safe, and well-accepted by patients. Advantages of the present invention include a quick recovery time; typically no more than a week, and significant cost savings. More importantly, the present invention provides a practical and efficient way to achieve uterine conservation on an out-patient basis.

[0007] In accordance with one embodiment of using the present invention, an ablation device is inserted into a pelvic region and the ablation device is positioned proximate the pelvic tumor, using a laparoscope and an imaging device to confirm placement of the ablation apparatus. Various ablation devices may be used. For example, the ablation device may include no arms, a plurality of deployable arms, or separate needles that are inserted into the pelvic tumor. Energy is delivered through the ablation device to the pelvic tumor to ablate the tumor. RF energy is used, however, other forms of energy, such as microwave, light (e.g., laser), or acoustic (e.g., ultrasound) energy may also be used to ablate the pelvic tumors.

[0008] In accordance with another embodiment of using the present invention, a patient is provided on an operating table, and at least one monitor for a laparoscope and an imaging device are provided with the at least one monitor located across the operating table from a surgeon and proximate the patient's waist. The at least one monitor may be mounted on a tower located proximate the patient's waist. An energy source and the imaging device are provided adjacent to the at least one monitor, with the energy source and imaging device being located proximate the patient's knees. An ablation device is inserted into a pelvic region of the patient and the device is positioned proximate a pelvic tumor. The location and

placement of the ablation device with respect to the pelvic tumor is confirmed using the laparoscope and the imaging device. Energy is delivered to the pelvic tumor to ablate the tumor. The tumor may be maintained at a temperature in the range of approximately 65 °C and 100 °C for at least 7 minutes to ablate the tumor.

[0009] In accordance with still another embodiment of the present invention, a surgical system for treating pelvic tumors in a patient lying on an operating table includes an ablation device, an energy source, a laparoscope, and an imaging device. The energy source is coupled to the ablation device and provides energy to the device to ablate a pelvic tumor. The laparoscope and the imaging device are connected to at least one monitor. The at least one monitor is located the operating table from a surgeon and proximate the patient's waist, while the energy source and imaging device are located alongside the at least one monitor and proximate the patient's knees.

[0010] Use of the present invention is performed by laparoscopy (i.e., open abdominal incision). The Halt procedure has most often utilized conventional laparoscopy with the additional placement of (1) a supra-pubic port or sleeve (10 mm) at the top of the uterus for an intra-abdominal ultrasound probe and (2) an ablation device, also usually in the lower abdominal region. The Halt procedure has also been performed by a trans-abdominal technique, utilizing conventional trans-abdominal ultrasound and placement of the ablation device trans-abdominally with laparoscopic confirmation, as well as by a transcervical technique.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011]

FIG. 1 is a perspective diagram of a surgical system for ablating pelvic tumors, in accordance with the present invention.

FIG. 2 is a top plan view of the surgical system of FIG. 1, illustrating an arrangement of certain equipment with respect to a patient lying on an operating table.

FIG. 3 is a flowchart illustrating a closed laparotomy method of ablating pelvic tumors.

DETAILED DESCRIPTION OF THE INVENTION

[0012] Referring first to FIG. 1, a surgical system 10 for ablating pelvic tumors includes a laparoscope 12, a video monitor 14 associated with laparoscope 12, an imaging device 16, a video monitor 18 associated with imaging device 16, an energy source 20 and an ablation device 22. Laparoscope 12, which is inserted into a patient P, is electrically connected to video monitor 14, which displays an image from laparoscope 12. As will be explained in greater detail below, laparoscope 12 enables a surgeon to view the insertion and placement of ablation device 22 into a pelvic region of the patient.

[0013] Imaging device 16 is electrically connected to video monitor 18 and provides images of the patient's pelvic region. These images, which are displayed on video monitor 18, enable the surgeon to determine the presence and location of any pelvic tumors. Imaging device 16 shown in FIG. 1 is an ultrasound machine, and includes an intra-abdominal ultrasound probe 24. Instead of intra-abdominal ultrasound probe 24, a transducer (not shown) may be coupled to the ultrasound machine for trans-abdominal ultrasound imaging. In addition, other imaging devices, such as an MRI machine or a CT device, may also be used instead of an ultrasound machine.

[0014] Ablation device 22 is a sterile, electrosurgical device that may include a plurality of retractable arms 26. FIG. 1 shows arms 26 of ablation device 22 deployed in a pelvic tumor 28. Examples of the ablation device include the Model 30 Electrosurgical Device and the RITA® StarBurst™ XL, both available from RITA Medical Systems, Inc. Each arm 26 of ablation device 22 is a retractable curved electrode for delivering energy and has a thermocouple (not shown) located at the distal end. Although FIG. 1 shows ablation device 22 as including deployable arms, an ablation device without any arms may also be used. Alternatively, the ablation device may include two or more needles that may be inserted into the tumor.

[0015] Ablation device 22 is coupled to energy source 20, which supplies energy to each of the arms 26 of ablation device 22. Energy source 20 may be an RF generator, such as the Model 500 Generator or the RITA® Model 1500 RF Generator, both available from RITA Medical Systems, Inc. The supply of RF energy from energy source 20 to ablation device 22 and to a dispersive electrode 30 is controlled by an operator control, such as by a foot pedal 32. The application of RF energy causes an increase in tumor temperature. At sufficiently high temperatures, cell death occurs, thereby destroying the tumor.

[0016] Energy source 20 may further include a mono-polar or bipolar energy source, which allows the ablation device 22 to utilize traditional mono-polar or bipolar cautery to treat very small, superficial tumors and to ablate the track formed during insertion of ablation device 22. Cauterizing the ablation device track reduces or prevents bleeding upon withdrawal of ablation device 22 from the patient.

[0017] As better illustrated in FIG. 2, the equipment of surgical system 10 in accordance with the present invention, is set up about the patient in a non-traditional arrangement. FIG. 2 illustrates the patient P lying in a dorsal position on an operating table 34. A tower 36, which supports video monitor 14 for laparoscope 12 and imaging device monitor 18, is located proximate the patient's waist, rather than at the foot of operating table 34. Since the surgeon S is located on the other side of operating table 34 across from tower 36, the surgeon S has a direct

view of the monitors 14 and 18. Video monitors 14 and 18 need not be provided on tower 36; they may be suspended from the ceiling and located on the other side of operating table 34 across from the surgeon S. During longer surgical procedures, the placement of video monitors 14 and 18 directly across from the surgeon is more comfortable for the surgeon, as the surgeon need not turn his/her head toward the foot of operating table 34 to view monitors 14 and 18.

[0018] Although FIGS. 1 and 2 show separate video monitors 14 and 18 for laparoscope 12 and imaging device 16, respectively, a single monitor capable of simultaneously displaying multiple images from the laparoscope and the imaging device, such as a picture-in-picture monitor, may also be used. The single monitor would be located across the table from the surgeon S and may be mounted on tower similar to tower 36, suspended from the ceiling, or otherwise located across the patient from the surgeon for easy viewing by the surgeon.

[0019] Tower 36 may include additional equipment (not shown), such as an insufflation machine, a printer, and a light source. Tower 36 may be provided with wheels so that it may be easily moved about the operating room. An additional monitor 37 for laparoscope 12 may also be provided across from a surgical assistant A, who is seated across the table from the surgeon S, at approximately the patient's chest level. Thus, additional monitor 37 would be located adjacent the surgeon S. Additional monitor 37 may mounted on a movable tower (not shown), suspended from the ceiling, or otherwise appropriately located.

[0020] Imaging device 16 and energy source 20, which are not located on tower 36, are positioned along operating table 34, across from the surgeon S, and toward the foot of operating table 34. For example, imaging device 16 and energy source 20 may be located proximate the patient's knees.

[0021] A method of treating pelvic tumors, will now be described, with reference to the flow chart illustrated in FIG. 3. This method 50 employs a laparoscopic technique for ablating pelvic tumors. First, at step 52, the patient is prepared for laparoscopy by placing and properly adhering dispersive electrode 30 to the lower back of the patient. At step 54, the patient is then placed under general anesthesia, and the surgeon performs an examination of the pelvic region. A manipulator 38 (FIG. 1), such as a tenaculum, is placed on the patient's cervix, and a 14 french foley catheter is inserted into the patient's bladder for emptying the bladder during the surgical procedure.

[0022] At step 56, the patient is placed in a dorsal position with her arms at her sides, rather than extended out as an airplane, and a blanket and a surgical drape are placed over the patient. This position provides the surgeon and surgical assistant with more room to move about. The dorsal position is also a safer position for the patient than a frog-leg or lithotomy position, as the dorsal position reduces the instance of nerve injuries and provides better circulation. In addition, the dorsal position does not require the use of custom drapes and stirrups. The surgical drape contains pouches for at least one laparoscopic cord. Serial compression devices (not shown) are placed on the patient's legs to improve circulation during the surgical procedure and reduce the possibility of thromboembolism. In addition, the patient may be placed in a bear hugger system (not shown) to maintain the patient's body temperature while under general anesthesia.

[0023] At step 58, the equipment is arranged about operating table 34. As illustrated in FIG. 2, tower 36, which includes video monitors 14 and 18, an insufflation machine, a printer and a light source, is placed proximate the patient's waist and across from the surgeon S. The surgical assistant A is seated across the table from the surgeon at about the patient's chest level, with tower 34 located behind the assistant and further toward the foot of operating table 34. Imaging device 16 and energy source 20 are situated alongside operating table 34 on the same side as the assistant A and toward the foot of operating table 34. The additional monitor 37 is positioned across from the surgical assistant A at about the patient's chest level.

[0024] At step 60, the patient P is placed in a trendelenburg position. The surgeon then makes an infra-umbilical or sub-umbilical incision. A verres needle is then inserted into the incision and into the peritoneal cavity. The insufflation machine is then used to insufflate the abdomen with carbon dioxide gas until the abdominal pressure is approximately 15 mm Hg.

[0025] Next, at step 62, a 5 mm trocar and sleeve are inserted through the infra-umbilical or sub-umbilical incision. The trocar is then removed and laparoscope 12 is inserted into the sleeve. Laparosope 12 and monitor 14 are then used to verify correct placement of laparoscope 12 within the peritoneal cavity and the absence of any trauma. The sleeve is attached to the carbon dioxide gas supply and includes a valve for controlling the abdominal pressure of the peritoneal cavity.

[0026] Steps 60 and 62 discussed above describe a closed laparoscopy procedure. For those patients, for whom the surgeon feels an open laparoscopy would be advantageous, the surgeon would make an infra- or sub-umbilical incision and use a combination of blunt and sharp dissection through subcutaneous tissue. The surgeon would then retract the instruments for exposure. When the fascia is visualized, it is grasped with one or more clamps, elevated and incised. This provides a view of the peritoneum below, which may be bluntly or sharply incised. An appropriate laparoscopic sleeve is then placed, and the abdomen is insufflated with carbon dioxide gas. The laparoscope is then inserted into the sleeve.

[0027] At step 64, the surgeon then uses laparoscope 12, while palpating a top of the uterine fundus, to determine an optimal location for an intra-abdominal ultrasound probe. The optimal location is generally at the top of the uterus, rather than supra-pubic. An incision is then

made at this location and a 10 mm trocar and sleeve are inserted. The trocar is removed and ultrasound probe 24 is inserted into the sleeve. By way of example, the ultrasound probe 24 may be an Aloka model no. UST-5526L-7.5 probe for use with an Aloka model no. SSD140U ultrasound machine. Ultrasound probe 24 transmits an image of the pelvic region to ultrasound machine 16. The image is displayed on ultrasound video monitor 18, which is located on tower 36 proximate video monitor 14 for laparoscope 12. Thus, the surgeon may simultaneously view the images on video monitors 14 and 18. As discussed above, a single monitor that simultaneously displays images from laparoscope 12 and imaging device 16 may be used instead of separate monitors 14 and 18.

[0028] At step 66, the surgeon examines the entire pelvis and abdomen to confirm the presence or absence of any pathologies. The surgeon also uses laparoscope 12 and ultrasound probe 24 to visualize any tumors, such as uterine leiomyomata. In particular, the surgeon takes note of the number of tumors, and the location and size of each, and compares that information with previously acquired data.

[0029] At step 68, the surgeon determines an order for treating the tumors. This order is determined based on the locations of the various tumors, and whether or not the tumors are accessible from a single midline location or require different locations from which to access the tumors. For example, if two tumors are generally along the same track of ablation device 22, the surgeon will first ablate the deeper tumor and, upon retraction of ablation device 22, ablate the remaining tumor. In addition, the surgeon may choose to ablate first a portion of the tumor that is furthest away from the vasculature and work toward the vasculature, or vice versa.

[0030] At step 70, the surgeon tests ablation device 22 to ensure that it is operating properly. Ablation device 22 is connected to generator 20, and proper feedback from the thermocouples, if any, is observed. In particular, the surgeon operates foot pedal 32, or any other appropriate operator control, to activate the supply of RF energy from generator 20 and notes an appropriate rise in temperature and any peaks.

[0031] At step 72, if the surgeon decides that all of the tumors are approachable via a single midline location, the surgeon makes an incision, approximately 2.5 to 3.0 mm long, and inserts ablation device 22. Entry of ablation device 22 is observed using laparoscope 12. The surgeon uses ultrasound probe 24 to visualize the size and location of the tumors with respect to ablation device 22.

[0032] Next, at step 74, the surgeon manipulates the patient's uterus using other techniques to stabilize the uterus..

[0033] At step 76, after the surgeon has stabilized the uterus and located the tumors, the surgeon guides ablation device 22 into the uterus and the into a wall of the uterus. The surgeon may guide ablation device 22 by changing the position of the uterus relative to ablation device 22. In addition, the surgeon may rotate the ablation device for better penetration of the uterine wall with less movement of the uterus. Ablation device 22 has a plurality of markings (not shown) that enable the surgeon to note the depth of penetration of device 22. Confirmation of the location and placement of ablation device 22 are provided by both laparoscope 12 and ultrasound probe 24.

[0034] Next, at step 78, the surgeon advances the tip of ablation device 22 to an appropriate depth for treating a tumor. In doing so, the needle makes only a very small puncture. For example, an ablation device having a needle of 16 gauge may produce a puncture site of approximately 1 mm to 2 mm in diameter. The appropriate depth depends on the size of the tumor. When ablation device 22 has been inserted to the appropriate depth, arms 26 of ablation device 22 are deployed to the appropriate extent in the tumor 28, as illustrated in FIG. 1. A 30° scope is used to ensure that all of the arms 26 remain within the confines of the tumor and do not extend outside of the organ. Arms 26 may effectively anchor ablation device 22 in tumor 28.

[0035] At step 80, the surgeon then records a baseline starting temperature of the tumor. The temperature of the tumor is obtained by the thermocouples located at the distal ends of arms 26 of ablation device 22.

[0036] At step 82, the surgeon then ablates the tumor by supplying RF energy from generator 20 to ablation device 22. While generator 20 is activated, it is important to monitor the temperature or impedance of all parts of the ablation device. If the temperature or impedance for any part of ablation device 22 is abnormal, it could indicate that that part of the device is external to the organ.

[0037] RF energy is supplied to the tumor to raise the temperature of the tumor, such that it is in the range of between approximately 65 °C and 100 °C, for about 14 minutes. Cell death occurs at a temperature of about 65 °C. However, since these tumors are heterogeneous and, therefore, can differ in density, vasculature and content, a preferred target temperature range for ablating pelvic tumors is between 85 °C and 100 °C. For small tumors the target time may be between approximately 7 minutes and 14 minutes. One of ordinary skill in the art, however, will appreciate that ablation times of less than 7 minutes may also be adequate.

[0038] The temperature of the tumor, as provided by the thermocouples, is monitored and recorded at least at a 7 minutes and a 14 minutes interval. Thus, at least a baseline starting temperature, half-time temperature, and end-of-ablation-period temperature are recorded for each tumor. While RF energy is being delivered to the tumor, the surgeon keeps an eye on the monitors 14 and 18 to ensure that none of the arms 26 of ablation device 22 inadvertently extends through the tumor. The uterus can contract as it is heated, causing arms 26 of ablation device 22 to project from the tumor and contact normal tissue, which may be damaged by the RF energy. When the tumor has been sufficiently ablated, energy source 20 is turned off.

[0039] After each ablation, at step 84 the uterus is irrigated with fluid. The fluid prevents the serosa from drying out as a result of the carbon dioxide gas that is pumped into the abdomen.

[0040] If the tumor is larger than the ablation field for the given ablation device, then at step 86, the surgeon may need to reposition ablation device 22 within another part of the tumor and reapply RF energy, repeating steps 76 through 84. Thus, if the tumors are greater in size than the ablation capacity of ablation device 22, multiple applications of energy, of overlapping ablation areas, may be necessary to ablate the bulk of the tumor. For tumors less than 3 cm, however, a single application of the RF energy should be sufficient to ablate the tumor.

[0041] At step 88, the surgeon then repositions ablation device 22 at the next tumor. The surgeon may leave ablation device 22 in the same track, if the next tumor is along the same line of approach. The surgeon would retract arms 26 and advance or withdraw ablation device 22 as needed for entry into another tumor. The surgeon would then repeat the ablation sequence of step 76 through step 86 described above.

[0042] If the subsequent tumor is in a different location, the surgeon may retract arms 26 of ablation device 22 and withdraw ablation device 22, while applying a mono-polar cautery to reduce or prevent bleeding from the ablation device track. Alternatively, rather than completely withdraw ablation device 22 and re-insert ablation device 22 through another incision, repeating steps 72 through 86, the surgeon may withdraw ablation device 22 until it is only 0.5 cm to 1 cm deep and adjust the uterus until the desired angle of approach is obtained and properly locating ablation device 22 with ultrasound probe 24 or applying traction or pushing inward with uterine manipulator 38.

[0043] Small, superficial, subserosal fibroids (e.g., less than 1 cm) may be ablated with a mono-polar cautery at step 90. Bipolar paddles may also be used if the fibroid extends from the wall of the uterus. Similarly, if the tumor is pedunculated, the surgeon may treat or incise the stalk. Mono-polar or bipolar cautery may be applied to subserosal, intramural, and submucuos leiomyomata. In addition, other pelvic pathologies are treated as appropriate.

[0044] After all of the tumors have been ablated, at step 92, the surgeon confirms hemostasis, withdraws ablation device 22, and applies a mono-polar cautery with ablation device 22 to the puncture sites, if necessary. A small amount of irrigation fluid may be left in the pelvis.

[0045] Finally, at step 94, documentation, including videotapes, ultrasound photographs, and photographs from the laparoscope are obtained. The sleeves are opened to allow the escape of the carbon dioxide gas. The patient is then removed from the trendelenburg position, and a local anesthetic agent is injected into the incisions. The surgeon then repairs the fascia of the 10 mm incision using an absorbable suture, S-retractors to facilitate visualization of the fascial edges. Alis™ clamps are used to facilitate grasping for elevating the fascial edges for suturing, re-approximating the subcutaneous tissue with sutures, closing the skin, and placing Steristrip™ bandages. The surgeon then removes the dispersive electrode 30 and examines the surrounding skin.

[0046] The patient is transported to a recovery room, where she will remain until she is tolerating liquids, ambulating with assistance, and voiding adequately.

[0047] If the patient's uterus is very large (e.g., 16 weeks or greater), the above-described laparoscopic technique may be less effective. Accordingly, a direct trans-abdominal insertion of ablation device 22 is performed with laparoscopic confirmation only (e.g., no intra-abdominal ultrasound confirmation). In this method the patient is prepared in the same manner as that described above at step 52. The surgeon also performs a pelvic examination, positions the patient, arranges the equipment, forms an infra-umbilical incision, insufflates the patient's abdomen, and inserts laparoscope 12, as in step 54 through to step 62 above. Specifically, the surgeon inspects the abdomen and documents the presence or absence of bowel adhesions or other pathologic conditions that would render this method inappropriate.

[0048] Next, the surgeon releases the gas from the patient's abdomen, allowing the abdominal wall to contact an anterior portion of the uterus. A sterile cover drape over a transducer allows for trans-abdominal ultrasound imaging using a non-sterile transducer (not shown). The ultrasound is used to locate and measure the tumors.

[0049] The surgeon then makes an incision for ablation device 22 and inserts ablation device 22, using abdominal ultrasonography to guide its insertion. Ablation device 22 may be inserted percutaneously, or trans-abdominally, into the tumor in the uterus.

[0050] Ablation device 22 is positioned at a tumor and arms 26 are deployed in the tumor, just as described above with respect to the laparoscopic method. Prior to applying RF energy to the tumor, the surgeon insufflates the abdomen and performs a laparoscopy to confirm that none of the arms 26 of ablation device 22 extend beyond the uterine tissue.

[0051] The surgeon then applies RF energy to the tumor, in the same manner as described at step 80 through step 84 above, including recording the baseline, half-time, and end-of-ablation-period temperatures. The surgeon may use the same approach as described above to ablate multiple pelvic tumors. Upon withdrawal of the ablation device 22, the surgeon fulgurates the ablation device track with a mono-polar cautery. Thus, remaining steps are the same as step 86 through step 94 described above.

[0052] The above-described methods of using the invention enable the surgeon to ablate substantially all of a tumor from a single, ablation device puncture site. In addition, depending on the location of the tumors, multiple tumors may be ablated from a puncture site. The methods further enable the surgeon to treat all sizes of tumors in any area of the pelvic region.

[0053] The foregoing description of the preferred em-

bodiments of the present invention have been provided for illustrative purposes only. They are not intended to be exhaustive or to limit the invention to the precise forms disclosed. Various modifications may be made without departing from the scope of the inventions as set forth in the appended claims. For example, although the present invention has been described with respect to the treatment of uterine leiomyomata, the present invention may also be used to treat other pelvic tumors, such as those present in the ovaries.

Claims

1. A surgical system for ablating a uterine fibroid in a patient, comprising:

   an ablation device positionable and configured for insertion into a uterine fibroid in a patient, the ablation device comprising at least three electrodes for direct ablation of the uterine fibroid, said electrodes being configured for engagement with the uterine fibroid within the uterine fibroid and to avoid contact with normal tissue outside of the uterine fibroid, said electrodes being mounted within the ablation device for deployment from the ablation device and retraction into the ablation device;
   an RF energy source coupled to the ablation device for providing RF energy to said electrodes;
   a laparoscope adapted to be disposed within the patient in a configuration to confirm placement of the electrodes within the uterine fibroid, said laparoscope being spaced apart from said ablation device;
   characterized by :
   an intra-abdominal ultrasound imaging probe, separate from the ablation device, adapted to be disposed within the patient in a configuration to also confirm placement of the electrodes within the uterine fibroid, the intra-abdominal ultrasound probe being separated by a distance from said ablation device to result in the intra-abdominal ultrasound probe imaging the uterus of the patient to image a location of the ablation device within the uterine fibroid; and
   an insufflation device disposed in a configuration for insufflating the abdomen and creating an air pressure within the abdomen of the patient with the uterus hosting the uterine fibroid, allowing laparoscope to visualize the uterus.

2. The surgical system of claim 1, wherein the laparoscope and the intra-abdominal imaging probe are operably coupled to at least one monitor.

3. The surgical system of claim 1, further comprising an operator control operably coupled to the energy source, said operator control being a foot pedal.

4. A surgical system for ablating uterine fibroids in a patient as in claim 1, further comprising:

   a manipulator positioned for mechanically engaging the uterus and for changing the position of the uterus and, in response to the changing of the position of the uterus to change the position of one of said uterine fibroids.

5. The surgical system of claim 1, wherein the laparoscope and the intra-abdominal imaging probe are operably coupled to at least one monitor, the at least one monitor being located along a first side of an operating table, and wherein the energy source is located adjacent the at least one monitor along the first side of the operating table.

6. A surgical system for ablating uterine fibroids in a patient as in claim 1, wherein the ablation device includes an elongated needle and a tip.

7. The surgical system of claim 1, wherein said ablation device, laparoscope and ultrasound probe are positioned relative to each other so that when said ablation device is in said tumor, said ultrasound probe is in contact with the uterus hosting said tumor.

Patentansprüche

1. Chirurgisches System für die Ablation eines Uterusmyoms in einer Patientin, das Folgendes umfasst:

   eine Ablationsvorrichtung, die zum Einführen in ein Uterusmyom in einer Patientin positionierbar und ausgeführt ist, wobei die Ablationsvorrichtung mindestens drei Elektroden für die direkte Ablation des Uterusmyoms umfasst, wobei die genannten Elektroden für den Eingriff mit dem Uterusmyom im Uterusmyom und dazu, den Kontakt mit normalem Gewebe außerhalb des Uterusmyoms zu vermeiden, ausgebildet sind, wobei die genannten Elektroden zum Ausfahren aus der Ablationsvorrichtung und zum Einfahren in die Ablationsvorrichtung in der Ablationsvorrichtung montiert sind;
   eine HF-Energiequelle, die an die Ablationsvorrichtung gekoppelt ist, um HF-Energie an die genannten Elektroden zu liefern;
   ein Laparoskop, das dazu angepasst ist, in einer Ausbildung in der Patientin angeordnet zu werden, um die Platzierung der Elektroden im Uterusmyom zu bestätigen, wobei das genannte Laparoskop in einem Abstand von der genannten Ablationsvorrichtung angeordnet ist;

gekennzeichnet durch:

eine von der Ablationsvorrichtung getrennte intraabdominale Ultraschall-Bildgebungssonde, die dazu angepasst ist, in der Patientin in einer Ausbildung angeordnet zu werden, um ebenfalls die Platzierung der Elektroden im Uterusmyom zu bestätigen, wobei die intraabdominale Ultraschallsonde **durch** einen Abstand von der genannten Ablationsvorrichtung getrennt ist, um dazu zu führen, dass die intraabdominale Ultraschallsonde den Uterus der Patientin abbildet, um eine Lage der Ablationsvorrichtung im Uterusmyom abzubilden; und
eine Insufflationsvorrichtung, die in einer Ausbildung angeordnet ist, um den Unterleib aufzublasen und einen Luftdruck im Unterleib der Patientin mit dem das Uterusmyom beherbergenden Uterus zu erzeugen, so dass das genannte Laparoskop den Uterus und die genannte Ablationsvorrichtung sichtbar machen kann.

2. Chirurgisches System nach Anspruch 1, wobei das Laparoskop und die intraabdominale Bildgebungssonde wirksam an mindestens einen Monitor gekoppelt sind.

3. Chirurgisches System nach Anspruch 1, weiter umfassend eine Bedienersteuerung, die wirksam an die Energiequelle gekoppelt ist, wobei es sich bei der genannten Bedienersteuerung um ein Fußpedal handelt.

4. Chirurgisches System für die Ablation von Uterusmyomen in einer Patientin nach Anspruch 1, das weiter Folgendes umfasst:

einen Manipulator, der dazu positioniert ist, mechanisch mit dem Uterus in Eingriff zu treten und die Lage des Uterus zu ändern und als Reaktion auf die Änderung der Lage des Uterus, die Lage eines der genannten Uterusmyome zu ändern.

5. Chirurgisches System nach Anspruch 1, wobei das Laparoskop und die intraabdominale Bildgebungssonde wirksam an mindestens einen Monitor gekoppelt sind, wobei sich der mindestens eine Monitor entlang einer ersten Seite eines Operationstischs befindet und wobei sich die Energiequelle neben dem mindestens einen Monitor entlang der ersten Seite des Operationstischs befindet.

6. Chirurgisches System für die Ablation von Uterusmyomen in einer Patientin nach Anspruch 1, wobei die Ablationsvorrichtung eine längliche Nadel und eine Spitze umfasst.

7. Chirurgisches System nach Anspruch 1, wobei die genannte Ablationsvorrichtung, das genannte Laparoskop und die genannte Ultraschallsonde so relativ zueinander positioniert sind, dass, wenn sich die genannte Ablationsvorrichtung im genannten Tumor befindet, die genannte Ultraschallsonde mit dem den genannten Tumor beherbergenden Uterus in Kontakt ist.

Revendications

1. Système chirurgical permettant l'ablation d'un fibrome utérin chez une patiente, comportant :

un dispositif d'ablation en mesure d'être positionné et configuré à des fins d'insertion dans un fibrome utérin chez une patiente, le dispositif d'ablation comportant au moins trois électrodes pour une ablation directe du fibrome utérin, lesdites électrodes étant configurées à des fins de mise en prise avec le fibrome utérin à l'intérieur du fibrome utérin et pour éviter tout contact avec le tissu normal à l'extérieur du fibrome utérin, lesdites électrodes étant montées à l'intérieur du dispositif d'ablation à des fins de déploiement en provenance du dispositif d'ablation et de rétraction dans le dispositif d'ablation ;
une source d'énergie radioélectrique couplée au dispositif d'ablation pour fournir une énergie radioélectrique auxdites électrodes ;
un laparoscope adapté pour être disposé à l'intérieur d'une patiente selon une configuration permettant de confirmer le positionnement des électrodes à l'intérieur du fibrome utérin, ledit laparoscope étant espacé à distance dudit dispositif d'ablation ;

caractérisé par :

une sonde d'imagerie ultrasonique intra-abdominale, séparée du dispositif d'ablation, adaptée pour être disposée à l'intérieur de la patiente selon une configuration permettant également de confirmer le positionnement des électrodes à l'intérieur du fibrome utérin, la sonde ultrasonique intra-abdominale étant séparée d'une distance dudit dispositif d'ablation pour amener la sonde ultrasonique intra-abdominale à imager l'utérus de la patiente pour imager une position du dispositif d'ablation à l'intérieur du fibrome utérin ; et
un dispositif d'insufflation disposé selon une configuration permettant d'insuffler l'abdomen et de créer une pression d'air à l'intérieur de l'abdomen de la patiente ayant l'utérus contenant le fibrome utérin, pour permettre audit laparoscope de visualiser l'utérus et ledit dispositif d'ablation.

2. Système chirurgical selon la revendication 1, dans lequel le laparoscope et la sonde d'imagerie intra-abdominale sont couplés fonctionnellement à au moins un moniteur.

3. Système chirurgical selon la revendication 1, comportant par ailleurs une commande d'opérateur couplée fonctionnellement à la source d'énergie, ladite commande d'opérateur étant une pédale.

4. Système chirurgical permettant l'ablation de fibromes utérins chez une patiente selon la revendication 1, comportant par ailleurs :

   une manette de manoeuvre positionnée à des fins de mise en prise avec l'utérus de manière mécanique et pour changer la position de l'utérus et, en réponse au changement de la position de l'utérus, pour changer la position de l'un desdits fibromes utérins.

5. Système chirurgical selon la revendication 1, dans lequel le laparoscope et la sonde d'imagerie intra-abdominale sont couplés fonctionnellement à au moins un moniteur, ledit au moins un moniteur étant situé le long d'un premier côté d'une table d'opération, et dans lequel la source d'énergie est située de manière adjacente audit au moins un moniteur le long du premier côté de la table d'opération.

6. Système chirurgical permettant l'ablation de fibromes utérins chez une patiente selon la revendication 1, dans lequel le dispositif d'ablation comprend une aiguille allongée et un embout.

7. Système chirurgical selon la revendication 1, dans lequel ledit dispositif d'ablation, ledit laparoscope et ladite sonde ultrasonique sont positionnés les uns par rapport aux autres de sorte que, quand ledit dispositif d'ablation est dans ladite tumeur, ladite sonde ultrasonique est en contact avec l'utérus contenant ladite tumeur.

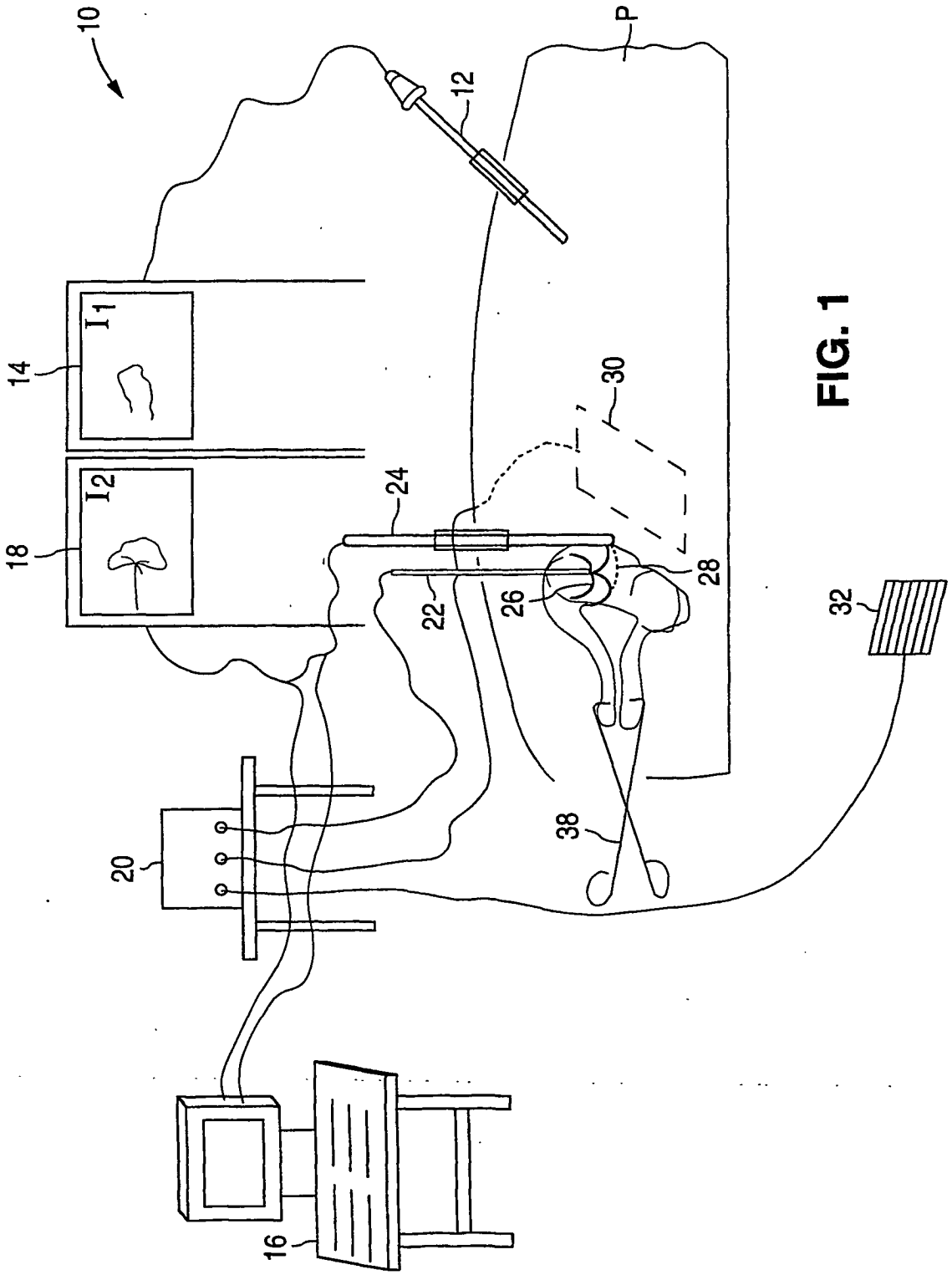

FIG. 1

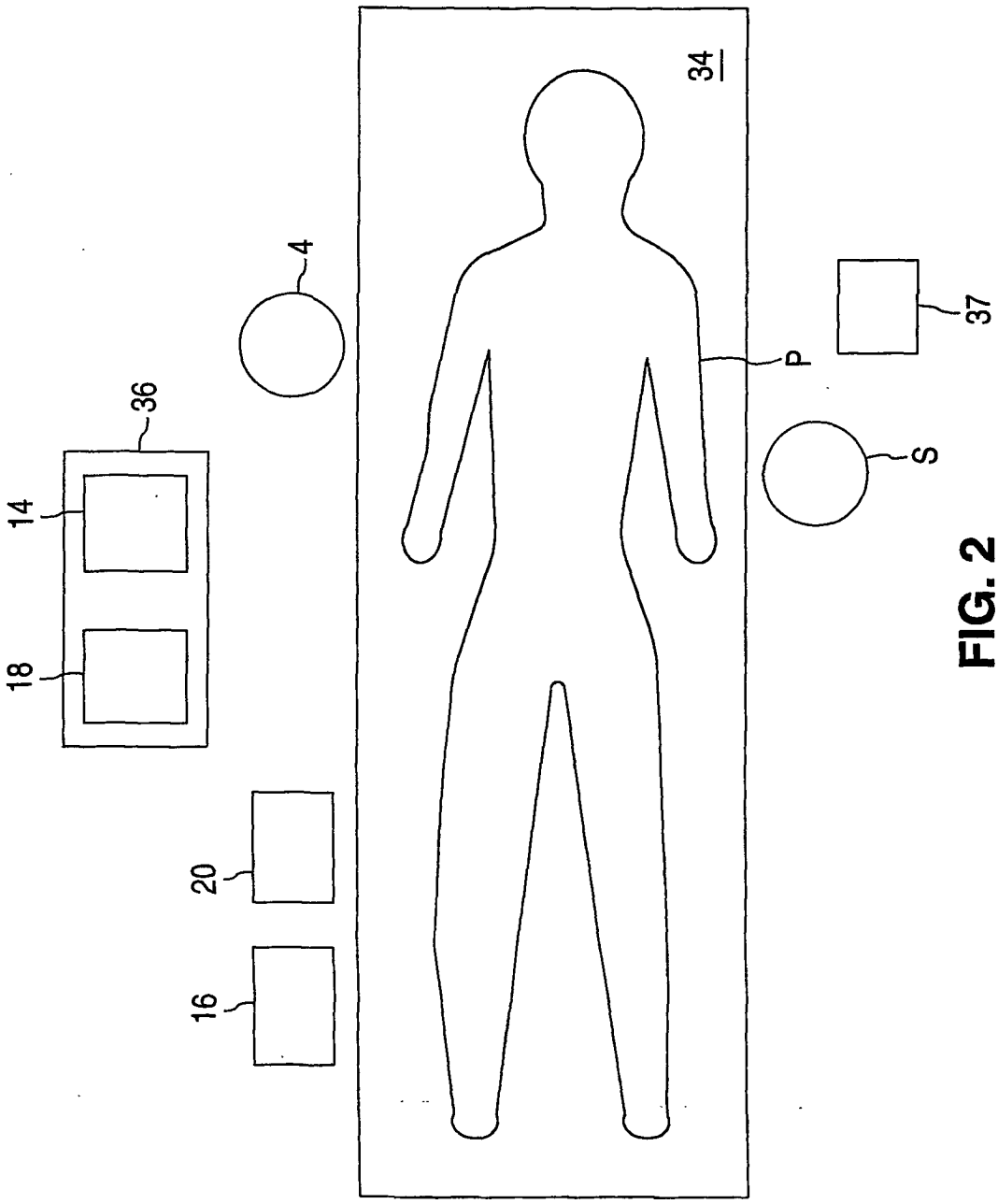

FIG. 2

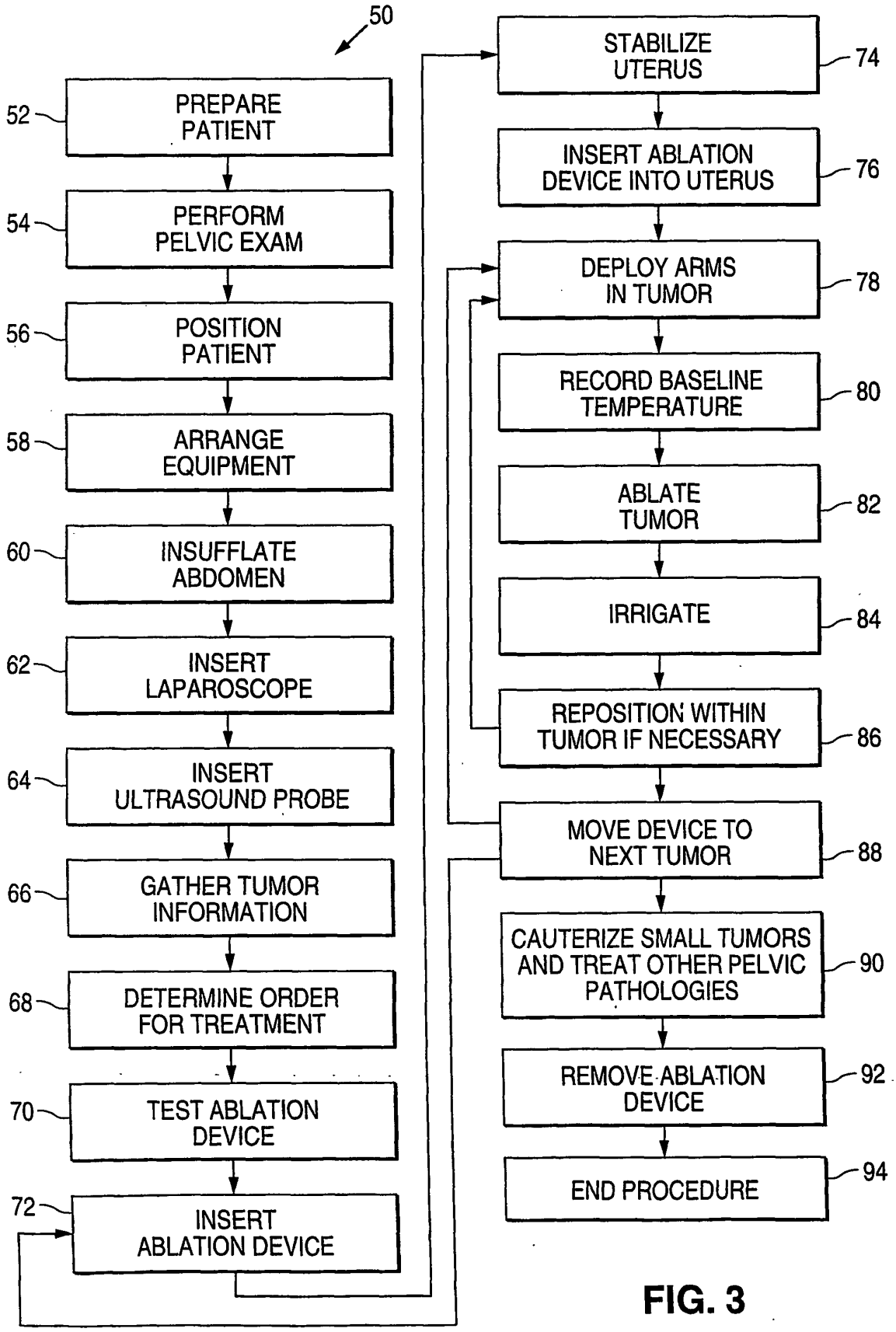
50
52
PREPARE PATIENT
54
PERFORM PELVIC EXAM
56
POSITION PATIENT
58
ARRANGE EQUIPMENT
60
INSUFFLATE ABDOMEN
62
INSERT LAPAROSCOPE
64
INSERT ULTRASOUND PROBE
66
GATHER TUMOR INFORMATION
68
DETERMINE ORDER FOR TREATMENT
70
TEST ABLATION DEVICE
72
INSERT ABLATION DEVICE
74
STABILIZE UTERUS
76
INSERT ABLATION DEVICE INTO UTERUS
78
DEPLOY ARMS IN TUMOR
80
RECORD BASELINE TEMPERATURE
82
ABLATE TUMOR
84
IRRIGATE
86
REPOSITION WITHIN TUMOR IF NECESSARY
88
MOVE DEVICE TO NEXT TUMOR
90
CAUTERIZE SMALL TUMORS AND TREAT OTHER PELVIC PATHOLOGIES
92
REMOVE ABLATION DEVICE
94
END PROCEDURE

FIG. 3

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	使用消融针的妇科消融系统		
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[标]申请(专利权)人(译)	BRUCE LEE乙		
申请(专利权)人(译)	李，布鲁斯，B.		
当前申请(专利权)人(译)	李，布鲁斯，B.		
[标]发明人	LEE BRUCE B		
发明人	LEE, BRUCE, B.		
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代理机构(译)	FREEMAN，杰奎琳CAROL		
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摘要(译)

用于治疗盆腔肿瘤（例如子宫平滑肌瘤）的方法包括将消融装置插入骨盆区域并将消融装置定位在骨盆肿瘤附近或其中。该方法还包括使用腹腔镜和诸如超声机器的成像装置来确认骨盆肿瘤的位置和消融装置的放置。可以使用各种消融设备，包括具有插入骨盆肿瘤的多个针或可展开臂以及没有臂的消融设备。该方法还包括通过消融装置将电磁能或其他能量输送到骨盆肿瘤以消融肿瘤。还提供了用于消融骨盆肿瘤的手术系统。

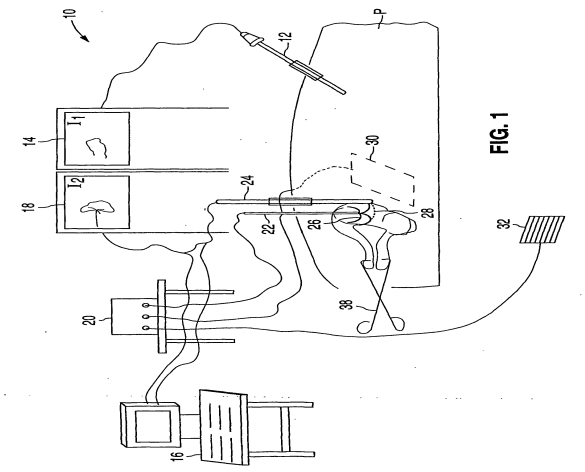

FIG. 1