ABSTRACT

A surgical electrode is described. This instrument is adapted to fit into a body cavity, to be directed by the surgeon to an operative area in the cavity and then to emit a cauterizing electric current. Several embodiments are disclosed. In one, a blind electrode is positioned and pulsed. In another, an electrode is coupled with optics to permit directing it by sight or by CRT display. In another, a forked or dual electrode is shaped to the body cavity and can be properly positioned with excellent reliability. Preferably, at least the portion of the instrument inserted in the body cavity is disposable. The present invention includes method and apparatus for female sterilization using the electrode for cauterization of fallopian tubes.

7 Claims, 15 Drawing Figures
FIG. 12

142 TO FLUID SUPPLY 145

144 TO CAUTERY POWER SUPPLY

143 TO LIGHT SOURCE

FIG. 10

102

106

FIG. 11

110

109

101

108

107

105

106
1 SURGICAL METHOD AND ELECTRODE THEREFOR
CROSS-REFERENCE TO CO-PENDING APPLICATION

This present application is a continuation-in-part of co-pending U.S. Pat. Application Ser. No. 123,194 filed Mar. 11, 1971 and now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to a new surgical instrument and to its use and operation.

This is a continuation-in-part of application Ser. No. 123,194 wherein it was disclosed that a fine electrode member is placed into a natural body cavity, the tip of the electrode positioned at a constricted point of such cavity, and that the electrode tip then is energized to cause a cauterizing spark. A consequence of the cauterizing spark is the cleaning or sterilization of the constriction or fine passageway. One specific consequence of such spark well within a fine passage is that scar tissue forms, thus sealing, healing or blocking the passageway. Thus, if the passage is the consequence of an injury or other physical or physiological defect, infection or the like, the electrode can be a healing mechanism. In one embodiment of the invention, a natural passageway can be blocked by proper use of this electrode. In particular, fallopian tubes can be blocked by use of this electrode with the consequence that female sterilization can be brought about. The present invention is directed to such female sterilization.

At the present time, there is a great need for a quick, easy and effective mechanism for female sterilization. This need is abundantly clear in the United States and is perhaps even more pressing in other countries, particularly, poverty stricken countries. Birth control and population reduction are easily and non-surgically accomplished by a wide variety of means dependent on continual cooperation by the people involved. Sterilization, however, has generally been a serious surgical operation requiring hospitalization and use of a surgical operating room. Obviously, therefore, the need is clear for a sterilization procedure which can be carried out for example, in the doctor's office. Even more pressing is the need for some form of mass sterilization techniques in which a doctor or a team of medical personnel can operate a sterilization technique at temporary field quarters. The present invention provides such a technique.

GENERAL NATURE OF THE INVENTION

The present invention comprises a surgical electrode adapted to be operated for female sterilization by insertion of an electrode tip well within the walls of the fallopian tubes. When properly positioned, the electrode is energized, causing a spark which in turn causes scar tissue, blocking the fallopian tube. A high percentage of success can be achieved, and within a few days of the operation, a clinical or medical test can be performed to determine whether it was or was not successful. No hospital visit is required and the operation can be carried out in a few minutes essentially painlessly in the doctor's office. If desired, clinic or field operations can be carried out to treat a large number of people quickly, easily, painlessly and effectively.

Operations intended to block fine passages such as fallopian tubes have been employed previously with a substantial lack of success, at least for the purpose of human sterilization. The problem is that side effects may result and also that sterilization is uncertain. In particular, if blockage of the passage occurs essentially at the mouth of the passage, then there is too large a likelihood that the passage will not be effectively blocked and that physiological disorders will result. Accordingly, in use of the electrode according to the present invention, it is essential that the tip of the electrode be sufficiently fine to fit well within the passage being blocked and it is essential that it be so positioned.

SPECIFIC DESCRIPTION OF THE INVENTION

The nature of the invention is more particularly set forth and apparent from the drawings, in which:

FIG. 1 is a diagrammatic view of a surgical instrument according to one embodiment of the invention;
FIG. 2 is an enlarged fragmentary view in cross-section of one form of an electrode for the device of FIG. 1;
FIG. 3 is an enlarged fragmentary view in cross-section of another form of an electrode for the device of FIG. 1;
FIG. 4 is a side view of an electrode according to another embodiment of the invention;
FIG. 5 is a front view of the electrode of FIG. 4 in partly closed position;
FIG. 6 is a front view of the electrode of FIG. 4 in open position;
FIG. 7 is a diagrammatic view of an electrode according to another embodiment of the invention;
FIG. 8 is a diagrammatic view of another form of an electrode;
FIG. 9 is a diagrammatic view of three electrode portions of an electrode according to another electrode embodiment;
FIG. 10 is a view of a surgical electrode for sterilization according to another embodiment of the invention;
FIG. 11 is a diagrammatic view of the operating end of the electrode of FIG. 10;
FIG. 12 is the electrode of one embodiment of the invention positioned to perform cautery inside a fallopian tube;
FIG. 13 is an enlargement in section of the end of the electrode of FIG. 12;
FIG. 14 is an enlargement in section of the eyepiece end of the electrode of FIG. 12;
FIG. 15 is a cross section view of the assembly of FIG. 13.

The surgical instrument according to this invention may be a general purpose instrument, but preferably, it has shape and configuration specifically adapting it to a single preferred type of application. The presently preferred device is adapted to sterilization of the female human being or female animal, as the present invention now is believed to have as its most important aspects a method and instrument for sterilization. In certain instances, it is desired to have simply a surgical electrode which can be manipulated to position its operative electrode tip at a desired position within a body cavity, which position can be readily determined by a practiced and experienced surgeon from a position external to the body. In this situation, the experienced surgeon need merely employ a single elongated electrode such as that shown in FIGS. 1, 2 and 3 which he can, by practice, and experience, manipulate to the de-
sired position within the body cavity. In many instances, the manipulation can be assisted visually either by looking into the body cavity from an external position or by optical means. In this way, for example, it is possible to employ the surgical instrument for many forms of corrective surgery where a relatively large body cavity is being treated or where a passage is accessible directly from outside the body. Certain cysts and infected channels can be treated in this manner and it is observed that electrical cauterization not only produces healing scar tissue, but also cleans or sterilizes the passage being treated.

In many instances, however, it is necessary to treat a fine passage positioned well within a cavity in the human body at a position which cannot be readily located with accuracy from outside the body. In such instances, it may be desirable to employ the electrode combination illustrated in FIG. 7. In this figure is illustrated a surgical instrument including a flexible maneuverable electrode having an operable electrode tip and including flexible optical means such as the fiber optics member illustrated in the figure. The surgeon employing such an instrument can direct it to a precise position within the body cavity and can with confident assurance, position the operable electrode tip at precisely the right location for electric cauterization to produce the desired scar tissue. The surgical electrode according to this embodiment of the invention has universal application and can be employed in the simplest of operations at or near the surface of the body and in the most difficulty accessible positions within the most tortuous body cavities. It is to be observed in particular that this electrode can be employed deeply within nasal passages or within the throat and even to the extent of being employed in the stomach or abdominal passages. Although certain embodiments of surgical electrodes according to this invention may be specifically designed for common surgical procedures repeatedly employing essentially a standard technique, it is still possible to employ this embodiment of the invention including both operative electrode tip and optical means in essentially any and all surgical procedures contemplated by the present invention.

In FIGS. 4, 5 and 6, there is also shown a special purpose surgical electrode which may be appropriately designed for an operation requiring two (or more than two) electric cauterizations in a standardized surgical operation which may be carried out time and time again. Such an operation typically may be animal sterilization in which a predetermined size and shape electrode including at least two operative electrode tips is appropriately positioned to trigger simultaneously two or more electric cauterization discharges which will produce scar tissue appropriately sealing fine body passages at uniformly predictable positions within a body cavity. It is possible according to this embodiment of the invention to produce simple, inexpensive surgical electrodes having a plurality of operable electrode tips and to produce these electrodes at a cost essentially the same as or perhaps even less than the cost of sterilization after use. Accordingly, a new and unused, and therefore sterilized, electrode may be employed on one animal and immediately thrown away to permit the use of another new, and therefore sterilized, electrode for at least those portions of surgical apparatus which are employed within a body cavity.

The use of the electric cauterization instrument and technique according to the present invention has many obvious advantages. The primary advantage is that a surgical result can be achieved at a difficulty accessible or otherwise inaccessible portion of the body without cutting or surgically opening body tissue. In this way, it is possible to accomplish surgery without hospitalization for operations which might otherwise require several or many days recuperation in a hospital.

Certain specific embodiments of devices according to this invention are illustrated in the drawings accompanying this description. It is to be understood, of course, that various modifications will be obvious to one skilled in the art.

FIG. 1 is a schematic representation in very simple form of an electrode according to the concept of this invention. As illustrated in FIG. 1, the device includes a handle 11 having an elongated flexible electrode tip 12. The handle may for example, have gripping means 13 to permit it to be conveniently held in the hand of the surgeon. It may have an external electric cord 14 adapted to be plugged into a conventional electric outlet or it may have self-contained electric circuitry suitable mounted within the handle. The flexible electrode 12 may consist of a double electrode wire as illustrated in other figures or there may be a ground lead 15 extending from the device and terminating in a ground plate or clamp (not shown) adapted to be positioned against the skin of the animal or patient as close as possible to the point of surgery.

Conventionally mounted on the handle 11 is an electric switch or button which is adapted to be thrown or pressed to operate the electric circuitry to produce a pulse at the tip of electrode 12 when desired. It is understood that the circuitry to produce the pulse is completely conventional and may comprise any desired electrical mechanism to produce a pulse or spark at a tip of the electrode. A conventional high frequency or a capacitance circuit may be triggered by switch or button 16 to produce such a pulse and the circuit can be energized by an internal battery-operated electric means or by electric means connectable to a conventional and convenient power outlet.

In FIG. 2 is shown in enlarged partial cross-section one form of electrode 12 of the device of FIG. 1. This flexible electrode comprises an electrically conductive wire 21 terminating in a tip 22 and surrounded by a plastic sheath 23. Desirably, the wire 21 is longitudinally moveable within the sheath and in such case, it is also desired that the wire 21 have a thin coating of plastic or other insulator along its length except the tip 22. In use and operation, the flexible electrode 12 is inserted into the body cavity until it is at the desired position. Electrode wire 21 is then advanced in sheath 23, or sheath 23 is then retracted from the tip to assure proper mechanical contact with the tissue to be cauterized. When the tip is properly positioned, switch or button 16 is activated to create an electric pulse or electric spark at tip 22 of electrode 12.

In FIG. 3 is shown a modified and presently preferred embodiment of flexible electrode 12. According to this embodiment, a pair of insulated wires 31 and 32 terminate in tips 33 and 34 and are encased in a plastic shield or sheath 35. The wires may or may not be longitudinally movable in the sheath 35. The electrode according to this embodiment of the invention is employed in the same way as the electrode according to FIG. 2. It
is inserted into the body cavity properly positioned and then an electric pulse is generated to produce a spark or similar pulse between electrode tip 33 and electrode tip 34 that produces electric cauterization of the tissue. The insulated conductors 31, 32 and tips 33, 34 may be coaxial in geometry.

Size and shape of the flexible electrode 12 is material to the function of the device, inasmuch as it relates significantly to size and shape of a natural body cavity of a human or other animal. A purpose to be achieved by the present invention is to permit easy and simple operation within a body cavity of an animal or human being and generally speaking, it is expected that such operations will be carried out within a tightly confined cavity or at a precisely positioned location within the cavity. Accordingly, the electrode 12 generally will be long enough to reach into the body cavity and to the rightelectrode length and preferably completely outside the cavity. For most purposes, the electrode will be roughly six to twelve inches long. Also, obviously, longer or shorter may be acceptable or necessary for certain purposes. In addition, the electrode 12 generally will be quite thin and it will be only unusual cases that the width or diameter of the electrode will exceed ¼ inch or at the most ¼ inch. Obviously, thicker electrodes can be used for certain purposes, but the convenience of the present surgical instrument generally will not be realized except with an extremely thin electrode which can reach positions within a body cavity where conventional instruments cannot find access. Likewise, electrode tips 33 and 34 (where a dual electrode is used) should be positioned as close together as possible consistent with producing a workable and effective electric spark or electric pulse by the tips. Generally speaking, the electrode tips will be spaced a small fraction of an inch apart to produce a highly concentrated localized pulse or spark, thus permitting accurate position and location of the electric cauterization.

Generally speaking, the electrode 12 will have a spring-like resiliency permitting it to be positioned within a body cavity without bending out of shape and without being so rigid as to harm the tissue which it contacts. This result can be achieved with the use of conventionally available spring steel electrode wires. The wires together with an electrically insulating coating can be appropriately thin and still have the desired degree of strength and flexibility. Accordingly, it is to be realized that the sections of electrode 12 illustrated in FIGS. 2 and 3 have been distorted in shape and do not represent a reasonable depiction of the preferred electrode and electrode dimensions.

In FIGS. 4 and 5 are illustrated another embodiment of the invention employing a forked electrode adapted to cauterize locations within a body cavity. This form of the electrode is presently preferred for an operation in which cauterization is desired at two predictably spaced locations within a single body cavity. A preferred purpose of the instrument is catarization of fallopian tubes and, accordingly, for this purpose, the preferred instrument is shown schematically in FIGS. 4, 5 and 6.

FIG. 4 illustrates the side view of a bifurcated electrode generally designated 41. The electrode has a single body section 42 from which extend two divergent electrode 43 terminating at electrode tips 44. The electrode illustrated in FIG. 4 tapers slightly from body 42 to the tip 44 and generally curves gradually to conform with a typical body cavity. As seen in FIG. 5, and FIG. 6, a sheath preferably a plastic sheath 46 retractably covers the two electrode sections 43 and can extend close to or if desired over electrode tips 44. The insulated conductors are longitudinally movable within the electrodes 43 to advance the tips 44 to their desired position.

In operation, the device according to FIG. 4 is first closed and protected with sheath 46 extending essentially to the electrode tips. It is then inserted into the body cavity after which sheath 44 is withdrawn to permit electrodes 43 to spread apart to their natural position. The device is then manipulated by the skilled operator until electrode tips 44 are both at the desired position and then the two electrodes 43 are simultaneously or sequentially pulsed to produce a cauterizing electric pulse or spark at tips 44. Generally, it will be preferred to have individual operating electric circuits for each of electrodes 43 and to employ dual wires in each as shown in FIG. 3. In this way, a first electrode 43 is energized to produce a cauterizing pulse and the pulse preferably will be indicated by suitable dials, gauges or other signals externally positioned. After the first pulse has been produced to the electrode, a second pulse is produced at another electrode and again is signaled appropriately externally.

The device of FIG. 1 in conjunction with the electrodes shown in FIGS. 2 through 6 can be extremely inexpensively manufactured particularly in moderate or large quantities. Accordingly, their cost can be so low as to make it economically feasible for the electrodes to be used once and thrown away. Disposable electrodes, accordingly, are contemplated and it is to be expected that at least that portion of the device which operates within the body cavity may be disposable to permit a single use, although, of course, the device may be sterilized and reused if so desired.

In FIG. 7 is illustrated another embodiment of the invention including self-contained optical means to permit a skilled operator or surgeon to position the operating tip of the electrode by sight or by other visual means. As schematically illustrated in FIG. 7, a flexible protective sheath 71 encases a plurality of electrode wires 72 suitably insulated and positioned in generally the same manner as shown in the other figures. Also positioned within the sheath 71 is a fiber optics bundle 73 for viewing the position of the electrode tip, optionally with a second fiber optics bundle 73A to carry light into the body cavity to illuminate the field of vision. Optionally, bundle 73 can operate to carry light both ways and to serve both the illumination and viewing purposes. Near the end of the fiber optics bundle 73 a fiber optics bundle 73A is an optical imaging means such as a maneuverable mirror 74 which may, for example, be rotatable around pivot 75. A control mechanism such as a control wire 76 can adjust the mirror 74. Optionally, an outer disposable sheath 78 permits a flow of water or other fluid to the end of the electrode to flush out the field of vision.

Associated with the electrode of FIG. 7 can be extremely small light sources or other devices to assist in viewing and positioning the electrode tip. In use and operation, after the electrode of FIG. 7 is properly positioned, sheath 71 may be partially retracted to bring electrode 72 into the proper location and the electrode may then be pulsed.
The surgical instrument according to the present invention can be employed for any desired electrical cauterization operation within the body cavity of a human being or other animal. The presently preferred purpose, however, is in connection with female sterilization for birth control where it is expected that a simple and convenient operation can be performed in a few minutes without the necessity for incision with other surgically designed instruments. It is also expected that a careful, skilled operator can achieve a successful result in excess of 95 percent of the occasions of use. Furthermore, with a medical check after the operation to detect incomplete success, it is expected that essentially 100 percent effectiveness can result from a single or once-repeated operation. It is also expected that the cost of such operation both in terms of money and in terms of patient care can be reduced perhaps at least to about 1 percent of the time and cost of conventional operations.

In FIG. 8 is shown another form of electrode probe according to this invention including an elongated electrode body 81 which may be one of the electrodes of a previously described such as the electrode of FIG. 7. The electrode body 81 has electrode tips 82 at the point thereof and means (not shown) for pulsing the tips. An outer sheath 83 retractably covers electrode body 81. At the end of the sheath furthest from the tip is a ring or handle 84 forming a finger grip to retract the sheath from the electrode tip and a cooperating base or finger grip 85 on the electrode body forms convenient means associated with the electrode to expose the electrode tips in operative position for a cauterizing electric pulse.

In FIG. 9 is shown diagrammatically a portion of an electrode adapted to be positioned within a disposable plastic sheath like, for example, the electrode of FIG. 7, or adapted to be encased in a plastic shield like, for example, the electrode structure of FIG. 3. In FIG. 9, a pair of electrodes 91 and 92 are positioned on each side of a central electrode 93. The tip of central electrode is a ring tip 94. All the tips of electrodes 91 and 92 are insulated, preferably being covered with plastic insulators 95 and 96 which may, if desired, be a single unitary elongated plastic body in which are embedded the three electrodes 91, 92 and 93. If electrode 93 is not embedded in a plastic body, it is covered along its length with insulator 97.

In FIGS. 10 and 11 is illustrated a specific electrode structure expressly designed for a surgical or medical method or process of rendering the human female sterile. In FIG. 10 is illustrated a fiber optic core, generally designated 101 for a surgical electrode specifically adapted for sterilization of the human female. The point 101A of this fiber optic core 101 in combination with other structures as will be described in connection with FIG. 11 is adapted to be maneuvered to a position proximate to the fallopian tube opening. The other end 101B is mounted into a handle 102 on which is an eyepiece 103, as for example, a rubber eyepiece. The entire instrument is approximately 24 inches long and the fiber optic core approximately 1/4 inch in diameter.

In FIG. 11, the fiber optic core 101 is sheathed within a plastic sheath 105, and is also encased in a transparent electrode generally designated 106 and a lens 107 optionally of glass or plastic is mounted at the end of the core 101 and adapted to focus an image onto the ends of the optical fibers. Mounted piggy back on sheath 105 is an electrode sheath 108 in which is positioned an electrode wire 109 terminating in an electrode tip 110. The wire 109 is easily slidable within the electrode sheath 108 so that the electrode tip may be withdrawn into resting contact with the end of the electrode sheath or, as shown, may be extended from the electrode sheath 109 into an operating position.

In use and operation, the electrode 106 is inserted within the uterus and guided by the doctor's eye into position at the entrance to the fallopian tube. The electrode tip 110 is then extended from its sheath 108 and maneuvered with optical guidance a short distance into the tube. The electrode is then energized causing electrical cauterization wholly within the fallopian tube. Scarring results, causing complete sealing of the tube. When the purpose of the treatment is individual and when it is important to know with certainty whether sterilization has been achieved, it is important to maintain post-operative tests and to be prepared for hospitalized surgery if the treatment was not effective. However, if the purpose of the treatment is solely economic, or if the patient has already elected otherwise, it is subsequently, is still possible to achieve a high ratio of success and to avoid in many instances the need for hospitalization.

In FIGS. 12, 13, 14, and 15, is illustrated another specific electrode structure expressly designed for a surgical or medical method or process of rendering the human female sterile.

Referring now to FIG. 12 in particular, the electrode or fiber optic scope 140 including sheath assembly 141, electrode 142, light source 143, power 144 and fluid supplies 145, eyepiece focusing lenses 146 is shown in place in the uterus with electrode 140 extended as in use for cauterizing a fallopian tube 148 via the cervix 147.

Referring now to FIG. 13 in particular, there is shown the cauterizing and objective end of the sheath assembly 141 which consists of an outer sheath 149, an electrode sheath 150 containing a retractable and advanceable electrode 151 which is coated with electrical insulating material along its length but not at the tip, a fiber optics sheath 152 and an objective lens or lens assembly 153. In the case where the fiber optics 154 consists of a coherent bundle, a single objective lens will distribute the light from the bundle to the field of view and also conduct the image back to the eyepiece 146. In the case where an incoherent bundle is used to light the field and a separate coherent bundle is used to conduct the image, a more complex lens 153 or lens assembly would be used. The electrode sheath, fiber optics sheath and outer sheath are made of tubing and may be bonded or fused together. The objective lens is fabricated separately and bonded or fused to the fiber optics sheath. The objective lens is so designed that when the fiber optics are in place, they abut the edge of the lens protruding into the fiber optics sheath 152 to so provide for the proper separations between the end of the fiber optics and the optical surface of the lens. The space 158 between the fiber optics sheath 152, the electrode sheath 150 and the outer sheath 149 may be used to conduct a solution into the uterus to clean the visual field at the objective lens 153. In order to prevent fluid leakage about the electrode, a fluid-tight seal 155 may be provided concentric to the electrode and its sheath after the electrode sheath emerges through the outer sheath proximate to the eyepiece end of the
sheath assembly. A seal 156 is also provided to close off the water conducting space between the fiber optic sheath 152 and the outer sheath 149 at the eyepiece end of the sheath assembly.

It is possible, according to this embodiment of the invention, to produce simple, inexpensive surgical electrode sheath assemblies at a cost essentially comparable to the cost of sterilizing these sheaths. Accordingly, a new and unused and therefore sterilized electrode sheath assembly 141 may be employed on one human or animal and immediately thereafter thrown away to permit the immediate use of a new, and therefore sterilized electrode sheath assembly 141. Since the electrode sheath assembly encloses that portion of the fiber optics core inserted into the body cavity, the fiber optics need not be sterilized.

I claim:

1. A method of sterilization of a female human being, comprising guiding a source of electric discharge under direct vision to the fallopian tubes of said female, generating a cauterizing electric discharge essentially completely, within the fallopian tubes removed from the uterus proper and allowing interior scar tissue to form, thus sealing said tubes.

2. A method of sterilization of a female human being, comprising inserting a fine electrode tip from the uterus into each fallopian tube in a manner to locate said active electrode tip within said tube essentially at the narrowest portion of said tube, and generating a cauterizing electric discharge from said electrode tip to cauterize the tissue within said tube, and allowing scar tissue to form.

3. A method of sterilization of a female animal comprising guiding a source of electric discharge under direct vision to the fallopian tubes of said female, generating a cauterizing electric discharge essentially completely within the fallopian tubes, avoiding the uterus wall with said discharge and sealing said tube by allowing scar tissue to form.

4. A surgical instrument for female sterilization by sealing the fallopian tubes, means for providing a cauterizing electric generated discharge wholly within the fallopian tube to cause tissue wall scarring and permanent blocking of said fallopian tubes comprising an elongated electrode of a size to fit well within said fallopian tubes, means for providing direct vision of the tip of said electrode to guide said electrode to a precise position adjacent the entrance of said tube, means to insert said tip into said tube, and means to supply an electric discharge pulse to said electrode tip, essentially completely within said tube.

5. A surgical instrument according to claim 4, wherein said means to guide said electrode comprises a fiber optics bundle for optical illumination and observation of the position of said electrode tip and said electrode includes means for maneuvering said electrode tip in response to said optical observation, said maneuvering being from a position outside the body.

6. A surgical instrument according to claim 5, wherein said instrument includes means to flush the optical tip and visual field.

7. In a surgical instrument according to claim 5, including a removable sheath completely surround said fiber optics device to protect said fiber optics device from contamination and containing a movable electrode and an optical tip positionable adjacent to the fiber optics tip and means in said sheath for fluid flushing of said optical tip and field of observation.

* * * * *