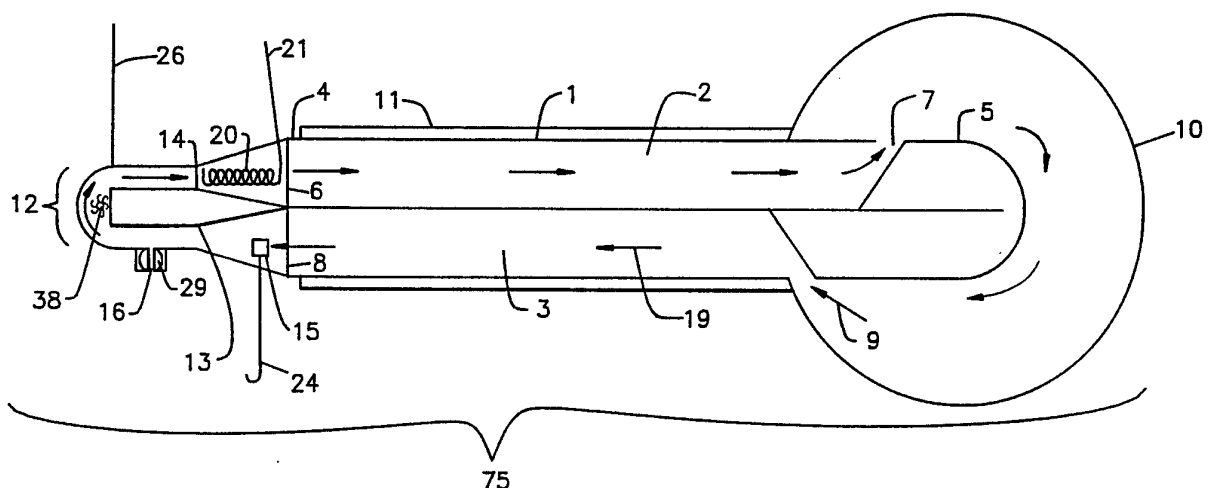




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(54) Title: HEATED BALLOON MEDICAL APPARATUS**(57) Abstract**

An apparatus (75) for treating a tissue lining of a mammalian body cavity, particularly a uterine endometrium comprising a pump (38) and a distensible bladder (10) connected to a catheter. The apparatus is introduced into the body cavity and the bladder is distended by introducing a non-toxic fluid under pressure. The fluid is heated by a heating element (20). A pump (38) circulates the fluid within the distensible bladder to help keep the fluid at a uniform temperature.

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HEATED BALLOON MEDICAL APPARATUS

FIELD OF THE INVENTION

This invention relates to an apparatus for treating the tissue lining of a human body cavity, particularly the endometrium of the uterus. More specifically, the apparatus of the present invention may be a self-contained closed-fluid system which can minimize the volume of fluid introduced into the area being treated in the event of a distendable bladder rupture or other failure. A heating means and a pump means may be incorporated in a handle portion of the apparatus so as to provide an improved device for treatment of tissues lining a body cavity without many of the disadvantages and dangerous features of known techniques.

BACKGROUND OF THE INVENTION

The following terms as used herein have the meaning given below:

"Cauterization" means the application of heat to
5 tissue in an amount sufficient to destroy the tissue.

"Necrosis" means the death of cells in tissue.

"Endometrium" is that portion of the inner lining of the uterus to which an embryo normally attaches and excludes the portions of the uterine inner lining forming
10 the cervix, to which the embryo usually does not attach.

Apparatus and methods for cauterization of the endometrium of a mammalian uterus, useful in sterilization procedures and cancer treatments, are well known. Thermal and cryogenic treatments have been
15 utilized in such cauterization techniques and typically involve either the direct or indirect application of heat or cold to the tissue to be treated.

For example, a laser hysteroscope has been used to cauterize the endometrial layer of the uterus. This laser
20 treatment suffers from several disadvantages. It requires the application of a large amount of thermal energy to a

relatively small area of tissue to produce intense heat even though such a large amount of heat may not be necessary to effectively cauterize the tissue. Further, this laser treatment requires the physician to

5 continually reposition the hysteroscope within the uterus in order to treat the entire endometrium. Such internal manipulation of a laser hysteroscope within the uterus of a patient is both difficult, requiring a significant level of skill to perform, and potentially dangerous.

10 Accidental puncture of the uterine or tissue wall may result from manipulation of the laser hysteroscope within the uterus or body cavity, and tissue layers beneath the endometrium may be burned if the laser's beam is left focused on one area of tissue for too long a period of

15 time.

A variety of alternatives to laser treatment in cauterizing the uterine endometrium are known. In U.S. Patent No. 3,924,628, Droegemueller et al. disclose a method and apparatus for necrosing tissue cells that

20 utilizes an extendable bladder which is inserted into the uterus and filled with a circulating fluid or gas at cryogenic temperatures (referring to temperatures sufficiently low to cause cell necrosis). The bladder disclosed by Droegemueller et al. is maintained in

25 substantially continuous contact with the inner surface of the uterine lining and is said to achieve necrosis of substantially all of the uterine endometrium in a single treatment. Droegemueller et al. disclose the use of liquid nitrogen that vaporizes prior to introduction into

30 the bladder, thereby pressurizing the bladder to a level which ensures adequate contact with the uterus. Other fluids disclosed by Droegemueller et al. as useful in their method include refrigerants such as freon. Droegemueller et al.'s method and apparatus suffers from

35 the disadvantage of employing cryogenic fluids which could prove toxic to a patient in the event of bladder rupture. Moreover, Droegemueller et al.'s apparatus does

not allow precise regulation of the pressure used to inflate the bladder. Another disadvantage of Droegemueller et al.'s technique is that cryogenic necrosis of the endometrium occurs at extremely low
5 temperatures that pose a threat to tissue layers adjacent to the uterine endometrium. Droegemueller et al. and similar cryogenic techniques also require the use of expensive equipment such as compressors and insulated vessels associated with the storage and handling of
10 refrigerants. Moreover, Droegemueller et al.'s technique may require warming of the bladder in order to remove it from the body and minimize tearing of the surrounding tissue which has adhered to the bladder during the freezing process.

15 In U.S. Patent No. 2,734,508, Kozinski discloses a therapeutic apparatus for applying dry heat to body cavities comprising an applicator that is introduced in the body cavity while deflated and which is subsequently inflated and heated by means of circulating hot air.
20 Kozinski does not disclose an applicator which conforms to the shape of a body cavity. Further, given the lower heat transfer coefficients of gases as compared with liquid, treatment with Kozinski's apparatus should involve a long period of time in order to achieve
25 necrosis, thereby exposing the patient to additional discomfort and risk. Moreover, Kozinski's apparatus does not provide for measurement and regulation of internal pressures and temperatures in the applicator.

U.S. Patent No. 2,077,453, issued to Albright,
30 discloses a therapeutic appliance comprising a relatively long tubular applicator which is shaped and formed generally to the passage into which it is to be inserted and which has relatively thin elastic rubber walls that transfer heat and which distend to fit irregularities of
35 the treated areas upon application of internal pressure. Albright also discloses that fluids such as heated water could be utilized as a heating means in his applicator.

The applicator of Albright, like that of Kozinski, however, suffers from the disadvantage that the distension of its walls to conform to the irregularities of the endometrium is limited as Albright provides an integral rubber web which serves to prevent undue distension of the applicator. Moreover, Albright requires that the fluid be circulated throughout the apparatus. Albright also does not provide an apparatus that allows regulation of temperature and pressure of the fluid or other bladder inflation means.

U.S. Patent No. 3,369,549, issued to Armao, discloses a therapeutic device for applying heat or cold to body cavities comprising a capsule probe containing a heat exchanger and a flexible bladder that can be inflated to conform to a body cavity. Armao does not, however, disclose a control means for regulating the temperature and pressure of the flexible applicator, nor does he disclose cauterizing tissue in the cavity being treated.

U.S. Patent No. 4,160,455 to Law discloses a heater for heating fluid within a body cavity of an animal, e.g., for heating tumors by irrigation, comprises a container having inlet and outlet ports through which fluid in the cavity is passed by an external pump, and a heating element in the container to heat at least some of the fluid that passes through the container. Pumping can be achieved by a fluid filled pipe coupled to the container, either directly by or by way of a diaphragm, and to a bellows or like arrangement for cyclicly varying the pressure of the fluid in the pipe and container.

A common problem associated with some of the above-described prior art devices is that a large volume of heated fluid, i.e., greater than about 30 cc is circulated through the system. In the event of balloon rupture, this volume of pressurized fluid would leave the confines of the balloon with possible adverse affects on the patient. Another problem associated with some of

these prior art devices is the difficulty of maintaining sterility of the fluid when the fluid is heated in a remote heating unit.

Other patents that disclose the use of thermal treatment of the interior lining of a body cavity include U.S. Patent Nos. 2,192,768; 2,466,042; 2,777,445; 3,369,549, and 4,949,718.

OBJECTS AND SUMMARY OF THE INVENTION

10 It is an object of the present invention to provide a safe and efficacious method for cauterizing the tissue lining of a body cavity, particularly the endometrium of a uterus.

15 It is another object of the present invention to provide a relatively inexpensive and easy to replace applicator heated by a nontoxic fluid that can be used to treat the tissue lining of a body cavity and which is controlled by means external to the applicator.

20 It is another object of the present invention to provide an apparatus for heating a fluid while it is in a distendable bladder within the uterus and for introducing the fluid under pressure into the bladder so as to assure substantially uniform contact of the bladder with the tissue lining of the body cavity being treated.

25 It is still another object of the present invention to provide an apparatus for regulating the temperature of the fluid in the distendable bladder while the bladder is within the tissue lining of the body cavity being treated.

30 It is still another object of the present invention to provide an apparatus for maintaining a substantially uniform temperature of the fluid in the distendable bladder while the bladder is within the tissue lining of the body cavity being treated.

35 It is still another object of the present invention to provide an apparatus which limits the amount of fluid that would be introduced into a body cavity being treated

in the event of a distendable bladder rupture.

It is still another object of the present invention to provide an apparatus with a closed fluid system in which no fluid is either introduced or extracted during a
5 procedure, thus preserving the integrity of the sterile field.

The present invention also provides an apparatus for thermally treating of the tissue lining of a body cavity, and, in particular, substantially the entirety of the
10 endometrium of a mammalian uterus comprising: a catheter having a proximal end and a distal end and provided with a first lumen and a second lumen, said first lumen provided with a proximal fluid access port and a distal fluid access port, said second lumen provided with a
15 proximal fluid access port and a distal fluid access port; a distendable bladder means attached to said distal end of said catheter for insertion into and distending the body cavity to be treated, said first lumen distal fluid access port and said second lumen distal fluid
20 access port in fluid communication with the interior of said bladder; circulating means for circulating said inflation medium attached to said proximal end of said catheter, said first lumen proximal fluid access port and said second lumen proximal fluid access port in fluid
25 communication with the interior of said circulating means; a fluid access port in fluid communication with the interior of said apparatus for the introduction and extraction of an inflation medium into and out of said apparatus, said fluid access port provided with a fluid
30 control means for controlling the flow of said inflation medium through said fluid access port; inflating means detachably connected to said fluid access port for introducing said inflation medium into the interior of said apparatus; control means connected to said inflating
35 means for regulating the inflating of said bladder; heating means positioned internal to said apparatus for heating said inflation medium; control means connected to

said heating means for regulating the heating of said inflation medium means; and control means connected to said circulating means for regulating the circulating of said inflation medium.

- 5 The present invention provides an apparatus for thermally treating the tissue lining of a body cavity, and in particular, substantially the entirety of the endometrium of a mammalian uterine comprising: a catheter having a proximal end and a distal end and provided with
- 10 a first lumen and a second lumen, said first lumen provided with a proximal fluid access port and a distal fluid access port, said second lumen provided with a proximal fluid access port and a distal fluid access port; a distensible bladder means attached to said distal
- 15 end of said catheter for insertion into and distending the body cavity to be treated, said first lumen distal fluid access port and said second lumen distal fluid access port in fluid communication with the interior of said bladder; a fluid access port in fluid communication
- 20 with the interior of said apparatus for the introduction and extraction of an inflation medium into and out of said apparatus, said fluid access port provided with a fluid control means for controlling the flow of said inflation medium through said fluid access port;
- 25 inflating means detachably connected to said fluid access port for introducing said inflation medium into the interior of said apparatus; control means connected to said inflating means for regulating the inflating of said bladder; heating means positioned internal to said
- 30 apparatus for heating said inflation medium; control means connected to said heating means for regulating the heating of said inflation medium; a flexible fluid conduit having a first end and a second end attached to said proximal end of said catheter, said first lumen
- 35 proximal fluid access port and said second lumen proximal fluid access port in fluid communication with said first end and said second end of said flexible fluid conduit;

circulating means cooperating with the external surface of said flexible fluid conduit so as to pump said inflation medium through said flexible fluid conduit; and control means connected to said circulating means for
5 regulating the circulating of said inflation medium.

The present invention also provides an apparatus for thermally treating the tissue lining of a body cavity, and in particular, substantially the entirety of the endometrium of a mammalian uterine comprising: a catheter
10 having a proximal end and a distal end and provided with a first lumen and a second lumen, said first lumen provided with a proximal fluid access port and a distal fluid access port, said second lumen provided with a proximal fluid access port and a distal fluid access
15 port; a distendable bladder means attached to said distal end of said catheter for insertion into and distending the body cavity to be treated, said first lumen distal fluid access port and said second lumen distal fluid access port in fluid communication with the interior of
20 said bladder; a distendable reservoir means attached to said proximal end of said catheter, said first lumen proximal fluid access port and said second lumen proximal fluid access port in fluid communication with the interior of said distendable reservoir means; a
25 sterilized fluid medium permanently sealed within said apparatus; inflating means in communication with the external surface of said distendable reservoir means for introducing said inflation medium from said distendable reservoir means into said distendable bladder means;
30 control means connected to said inflating means for regulating the inflating of said bladder; heating means for heating said inflation medium; control means connected to said heating means for regulating the heating of said inflation medium; a flexible fluid
35 conduit having a first end and a second end, said first end and said second end in fluid communication with the interior of said distendable reservoir means; circulating

means cooperating with the external surface of said flexible fluid conduit so as to pump said inflation medium through said flexible fluid conduit; and control means connected to said circulating means for regulating the circulating of said inflation medium.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts an apparatus having an internal pumping means constructed in accordance with the invention;

FIG. 2 depicts a fluid introduction and extraction means constructed in accordance with the invention;

FIG. 3 depicts an apparatus having pumping means external to the fluid system constructed in accordance with the invention;

FIG. 4 is a detailed view of the pumping means shown in FIG. 3;

FIG. 5 depicts an apparatus having a closed fluid system;

FIG. 6 depicts a housing for the closed fluid apparatus shown in FIG. 5;

FIG. 7 depicts the unpressurized apparatus of FIG. 5 inserted into the housing shown in FIG. 6;

FIG. 8 shows the pressurized apparatus of FIG. 5 inserted into the housing of FIG. 6; and

FIG. 9 shows a control panel constructed in accordance with the invention.

DESCRIPTION OF A PREFERRED EMBODIMENT

FIG. 1 shows an apparatus 75 provided with a dual lumen catheter 1 having a proximal end 4 and a distal end 5. The dual lumen catheter 1 is provided with a first lumen 2 and a second lumen 3. The catheter 1 may be made from a wide variety of materials well known to those skilled in the art as suitable for this purpose, however, in a preferred embodiment Teflon™ or A B S type tubing are utilized. First lumen 2 is provided with a proximal

fluid access port 6 and a distal fluid access port 7. Second lumen 3 is provided with a proximal fluid access port 8 and a distal fluid access port 9. In a preferred embodiment, the catheter 1 is thermally non-transmissive so that heated fluid 19 does not lose heat to the cooler fluid as it traverses the catheter 1 in first lumen 2 and second lumen 3. This also helps protect the tissue which comes in contact with the external surface of catheter 1. A means for insulating 11 may be applied to the external surface of catheter 1 to protect tissue which comes into contact with the external surface of catheter 1. An inflatable distendable bladder 10 is attached to the distal end 5 of dual lumen catheter 1 and forms a fluid tight seal with the external surface of dual lumen catheter 1 proximal to fluid access ports 7 and 9. It will be appreciated that the distendable bladder 10 could be integrally formed in the distal end 5 of the catheter 1. Fluid access ports 7 and 9 are in fluid communication with the interior of distendable bladder 10. A pumping means 12 having an inlet port 13 and an outlet port 14 is attached to the proximal end 4 of dual lumen catheter 1. The interior of the pumping means 12 is in fluid communication with fluid access ports 6 and 8. The apparatus 75 is provided with a fluid access port 16 for the introduction and extraction of sterilized fluid 19 into and out of the apparatus 75. The fluid access port 16 is adapted to fluidly cooperate with means 28 (FIG. 2) for introducing and extracting sterilized fluid 19 into and out of the apparatus 75. Fluid control means 29 controls the fluid 19 entering or leaving pumping means 12 via fluid access port 16. A variety of fluid control means well known to those skilled in the art as suitable for this purpose may be employed, however, in a preferred embodiment a stopcock is utilized. A heater 20, e.g., a nichrome resistance coil, is positioned in the apparatus 75 to heat the fluid 19 to the desired temperature. Heater control means 22 on control panel 23 (FIG. 9)

provides electricity via lead 21 to energize heater 20. The duration and temperature to which heater 20 is heated are controlled by the flow of electricity to heater 20 which is regulated by heater control means 22 on control panel 23. Temperature sensing means 15, e.g., a thermocouple senses the temperature of fluid 19 and transmits the readings via lead 24 to temperature display means 25 on control panel 23. In a preferred embodiment, the pumping means 12 is an electric motor coupled to an impeller 38. Pumping means 12 is energized via lead 26 from pumping means control means 27 on control panel 23.

FIG. 2 shows a means 28 for introducing and extracting fluid 19 from the interior of the apparatus 75. Tubing 30 is provided with a first end 31 adapted to form a substantially fluid tight seal with fluid access port 16 and a second end 32 adapted to form a fluid tight seal with a sterile fluid reservoir capable of imparting pressure on the fluid 19. Fluid tight connections are conventionally made with luer connectors or the like. A variety of fluid reservoirs well known to those skilled in the art as suitable for this purpose may be employed, however, in a preferred embodiment a syringe means 33 is utilized. A pressure transducer 34 is in fluid communication with the interior of tubing 30 and transmits the internal pressure of the fluid 19 within the tubing 30 via lead 36 to fluid pressure display means 35 where the information is displayed on control panel 23.

In operation, the apparatus 75 is unpacked from a sterile package and leads 24, 26, and 21, are connected to control panel 23 and the distendable bladder 10 portion of apparatus 75 is introduced into the area to be treated, e.g., a uterine endometrium. The dual lumen catheter 1 and the attached distendable bladder 10 must be sufficiently small so that they can be conveniently and safely inserted into the body cavity to be treated, e.g., a uterus through a partially dilated cervix, when

the distendable bladder 10 is deflated.

Distendable bladder 10 must be capable of withstanding high temperatures without rupturing and preferably have as good a heat transfer characteristic as
5 is obtainable in such materials to provide efficient heating action. A distendable bladder of a heat curing rubber such as latex and silicone has been found satisfactory.

The means for introducing and extracting fluid 28 is
10 then unpacked from a sterilized package and lead 36 is connected to control panel 23. The means for introducing and extracting fluid 28 is then filled with sterile fluid 19. Fluid 19 preferably should be a sterile non-toxic fluid with a boiling point of at least 212°F. A five
15 percent dextrose in water solution has been found satisfactory. After the distendable bladder 10 has been inserted into the area to be treated, the distendable bladder 10 should be inflated to a pressure sufficient to ensure firm contact with the tissue to be treated. The
20 first end 31 of tubing 30 is placed in fluid communication with fluid access port 16 and the fluid 19 is introduced into the apparatus 75 by depressing the plunger 37 of syringe means 33. Distendable bladder 10 should preferably be maintained at or about 40 to 240
25 mmHg, and preferably about 75 mmHg, to minimize risk of rupture of the distendable bladder 10 and possible internal injury to the patient. Inflation of the distendable bladder 10 with a fluid 19 assures uniform contact of the distendable bladder 10 with the tissue to
30 be treated.

When the desired pressure has been reached, as measured by transducer 34 and displayed at fluid pressure display means 35, fluid control means 29 is turned to a closed position so as to restrict the flow of fluid 19 in
35 or out of apparatus 75. The first end 31 of tubing 30 of fluid introducing and extracting means 28 is then removed from fluid access port 16. The fluid introducing and

extracting means 28 is put aside for use later in the procedure.

Heater 20 is then energized via lead 21 from heating means control means 22 on control panel 23 for a period
5 of time and to a temperature sufficient to raise the temperature of the fluid 19 to the desired temperature. While fluid 19 is being heated to the desired temperature, as measured by sensing means 15 and displayed at temperature display means 25, internal pump
10 means 12 is energized via pump means control means 27. Impeller 38 turns in response to the electrical current provided by lead 26 and the fluid 19 is drawn into internal pump means 12 via inlet port 13 and is expelled out of internal pump means 12 via outlet port 14. As the
15 fluid 19 leaves outlet port 14 it is heated by heater 20. The fluid 19 then enters first lumen proximal access port 6 and traverses the first lumen 2 in a direction towards its distal end 5 and enters distendable bladder 10 via first lumen distal fluid access port 7. After
20 circulating within distendable bladder 10, fluid 19 leaves distendable bladder 10 and enters second lumen 3 via second lumen distal fluid access port 9. The fluid 19 then traverses the second lumen 3 in a direction towards its proximal end 4 and leaves second lumen 3 via
25 second lumen proximal fluid access port 8. The fluid 19 then enters internal pump means 12 via inlet port 13, and is recirculated. Temperature sensing means 15 measures the temperature of fluid 19 and displays the temperature at temperature display means 25 on control panel 23.
30 Automatic temperature regulating means 50 may be provided between the temperature display means 25 and the heating control means 22 for automatically regulating the temperature of fluid 19.

Upon completion of the procedure the first end 31 of
35 tubing 30 is connected to fluid access port 16. Fluid control means 29 is again manipulated to allow the fluid to be withdrawn through fluid access port 16.

Manipulating the plunger 37 of syringe means 33 causes fluid 19 to be withdrawn from the interior of the apparatus 75 through fluid access port 16 and the distendable bladder 10 deflates. Upon deflation, the
5 distendable bladder 10 of apparatus 75 may be safely withdrawn from the patient.

The apparatus 75 may then be discarded or may be sterilized for subsequent use. The time and expense associated with sterilizing apparatus 75 may be warranted
10 by the cost of the pumping means 12 which is contained within the apparatus 75.

FIG. 3 depicts an alternative embodiment 90 of the present invention wherein the pumping means is an externally mounted peristaltic pump means 18 which does
15 not come in direct contact with fluid 19. The externally mounted peristaltic pump means 18 is removably attached to the outside of the fluid loop 79 of flexible fluid conduit 78. FIG. 4 is a detailed view of the externally mounted peristaltic pump means of FIG. 3. Attachment and
20 detachment may be facilitated by "snap" type mounting means 108. Because the externally mounted peristaltic pump 18 never comes in contact with fluid 19, it need not be sterilized after use. When the procedure is completed, the externally mounted peristaltic pump 18 can
25 be quickly and easily disengaged from flexible fluid conduit 78 and can be stored and used in subsequent treatments. Thus, pumping means 18 can be repeatedly utilized in subsequent treatments and the flexible fluid conduit 78, dual lumen catheter 1', and distendable
30 bladder 10' may be disposed of with a significant reduction in cost. The flexible fluid conduit 78, dual lumen catheter 1', and distendable bladder 10' may also be sterilized and used again if desired.

In the embodiment shown in FIGS. 3 and 4, the
35 apparatus 90 is provided with a flexible fluid conduit 78 having an inlet port 76 and an outlet port 77. Inlet port 76 and outlet port 77 are in fluid communication

with the interior of lumens 2' and 3'. A portion of fluid conduit 78 forms a fluid loop 79. External peristaltic pump means 18 communicates with the outer surface of external fluid loop 79 so as to pump the fluid 19 through flexible fluid conduit 78. A variety of means well known to those skilled in the art as suitable for this purpose may be employed to mechanically impinge upon external fluid loop 79, however, in a preferred embodiment a peristaltic pump available from A.S.F. Inc., 2100 Norcross Parkway, Norcross, Georgia 30071, U.S.A. is employed. A longitudinal member 100 having a first end 101 and a second end 102 is fixedly mounted on motor shaft 103 of motor 104 so that the longitudinal member 100 will turn in response to the rotation of the motor shaft 103. The motor 104 is activated by pump means control means 27' which provides electricity to motor 104 via lead 26'. The first end 101 of longitudinal member 100 may be provided with a first roller 105 and the second end 102 may be provided with a second roller 106 to reduce friction on the external surface of external fluid loop 79. The length of longitudinal member 100 and the diameter of rollers 105 and 106 is such that as longitudinal member 100 rotates, rollers 105 or 106, impinge upon and compress external fluid loop 79 to approximately one-half of its diameter. When motor 104 is energized, longitudinal member 100 rotates and rollers 105 or 106 come into contact with and compress external fluid loop 79 against housing 107 so that fluid 19 is expelled from fluid conduit 78 via outlet port 77 and is drawn into fluid conduit 78 via inlet port 76.

In operation, the distendable bladder 10' of apparatus 90 is positioned in the area to be treated and the treatment is performed as previously discussed. When the treatment has been completed the external pumping means 18 is disconnected from the fluid loop 79 of flexible fluid conduit 78 before flexible conduit 78, catheter 1', and distendable bladder 10' are either

disposed of or sterilized for subsequent use.

In an alternative embodiment, shown in FIGS. 5, 6, 7, and 8, the apparatus is a closed fluid apparatus 125 wherein fluid is neither introduced nor withdrawn from the interior of the apparatus. Thus, the integrity of the sterile field is maintained. A distendable reservoir 127 is attached at the proximal end 4" of catheter 1". In a preferred embodiment the distendable reservoir 127 is made of a thermally transmissive material so that the fluid 19" can be heated by a heater 20" positioned external to the distendable reservoir 127.

FIG. 5 shows the closed fluid apparatus 125 which is provided with a flexible fluid conduit 78" having an inlet port 76" and an outlet port 77". Inlet ports 76" and 77" are in fluid communication with the interior of distendable reservoir 127. A portion of fluid conduit 78" extends outside distendable reservoir 127 to form an external fluid loop 79". The external surface of fluid conduit 78" forms a fluid tight seal at its points of exit 80" and 81" from distendable reservoir 127.

FIG. 6 shows an apparatus housing 126 provided with an external peristaltic pump means 18" and a breech 129 for receiving the distendable reservoir 127. When closed fluid apparatus 125 is inserted into housing 126, peristaltic pump means 18" communicates with and impinges upon the outer surface of external fluid loop 79" so as to pump the fluid 19" in and out of external fluid loop 79" as previously discussed. A temperature sensing means 15", a pressure transducer 34" and a heater 20" are disposed on a pressure plate 128. An inflating means, such as a pressure plate 128, is used to selectively apply pressure to the distendable reservoir 127 so as to increase the pressure of the fluid 19" within the closed fluid apparatus 125. The temperature sensing means 15", pressure transducer 34" and heater 20" may be housed within the distendable reservoir 127, however, in a preferred embodiment they are mounted externally so as to

minimize the one-time use cost. The trigger 130 is coupled to the pressure plate 128 via a ratchet means so that each pull of the trigger 130 causes the pressure plate 128 to be moved in small increments. When ratchet control lever 131 is moved to a first position 132, pulling the trigger 130 causes pressure plate 128 to move in a direction towards distendable reservoir 127. When ratchet control lever 131 is moved to a second position 133, pulling the trigger 130 causes pressure plate 128 to move in a direction away from distendable reservoir 127. A hinged lid 150 is provided to secure closed fluid apparatus 125 within breech 129 of housing means 126. A cord 152 houses leads 21", 24", 26" and 36" which communicate with control panel 23".

In operation, the closed fluid apparatus 125 is removed from a sterile package and is inserted into housing means 126 as shown in FIG. 7. The closed fluid apparatus 125 is inserted into the breech 129 of housing means 126 so that temperature sensing means 15", pressure transducer 34" and heater 20" are in intimate contact with the external surface of distendable reservoir 127. Lid 150 is then lowered so as to secure the closed fluid apparatus 125 within the breech 129 of applicator means 126 as shown in FIG. 8. Heater 20" is then energized and the fluid 19" is heated to the desired temperature as measured by temperature sensing means 15" as previously discussed. Pump means 18" is also energized to circulate the fluid 19" as previously discussed. The closed fluid apparatus 125 is then inserted into the body cavity to be treated. Ratchet control lever 131 is moved to a first position 132 and trigger 130 is pulled so as to move the pressure plate 128 in a direction towards distendable reservoir 127 so as to impart a pressure on the fluid 19" within the reservoir 127. In response, the fluid 19" takes the path of least resistance and enters distendable bladder 10" via lumens 2" and 3" of catheter 1" as shown in FIG. 8. When the desired pressure has been reached,

as measured by pressure transducer 34", the treatment commences.

When the treatment is complete, the ratchet control lever 131 is moved to the second position 133. The
5 trigger 130 is repeatedly pulled and pressure plate 128 moves away from distendable reservoir 127, thus, reducing the pressure of the fluid 19" within the closed fluid apparatus 125. The fluid 19" then moves from distendable bladder 10" into the distendable reservoir 127, thus,
10 decreasing the volume of the distendable bladder 10". The closed fluid system 125 is then removed from the body cavity being treated. The lid 150 is lifted and the distendable reservoir 127 is removed from breech 129 and the closed fluid apparatus 125 may be discarded or may be
15 sterilized for subsequent use. The housing means 126 is saved and can be used again in subsequent treatments.

What is claimed is:

1. An apparatus for thermally treating a tissue lining a body cavity, comprising:

5 a catheter having a proximal end and a distal end and provided with a first lumen and a second lumen, said first lumen provided with a proximal fluid access port and a distal fluid access port, said second lumen provided with a proximal fluid access port and a distal
10 fluid access port;

a distendable bladder means attached to said distal end of said catheter for insertion into and distending the body cavity to be treated, said first lumen distal fluid access port and said second lumen
15 distal fluid access port in fluid communication with the interior of said bladder;

circulating means for circulating said inflation medium attached to said proximal end of said catheter, said first lumen proximal fluid access port and
20 said second lumen proximal fluid access port in fluid communication with the interior of said circulating means;

a fluid access port in fluid communication with the interior or said apparatus for the introduction and
25 extraction of an inflation medium into and out of said apparatus, said fluid access port provided with a fluid control means for controlling the flow of said inflation medium through said fluid access port;

inflating means detachably connected to said
30 fluid access port for introducing said inflation medium into the interior of said apparatus;

control means connected to said inflating means for regulating the inflating of said bladder;

heating means positioned internal to said
35 apparatus for heating said inflation medium;

control means connected to said heating means for regulating the heating of said inflation medium

means; and

control means connected to said circulating means for regulating the circulating of said inflation medium.

5

2. The apparatus of claim 1, wherein said inflating means comprises a pumping means in fluid communication with said fluid access port for pumping said inflation medium into said apparatus so as to
10 inflate said bladder.

3. The apparatus of claim 2, wherein said pumping means comprises a hypodermic barrel.

15 4. The apparatus of claim 1, further comprising means for engaging and disengaging said hypodermic barrel from said fluid access port so that the apparatus and the inflating means may be separated.

20 5. The apparatus of claim 4, wherein said means for engaging and disengaging said hypodermic barrel from said fluid access port is a bayonet coupling.

25 6. The apparatus of claim 1, wherein said catheter is selected from the group comprising Teflon™ and A B S type tubing.

30 7. The apparatus of claim 1, further comprising a positioning means for positioning said distendable bladder in the body cavity.

8. The apparatus of claim 7, wherein said positioning means comprises scale gradations on the catheter for indicating depth of insertion of said
35 distendable bladder into the body cavity.

9. The apparatus of claim 1 wherein said

distendable bladder is capable of resisting an internal pressure of at least 300 mmHg without rupturing and a temperature of at least 250° Fahrenheit without carbonizing.

5

10. The apparatus of claim 9, wherein said bladder is selected from the group comprising latex and silicone rubber.

10

11. The apparatus of claim 1, wherein said temperature control means comprises a thermocouple for measuring the temperature of said inflation medium positioned internal to said apparatus, said thermocouple connected to said temperature control means.

15

12. The apparatus of claim 1, wherein said pressure control means comprises a pressure sensor in fluid communication with said inflating means, said pressure sensor connected to a pressure display means for displaying the internal pressure of said inflating means.

20

13. An apparatus for thermally treating a tissue lining a body cavity, comprising:

25 a catheter having a proximal end and a distal end and provided with a first lumen and a second lumen, said first lumen provided with a proximal fluid access port and a distal fluid access port, said second lumen provided with a proximal fluid access port and a distal fluid access port;

30

a distendable bladder means attached to said distal end of said catheter for insertion into and distending the body cavity to be treated, said first lumen distal fluid access port and said second lumen distal fluid access port in fluid communication with the interior of said bladder;

35

a fluid access port in fluid communication with the interior of said apparatus for the introduction and

extraction of an inflation medium into and out of said apparatus, said fluid access port provided with a fluid control means for controlling the flow of said inflation medium through said fluid access port;

5 inflating means detachably connected to said fluid access port for introducing said inflation medium into the interior of said apparatus;

 control means connected to said inflating means for regulating the inflating of said bladder;

10 heating means positioned internal to said apparatus for heating said inflation medium;

 control means connected to said heating means for regulating the heating of said inflation medium;

 a flexible fluid conduit having a first end and
15 a second end attached to said proximal end of said catheter, said first lumen proximal fluid access port and said second lumen proximal fluid access port in fluid communication with said first end and said second end of said flexible fluid conduit;

20 circulating means cooperating with the external surface of said flexible fluid conduit so as to pump said inflation medium through said flexible fluid conduit; and

 control means connected to said circulating means for regulating the circulating of said inflation
25 medium.

14. The apparatus of claim 13 wherein said circulating means is a peristaltic pump.

30 15. A closed fluid apparatus for thermally treating a tissue lining a body cavity, comprising:

 a catheter having a proximal end and a distal end and provided with a first lumen and a second lumen, said first lumen provided with a proximal fluid access
35 port and a distal fluid access port, said second lumen provided with a proximal fluid access port and a distal fluid access port;

a distendable bladder means attached to said distal end of said catheter for insertion into and distending the body cavity to be treated, said first lumen distal fluid access port and said second lumen distal fluid access port in fluid communication with the interior of said bladder;

a distendable reservoir means attached to said proximal end of said catheter, said first lumen proximal fluid access port and said second lumen proximal fluid access port in fluid communication with the interior of said distendable reservoir means;

a sterilized fluid medium permanently sealed within said apparatus;

inflating means in communication with the external surface of said distendable reservoir means for introducing said inflation medium into said distendable bladder means from said distendable reservoir means;

control means connected to said inflating means for regulating the inflating of said bladder;

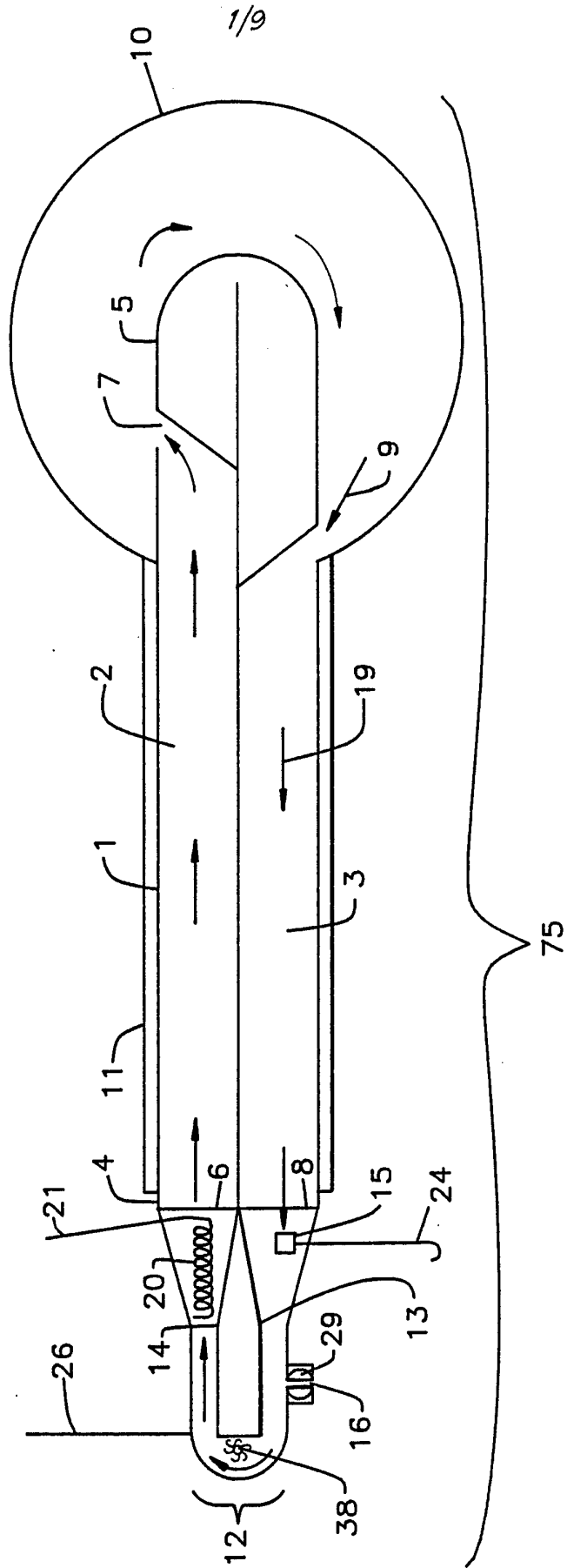
heating means for heating said inflation medium;

control means connected to said heating means for regulating the heating of said inflation medium;

a flexible fluid conduit having a first end and a second end, said first end and said second end in fluid communication with the interior of said distendable reservoir means;

circulating means cooperating with the external surface of said flexible fluid conduit so as to pump said inflation medium through said flexible fluid conduit; and

control means connected to said circulating means for regulating the circulating of said inflation medium.



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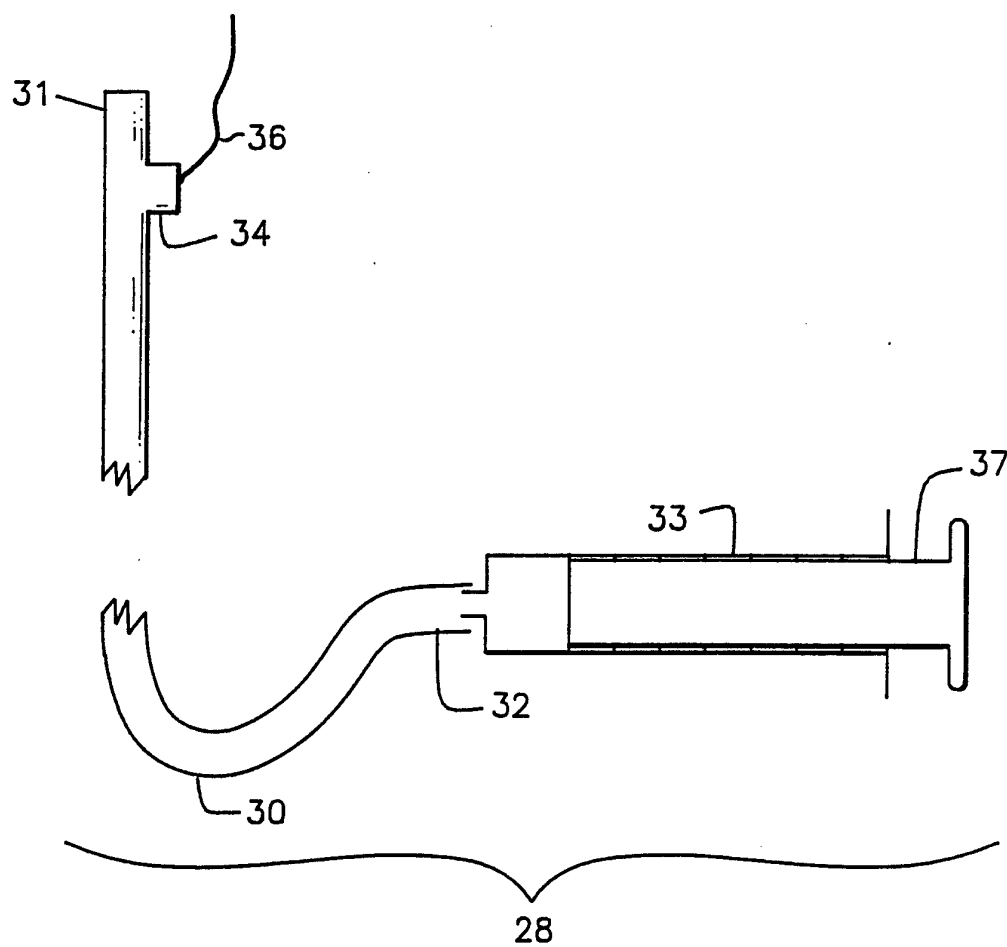


FIG. 2

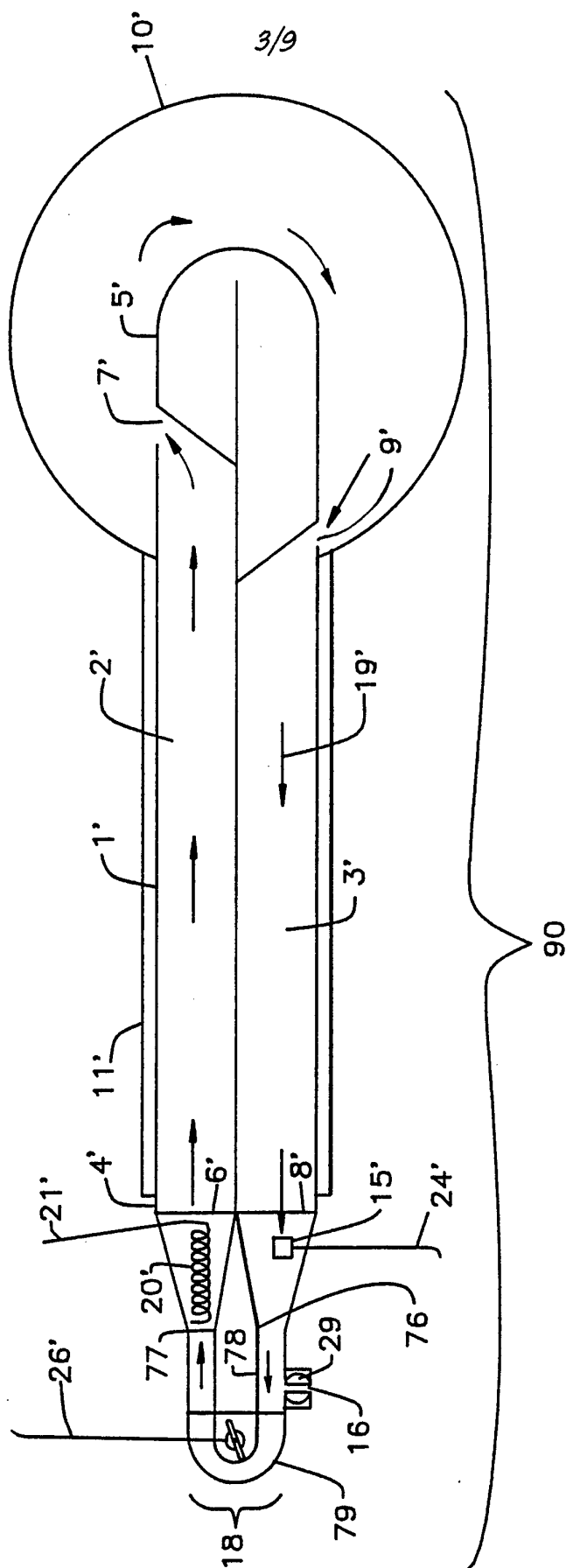


FIG. 3

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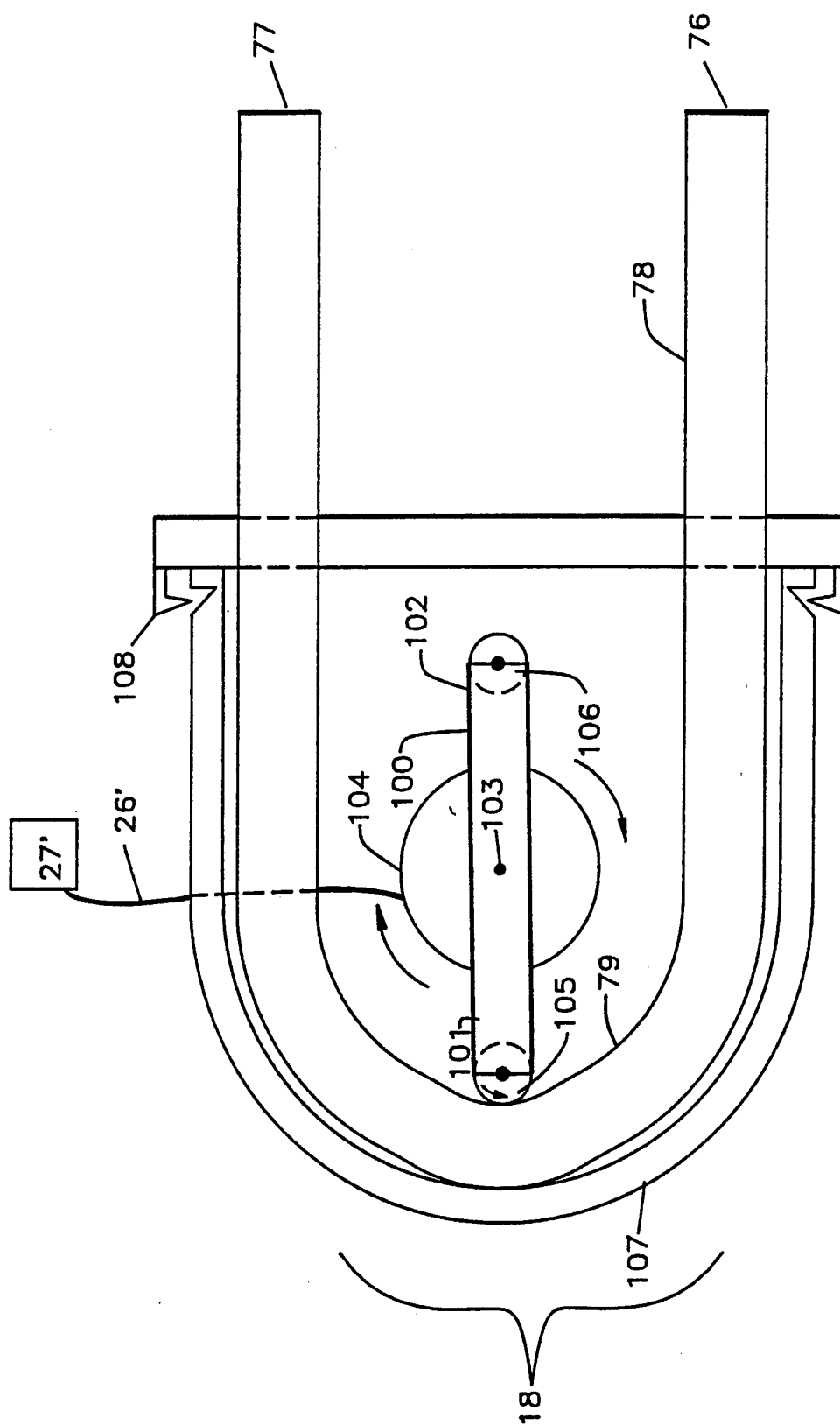


FIG. 4

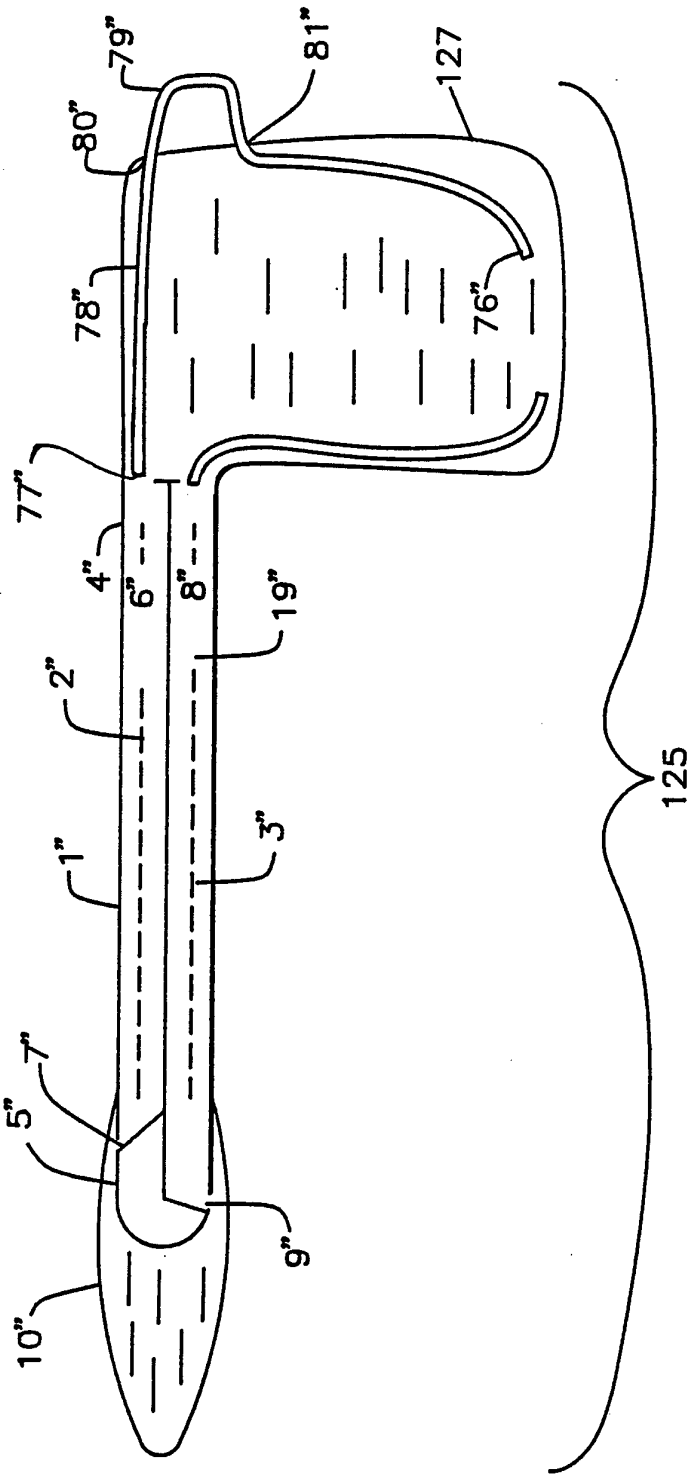


FIG. 5

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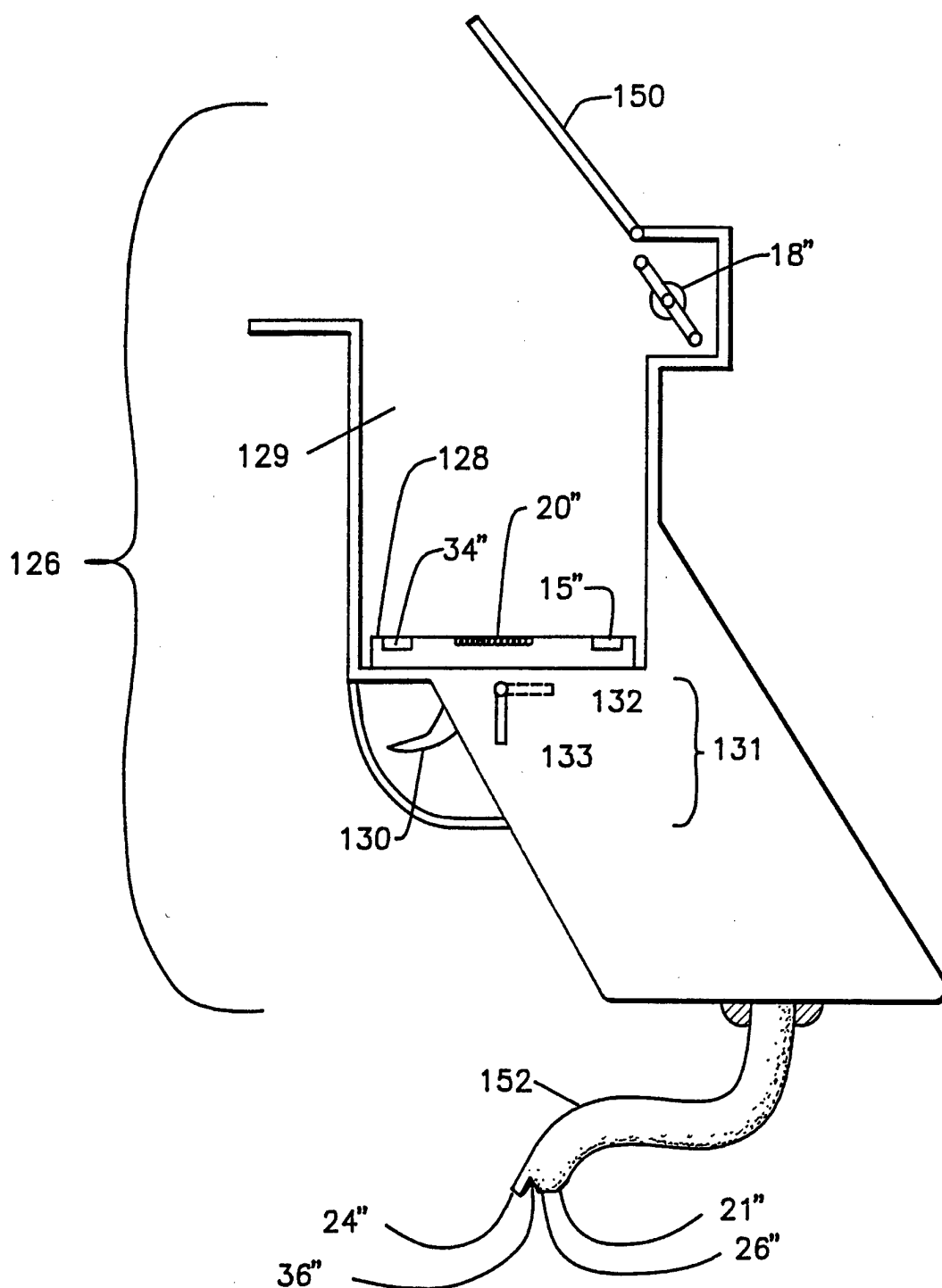


FIG. 6

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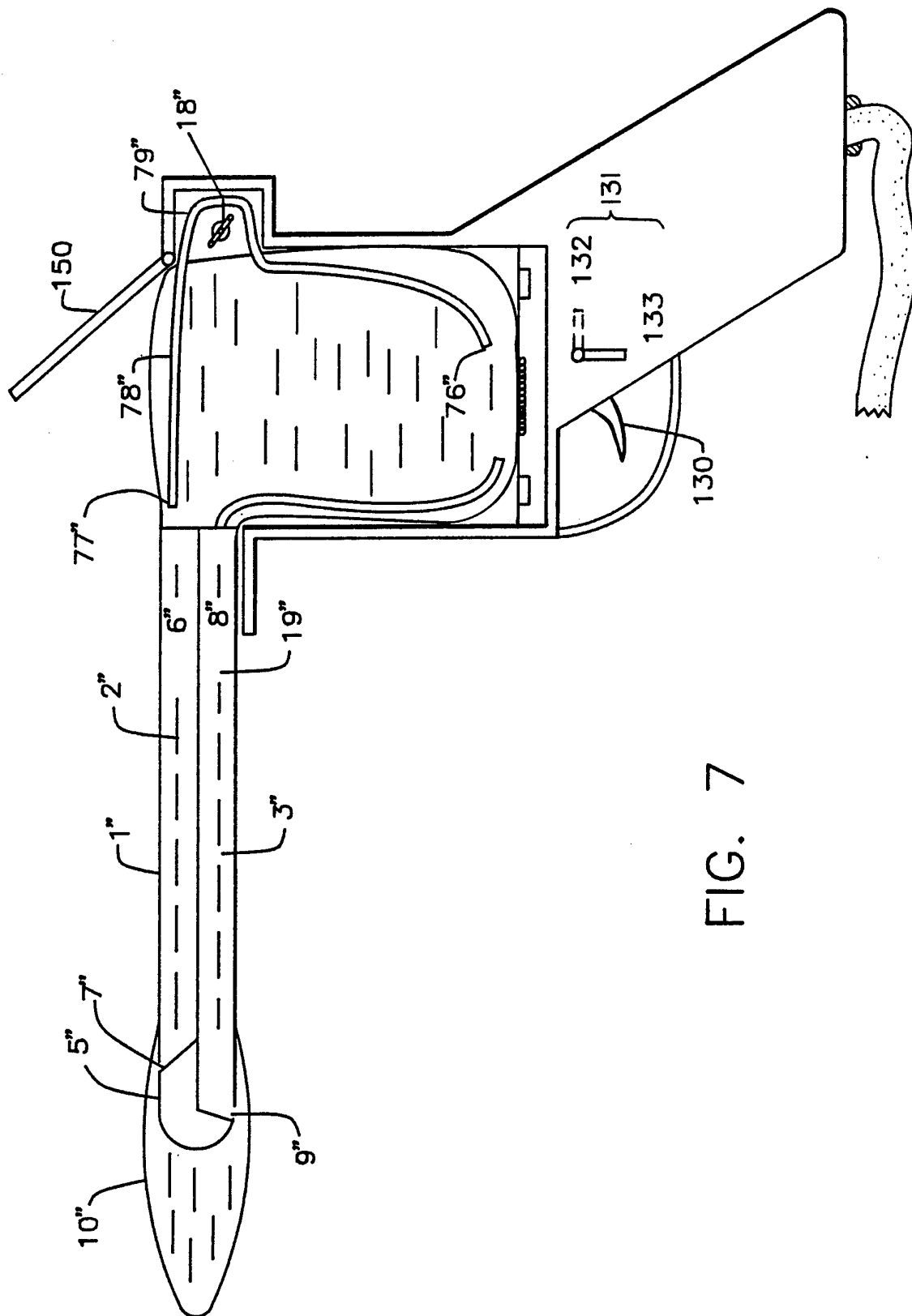


FIG. 7

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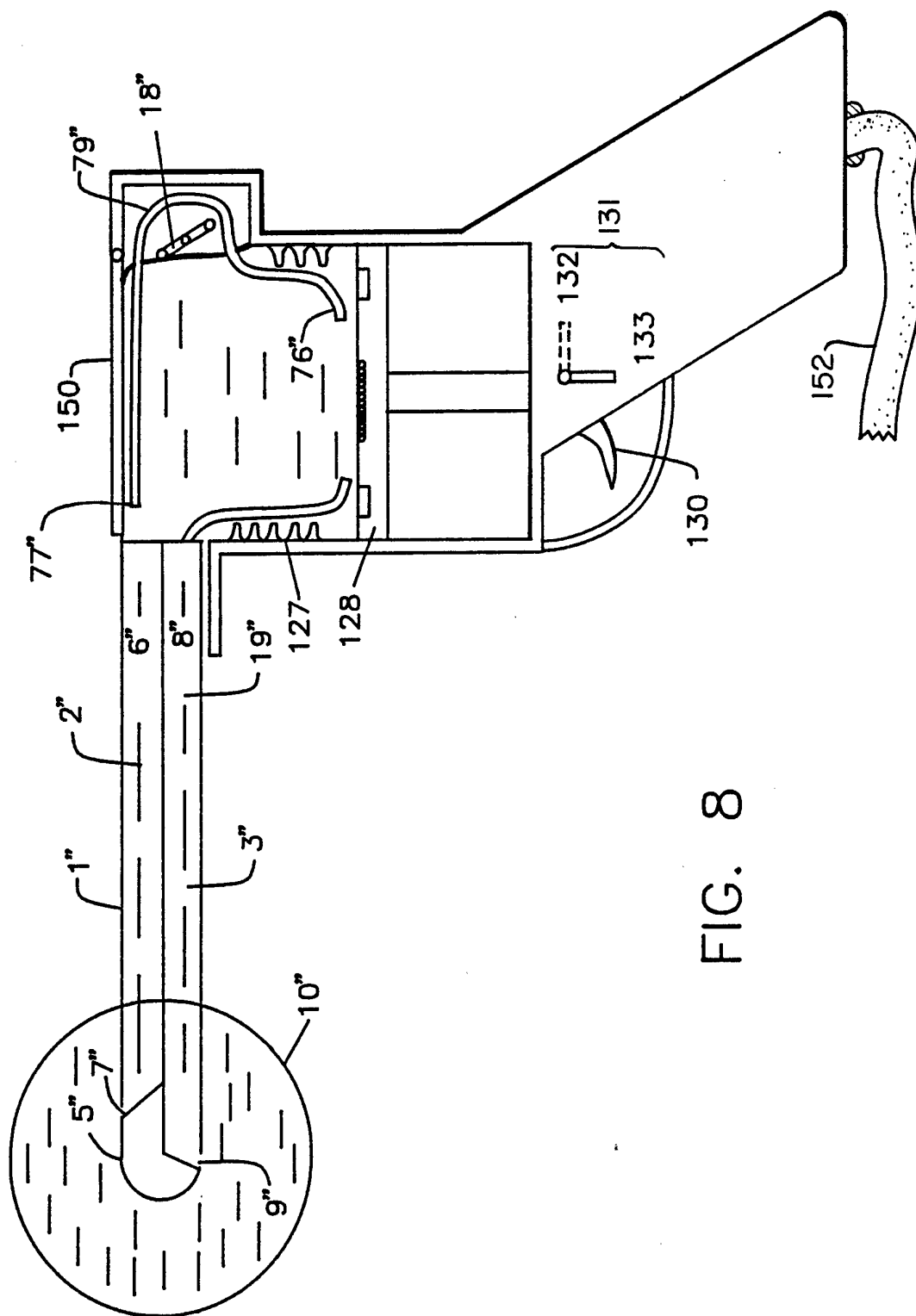


FIG. 8

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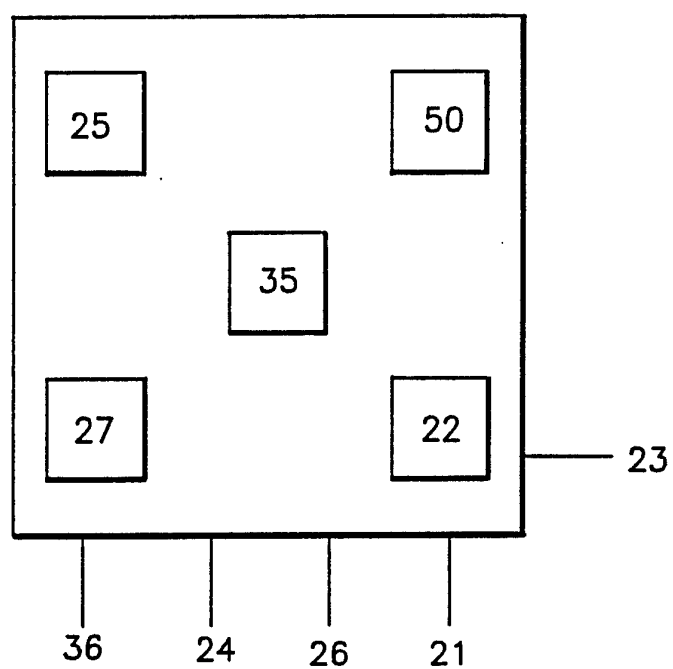


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/10838

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 7/12

US CL :606/27, 193; 128/401

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/27-31, 193; 128/400, 401; 604/32, 33, 43, 96-99, 113-114, 117, 118, 131-133, 153, 185, 212, 214

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---, P Y	US, A, 5,195,965, (Shantha), 23 March 1993, see entire disclosure.	1-4, 7, 11, 13-14 ----- 1-14
Y	US, A, 2,190,383 (L. B. Newman), 13 February 1940, see entire disclosure.	1-14
Y	US, A, 2,190,384, (L. B. Newman), 13 February 1940, see entire disclosure.	1-14
Y	US, A, 3,154,078, (E. G. Goodrich, Jr.), 27 October 1964, see inflator 29.	15
Y	US, A, 4,332,254, (Lundquist), 1 June 1982, see bayonet coupling.	5, 12

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

14 DECEMBER 1993

Date of mailing of the international search report

25 APR 1994

Name and mailing address of the ISA/US
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INTERNATIONAL SEARCH REPORT

Int ernational application No.

PCT/US93/10838

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,084,044, (Quint), 28 January 1992, note thermocouples.	11
Y	US, A, 5,105,808, (Neuwirth et al.), 21 April 1992, see graduations.	8