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R. Colombo et al., "A New Approach Using Local Combined Microwave Hyperthermia and Chemotherapy in Superficial Transitional Bladder Carcinoma Treatment," *J. Urology*, vol. 153, pp. 959-963, (Mar. 1995).

U.S. PATENT DOCUMENTS

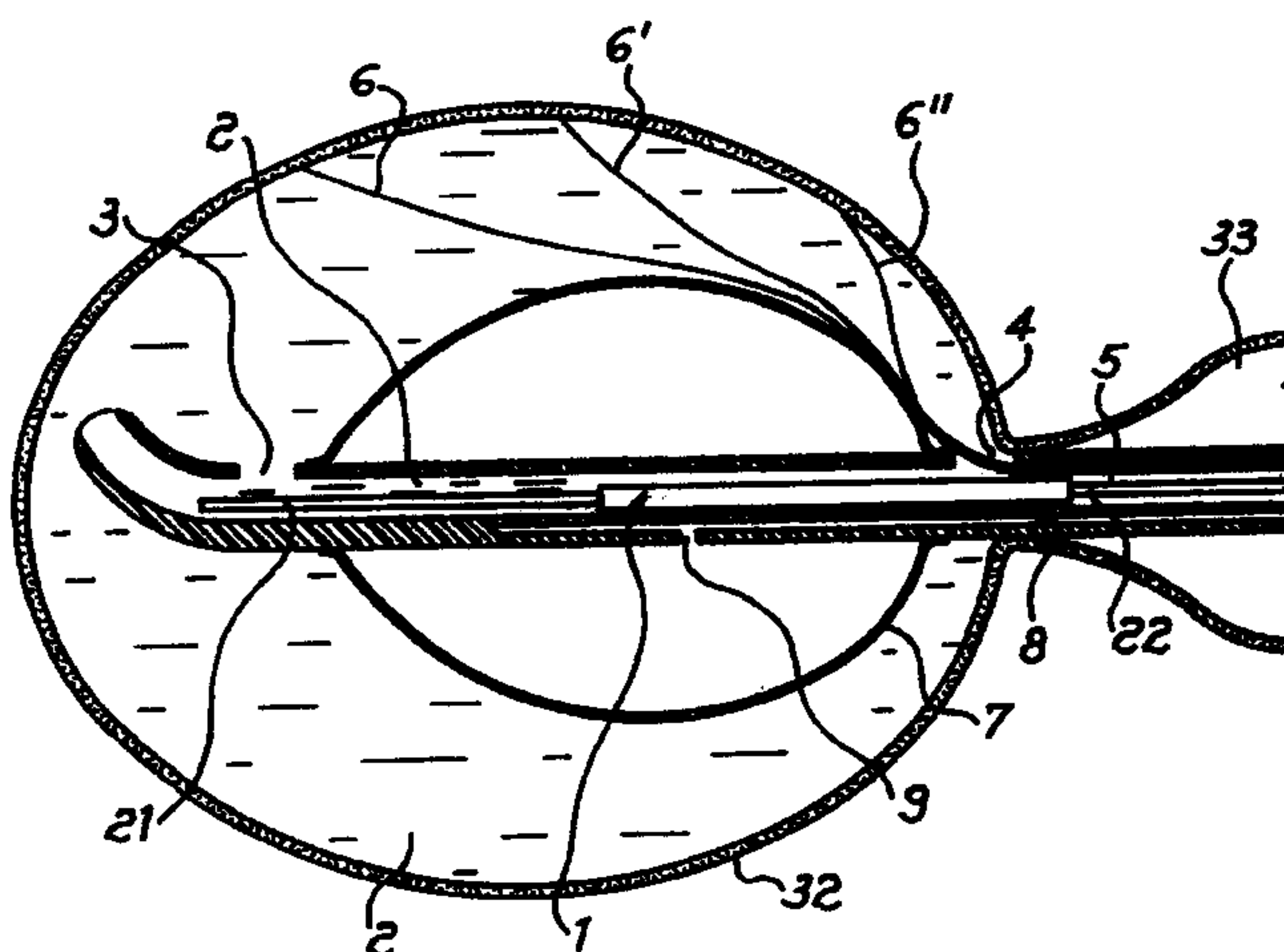
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(List continued on next page.)

FOREIGN PATENT DOCUMENTS

A flexible three-paths catheter provided with a balloon carries a sealingly sheathed radiofrequency radiating antenna, together with the shielded power supply cable and with some thermocouples, within a plastic lining surrounded by a flow of liquid; a second path carries the power supply cables of some outer thermocouples, flooded by the reverse liquid flow, while the third path allows a fluid to flow through for inflating the balloon. Introduction of the catheter into a hollow organ makes it possible to perform hyperthermal therapy of tumors by means of radiation.

**91 Claims, 4 Drawing Sheets**



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Fig. 1

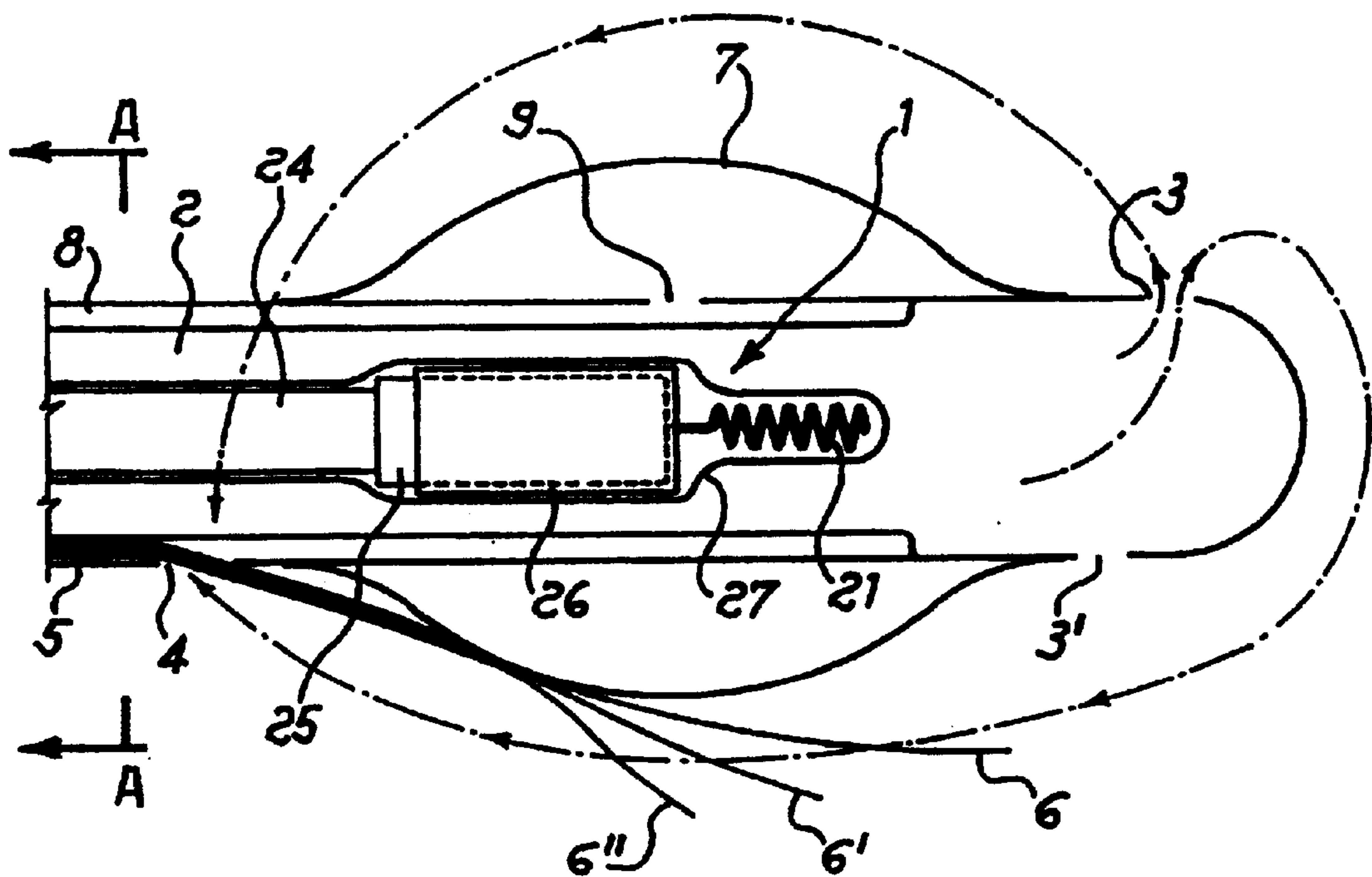
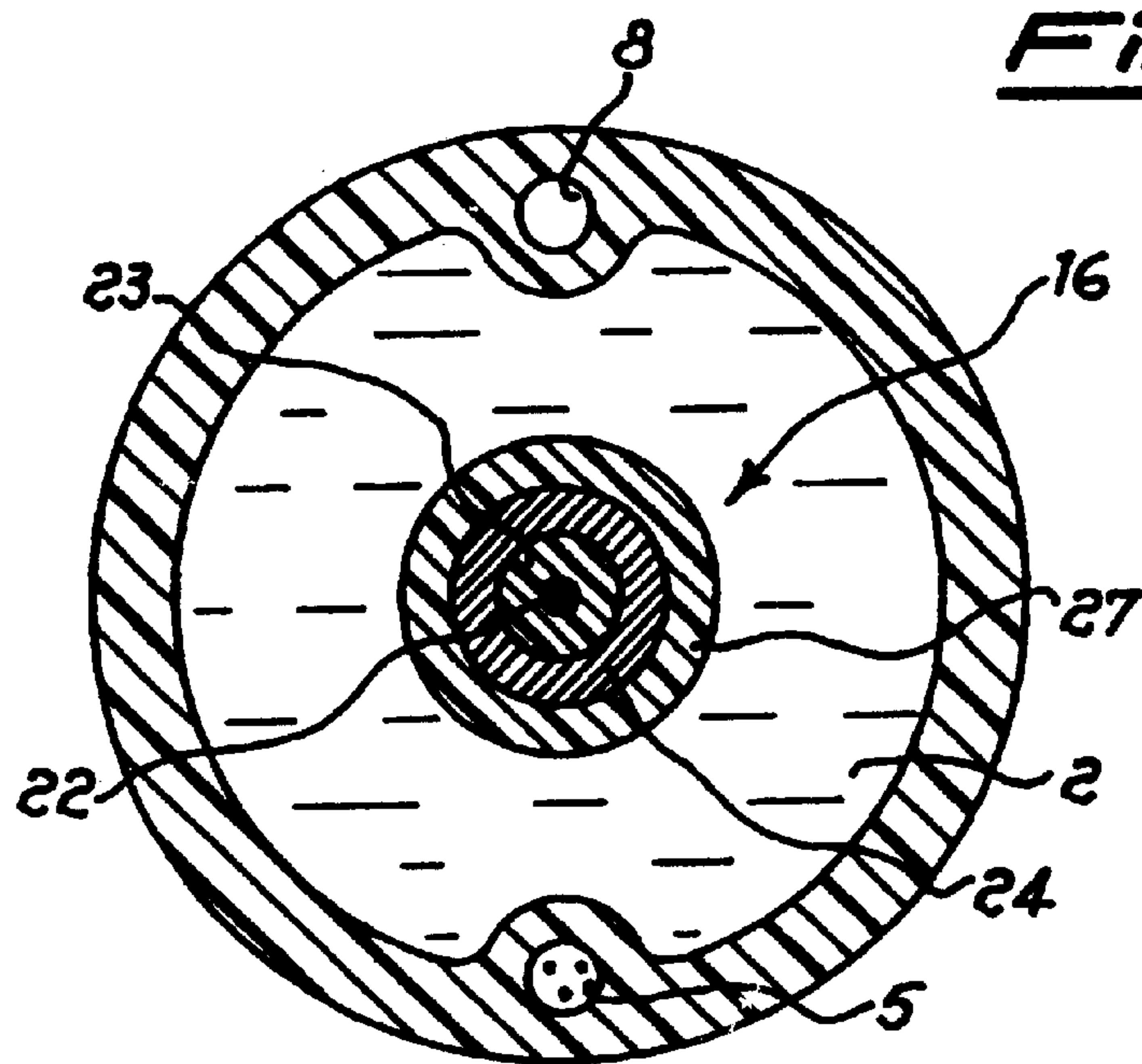
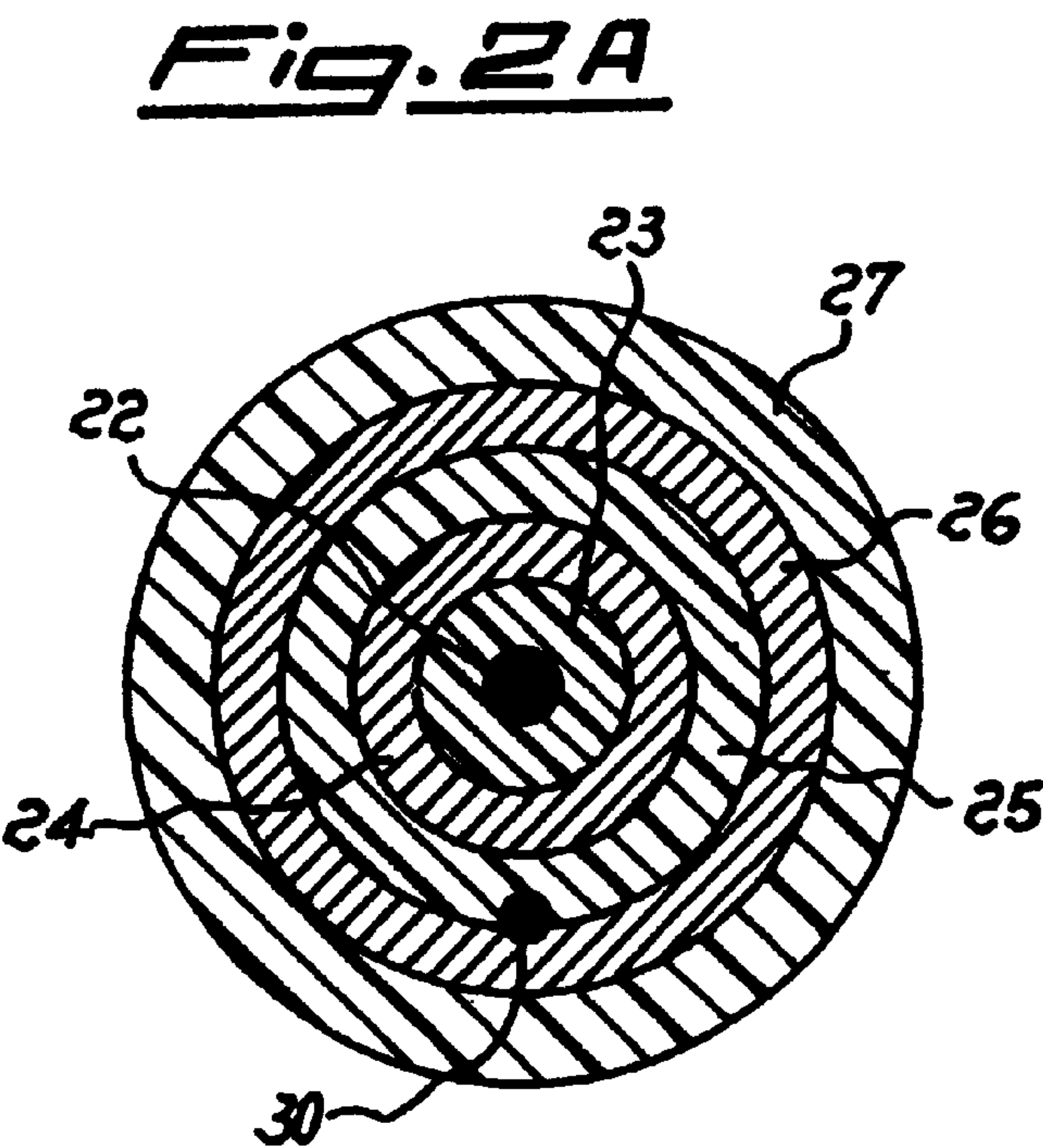
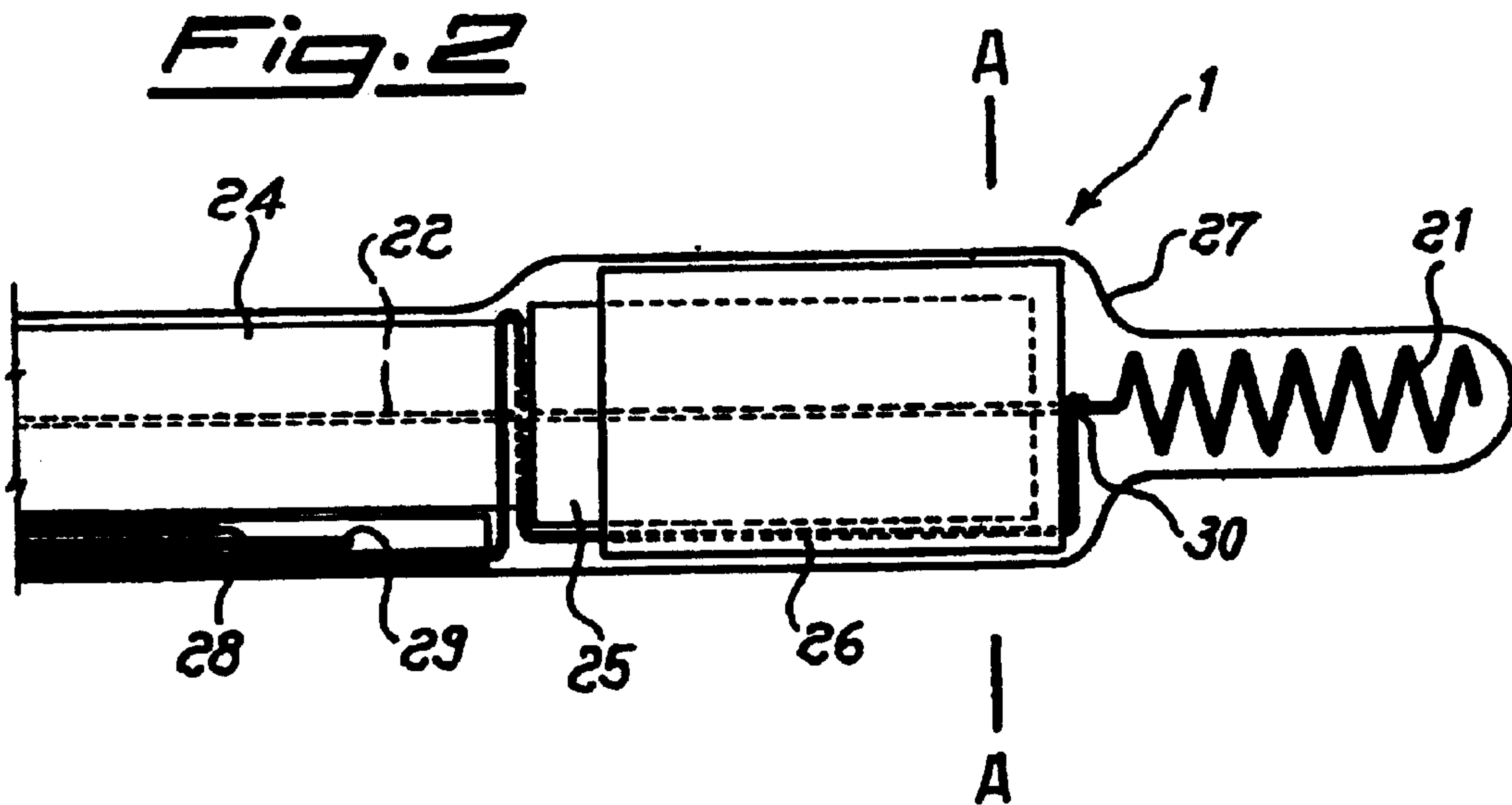


Fig. 1A







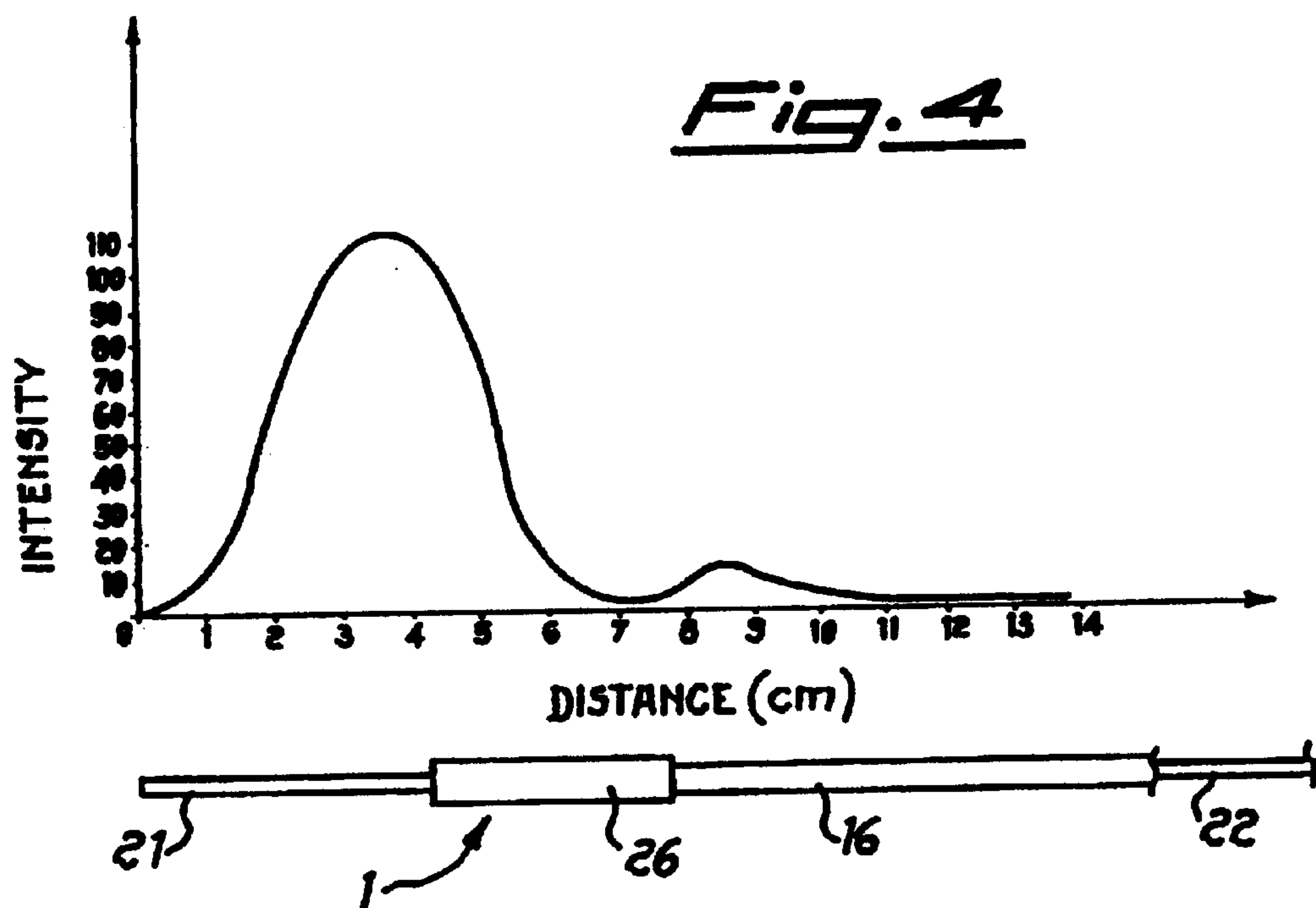
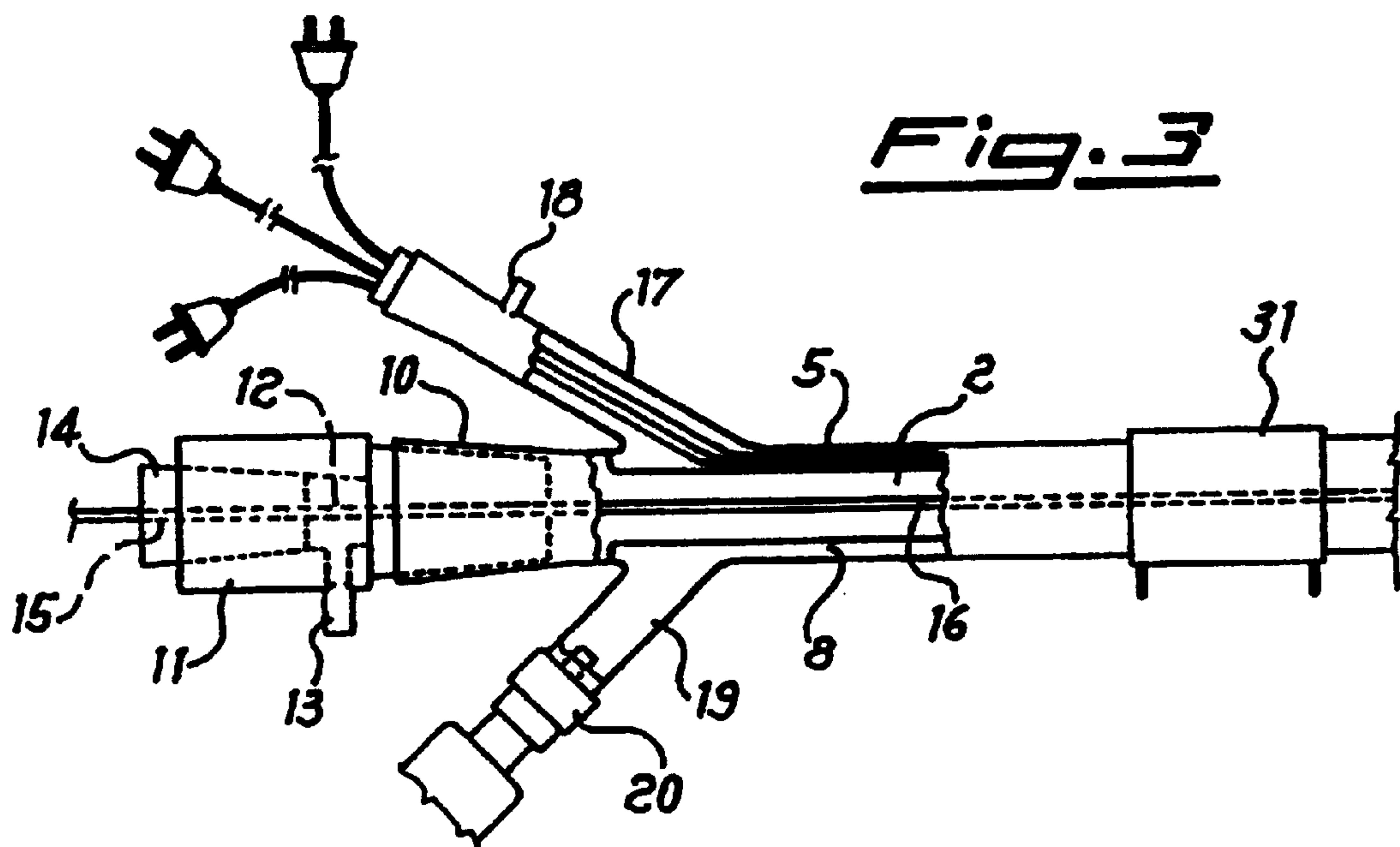


Fig. 5

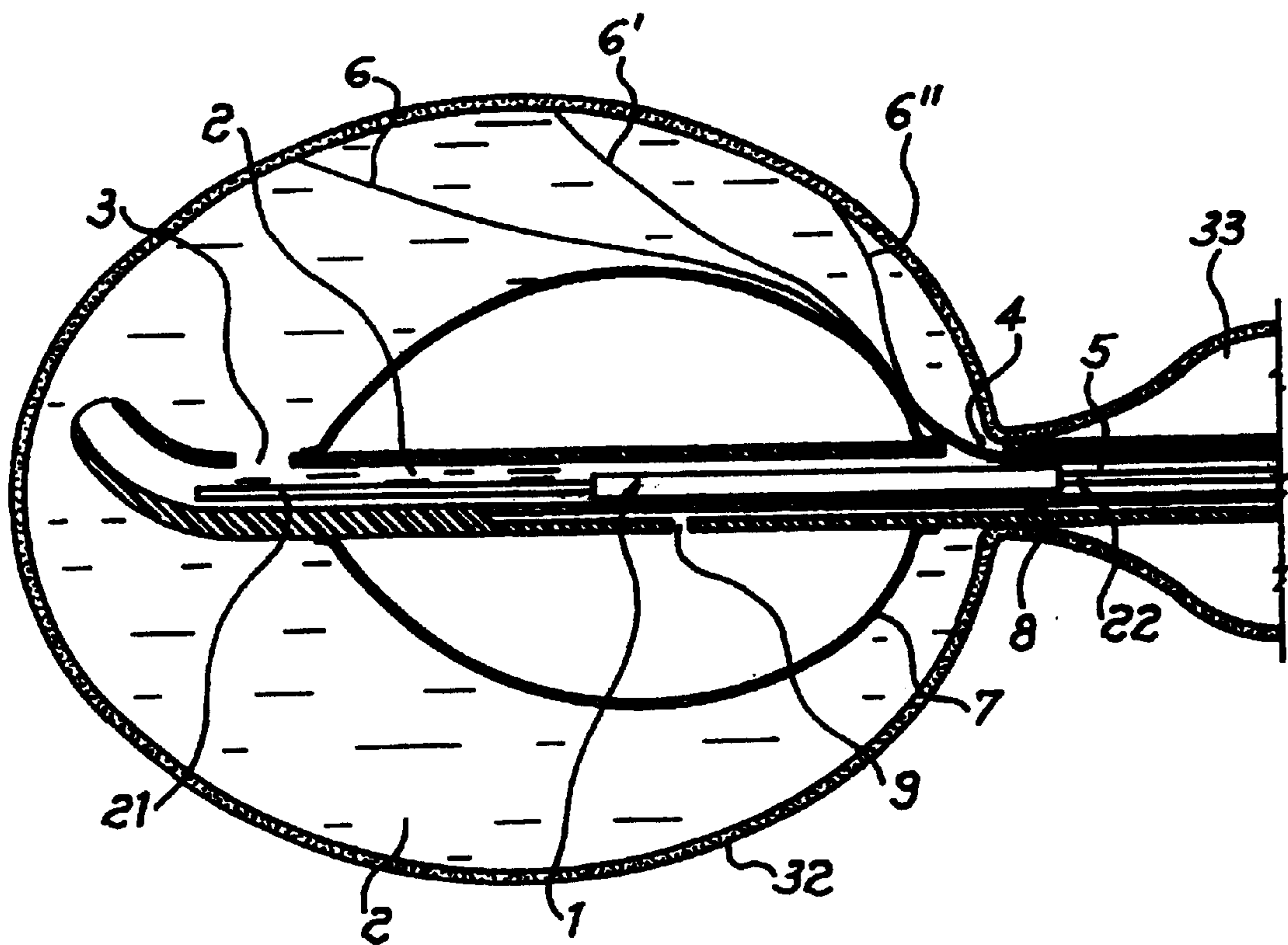
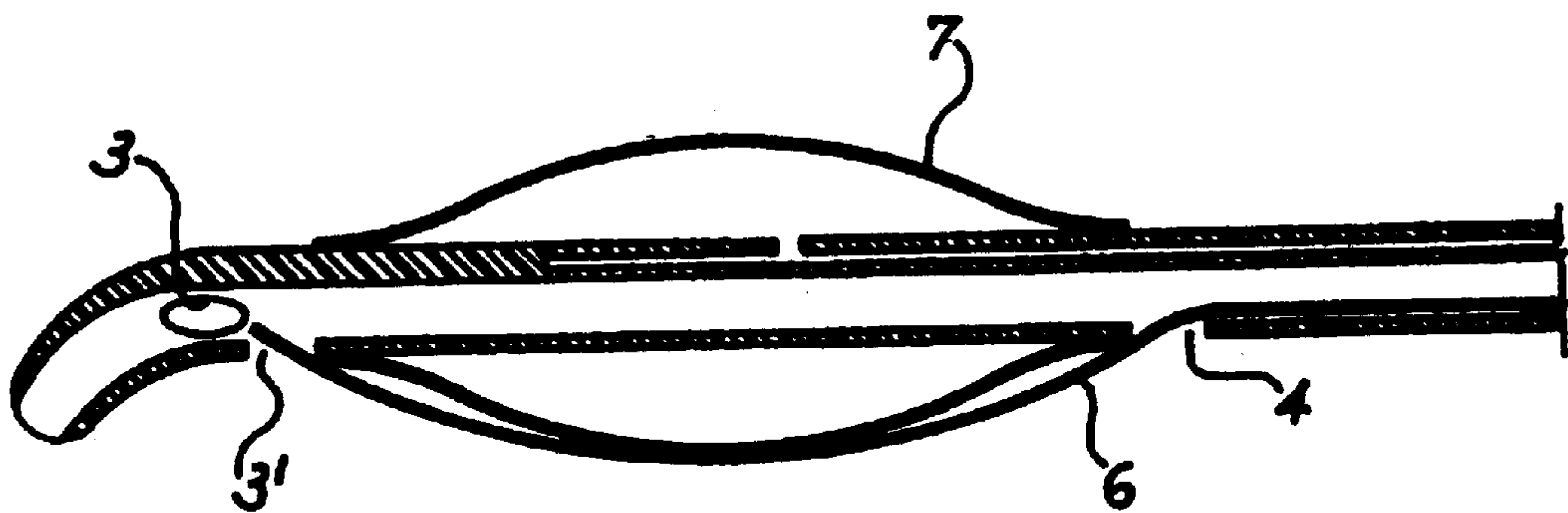


Fig. 6





## RADIATING DEVICE FOR HYPERTHERMIA

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

## BACKGROUND OF THE INVENTION

This invention concerns a radiating device for hyperthermia and, more particularly, a radiofrequency radiating device, for hyperthermal treatment of tumors of the bladder.

Devices for hyperthermal treatment of various human body illnesses are already known, and they use heating liquids, light radiations, radiofrequency antennas, thermistors, and so on.

U.S. Pat. No. 4,776,334 describes a catheter for treating tumors by inserting within the tumor to be treated a radiofrequency device provided with temperature sensors.

French patent application 2600205 concerns an apparatus for light irradiation of a cavity with the help of an inflatable balloon and of light sensors.

In U.S. Pat. No. 4,154,246 there is described a radiofrequency resonating circuit which is introduced in natural cavities of the body or directly inserted into the tumoral mass.

German patent application No. 2,848,636 claims usage of a heated liquid which is circulated in a closed loop by means of a pump within a body cavity, wherein the liquid temperature is controlled by an external thermostat. EP-A-0 370 890 discloses a radiating urethral device for hyperthermia including a catheter provided with an inflatable balloon and adapted to receive one or more liquid flows passing therethrough, a radiofrequency radiating antenna, and one or more thermocouples, the radiating antenna being submerged within one said liquid flow coming back from the closed terminal end of the antenna. The radiating device comprises in addition a separate rectal control means.

GB-A-2 045 620 relates to an applicator for hyperthermia comprising a rectal radiating probe and a spaced apart transurethral catheter including a temperature sensing means and an inflatable balloon. U.S. Pat. No. 4,957,765 discloses a transurethral radiating applicator for hyperthermia including a multi-tubes balloon type catheter comprising closed end tubes respectively surrounding a helical coil antenna and a temperature sensor, as well as a passive drainage tube for urine.

It is an object of this invention to provide a device for hyperthermal treatment of tumors within natural cavities of the human body, which gathers the advantages of the known devices while being free from their drawbacks.

## SUMMARY OF THE INVENTION

The device according to this invention substantially comprises a flexible triple path catheter carrying a radiofrequency radiating antenna, sealingly sheathed together with the shielded cable providing power supply and with several thermocouples within a plastic casing and surrounded by a flow of liquid; a second path carries the power supply cables for several outer thermocouples, which are flooded by return flow of said liquid, and a third path allowing a fluid to flow through in order to inflate a balloon located near the catheter distal end, once the latter has been introduced into the cavity to be treated.

This invention will be described more particularly in the following based on a specific embodiment thereof reported

herein for exemplary and non limiting purposes, as well as on the attached schematic drawings. In connection with the above it should be pointed out that in said drawings the parts shown are not to scale and the mutual dimensions are out of proportion, the members having in fact a very thin cross-section.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows schematically, in an enlarged scale, the distal end of the device according to this invention, which has to be introduced into a natural cavity of the human body;

FIG. 1A shows an enlarged schematic cross-section of the device according to this invention, taken along line A—A of FIG. 1;

FIG. 2 is a schematic of some structural details of a radiofrequency antenna shown in general within the device of FIG. 1;

FIG. 2A shows a schematic enlarged cross-section of the radiating antenna, taken along line A—A of FIG. 2;

FIG. 3 is a schematic of the proximal end of the device according to this invention, opposite to the distal end shown in FIG. 1;

FIG. 4 is a plot of the intensity of the radiation generated by the radiating antenna of FIG. 2, along the longitudinal axis thereof;

FIG. 5 shows schematically the distal end of the device of FIG. 1, as it is seen after having been introduced into a urinary bladder; and

FIG. 6 shows schematically the structure at the distal end of the device shown in FIG. 1, when ready for introduction into the organ to be treated.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

The device according to this invention has a shape and consistency of a flexible catheter whose distal end, as it is shown in FIG. 1, encloses therewithin an antenna 1 surrounded by a flow of liquid 2 which is introduced into the bladder through an opening 3 and, after being freely circulated within said bladder, is again sucked into the catheter through an opening 4. Said opening 4 is in communication with a second way or catheter side channel 5 housing the leads of several thermocouples, like for instance 6, 6', 6" adapted to be deflected outwards by inflating a balloon 7 in which a gaseous fluid or a liquid is made to flow through a third path or side channel 8 and through an end opening 9.

The catheter opposite (proximal) end (FIG. 3) whose tip is shown in FIG. 1, has three diverging inlets corresponding to the three paths or channels 2, 5, 8 of said catheter. Within center inlet 10 there is inserted with a pressure fit a plug 11 provided with a center through passage and with a side branch 13; in center passage 12 of plug 11 there is in turn pressure fitted a second plug 14 which is provided as well with a center opening 15. Shielded cable 16 supplying power to antenna 1 runs through the center passages 12 and 15 of said two coaxially arranged plugs, while side branch 13 is provided as an inlet and an outlet of a conditioning fluid flowing along channel 2. Thermocouple power supply cables 6, 6', 6" are laid through side entrance 17 provided with a branch 18, and they run along side path or channel 5 having said conditioning liquid flowing in a reverse direction therethrough, said liquid entering and exiting in turn through said branch 18. The other side entrance 19 is provided with a one-way valve 20 for introducing the fluid that, flowing along second side channel 8, is used to inflate balloon 7.



Slightly downstream from said three entrances **10, 17, 19** there is provided, in a sleeve-like fashion and in intimate contact around the catheter body, a heat exchanger **31**, operated in a known fashion from outside, and used to cool or to heat said conditioning liquid flowing through central channel **2** and coming back through side channel **5**, or viceversa.

Referring now to FIGS. **2** and **2A**, radiating antenna **1** will be described more in detail; the useful radiating portion of linear dipole antenna **1** comprises a terminal coil-shaped segment **21** of central conductor **22** which, immediately upstream from coil **21** is tightly surrounded, in sequence, by a first plastic inner sleeve **23**, by a metal braiding **24**, by a second intermediate plastic sleeve **25**, by a metal cylinder **26** electrically connected with shield **24**, and eventually by an outer plastic sleeve **27**.

Immediately beneath sleeve **27** there is provided the power supply cables for several thermocouples located in a way suitable to detect the operating temperatures in predetermined positions of the antenna and of the power supply cable thereof. For instance, a first thermocouple **28** may be located in the position of the stretch of catheter which will be located at the prostatic urethra when the catheter with its antenna are inserted within the bladder; a second thermocouple **29** slightly upstream from antenna **1**, at the bladder neck, while a third thermocouple **30** is located close to central conductor **22**, between metal cylinder **26** and end coil **21**, after having been wrapped with one or more coils around shield **24** immediately upstream from intermediate sleeve **25** and metal cylinder **26**, and a second time, with a larger number of coils, around the stretch of central lead **22** projecting out of metal cylinder **26** before winding up to form end coil **21**, the stretch of thermocouple **30** power supply cable connecting said two points being inserted with intimate contact between intermediate sleeve **25** and metal cylinder **26**.

In any case, the end stretches of the power supply cables, immediately ahead of the thermocouples, are wrapped in a number of helical coils in order to increase the thermal capacity and the radiofrequency resistance of the ends which are designated to detect the temperature, while reducing to a minimum, or completely avoiding the dispersive thermal conduction along said cables.

In FIG. **1A**, which shows schematically a cross-section of the catheter according to this invention, taken in any position of the stretch going from heat exchanger **31** to intermediate sleeve **25**, there is shown side channel **5** carrying the power supply cables of thermocouples **6, 6', 6"** and side channel **8** for the flow of the fluid used to inflate balloon **7**, both said channels **5** and **8** being managed within the thickness of the actual catheter whose inner bore **2** intended for the flow of the conditioning liquid carries, in a central position, shielded cable **16** comprised of central conductor **22**, inner sleeve **23**, shield **24** and outer sleeve **27**, as well as inner thermocouples **28, 29** and **30** power supply cables (not shown).

FIG. **2A** is a schematic cross-section of antenna **1**, taken along line A—A of FIG. **2**. The following are shown therein, starting from the center: conductor **22**, inner sleeve **23**, metal shield **24**, an intermediate sleeve **25**, a metal cylinder **26**, and outer sleeve **27**, as well as thermocouple **30** power supply conductor.

FIG. **4** is a diagram showing the radiation intensity starting from the coil-shaped end **21** of antenna **1** towards shielded power supply cable **22, 16**. As it is shown, intensity is a maximum when passing from radiating coil **21** to the stretch protected by metal cylinder **26**, and it tends to nil at the position of shielded cable **16**.

There is shown schematically in FIG. **5** the longitudinal section of the catheter provided with a radiating antenna according to this invention, once it has been introduced into the bladder, in an operative condition. The catheter, carrying the radiating antenna therewithin, is introduced into bladder **32** through the urethra, in such a way that the rear end of protective metal cylinder **26** is located approximately at the bladder neck, in the transition area between prostrate **33** and bladder **32**, while simultaneously taking care that the catheter front end does not subject the bladder internal wall to any pressure. Once the catheter has been introduced into the bladder in such a way, one actuates the supply pump of conditioning liquid **2** preferably comprising a solution of a selective [citotoxicity] cytotoxicity substance, which is accordingly forced to circulate through the bladder coming out from opening **3** and going back through opening **4**, or viceversa, along side channel **5** which carries the power supply cables of thermocouples **6, 6', 6"** therewithin. The liquid forced circulation, provided by the variable flowrate supply pump, suitably combined with an outer balancing and degassing chamber, allows the volume of liquid within the bladder to be balanced at will, in such a way as to compensate the pathological or physiological urine production, while thoroughly ejecting the gases generated or unwillingly introduced in circulation, out of the bladder, in order to prevent irradiation non-uniformities which would otherwise be caused by coexistence of anisotropic media. Once bladder **32** has been completely filled with conditioning liquid **2**, balloon **7** is inflated by introducing a fluid, which may be a gas but it is preferably a liquid, along side channel **8** and through the end opening **9** thereof; balloon **7** inflated as mentioned above, pushes then against outer thermocouples **6, 6', 6"** power supply cables thereby moving said thermocouples into tangential engagement against bladder wall **32** in different positions, in order to detect the temperatures prevailing therein as caused by irradiation generated by antenna **1**. The possibility of changing the location and the number of the outer thermocouples, enables the thermocouples to be positioned at will, on the bladder wall, or in any [case] place of the body organ to be treated, while being able to individually check the temperatures in the various locations. The inflated balloon **7** protects the bladder neck wall from an excess heat caused by the proximity of the radiating antenna, and in the meantime it prevents the catheter from being accidentally displaced or from coming out through the bladder neck.

The dimensions of antenna **1** are such that it may be freely positioned along the catheter while being obviously wholly contained within the human bladder to be treated, but in the meantime they must be suitable to generate a therapeutically active radiation, in order to reach the temperatures considered lethal for the cancer cells. Since the physical length of an antenna is related to the virtual electrical length thereof through an equation involving the impedance of said antenna, as well as the impedance deriving from the environment irradiated by the antenna, the antenna electrical length comes out to be inversely proportional to the irradiated medium conductivity. Accordingly, since the conductivity of an aqueous solution is for instance many times higher than the conductivity of air, when operating in an aqueous environment it is possible to use an antenna which is physically quite shorter than the length needed if it were necessary to operate in air.

The dipole according to this invention corresponds to a dipole of the quarter wave type and in the aqueous environment comprising the solution filled bladder, it makes it possible to operate at frequencies in the range of 900–1000



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MHz; in particular, a frequency of 915 MHz has been chosen since very different frequencies would result in penetration, intensity, and other effects not always exactly predictable and controllable in the body tissues, since in general high frequencies have a low penetration power and therefore they do not provide the desired local heating, while lower frequencies, having a higher penetration power, may get deeper tissues involved and damaged.

On the other hand, radiations having different wavelengths might create a disturbance for radio and telephone communications, protected by constraints imposed by the legislations of the various countries.

In order to reduce to a minimum and possibly to nil the influence of the radiofrequency field on the thermocouples, as well as the various thermoelectric effects connatural with said thermocouples, the supply cable end stretches close to the thermocouples are wound into an helical shape whereby the temperature measured in the various sensing points is a reliable data, unaffected by said influences. The above structure construction prevents measuring errors due to conduction, it provides a reliable temperature indication, for instance exactly in the area of the dipole power supply position in the case of thermocouple 30, and it reduces in an extremely effective manner the thermocouple self-heating process due to radiofrequencies, also when there is an extremely high concentration of energy, whereby said structures are almost unaffected by the disturbances in the radio-frequency field.

Since the sizes, and in particular the cross-sections of the plural device components according to this invention must be extremely small, to suit the particular field of use desired for the device, the energy losses due for instance to self-heating of the antenna power supply cable are particularly high, for instance in the range of 20–40%. Since this undesirable self-heating, due to the Joule effect, might cause excessive heating of the urethral walls, and accordingly a discomfort for the patient subjected to treatment, or even damages to the tissues, the antenna cable, and the antenna itself are continuously cooled, while in operation, by using the conditioning liquid flow directed to the bladder and then withdrawn again therefrom, whereby a simultaneous control action is obtained, for controlling the temperature prevailing both in the liquid within the bladder and along the urethra. Temperature control is effected by variations of the conditioning liquid supply flow and of the cooling source temperature. In such a way it is possible both to increase the temperature and to withdraw heat.

In order to enable outer thermocouples 6, 6', 6" for detecting the bladder wall temperature to be safely deflected outwards when balloon 7 is inflated, the power supply cables thereof are reinforced along their whole length by inserting within the protecting sheath thereof a thin stainless steel wire providing them with the required rigidity and flexibility. The presence of said reinforcing wire provides as well the thermocouple power supply cables with the mechanical strength necessary to bear the compressive and tensile stresses caused when the cables are inserted within side channel 5, and when thermocouples 6, 6', 6" are laid in the desired locations.

When the catheter, provided with all its components, is introduced into the urethral channel, all the way to the bladder, the ends of outer thermocouples 6, 6', 6" projecting upstream of balloon 7 through opening 4 are temporarily locked by inserting them, downstream of balloon 7, in one or more notches provided, as the case may be, in suitable positions according to the different body organ or the

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particular patient to be treated, close to the catheter end, as it is shown in FIG. 6. When balloon 7 is inflated it causes the thermocouple ends to come out from the notches and then to deflect outwards until the thermocouple tips come into engagement with the bladder wall. The particular outwards deflecting system of thermocouples 6, 6', 6" causes the ends of the respective power supply cables comprising the actual thermocouple, to tangentially engage the bladder wall, whereby no excessive concentrated pressures are generated. On the other hand, the tangential position taken by the thermocouple tips when contacting the bladder wall, makes it possible to measure the actual temperature of the wall position considered in that at the boundary between said wall and the liquid filling the bladder there is a thin liquid layer substantially stationary, which is not affected by the liquid circulation within the bladder, since it clings to the tissue because of a physical attraction, while the coil shape of the cable terminal stretches increases the thermal capacity of the thermocouple whose diameter, inclusive of the coils, is less than 0,7 mm whereby the thermocouple is completely submerged within the liquid stationary layer having a thickness of approximately 1 mm.

After the thermocouples have been deflected outwards within the bladder, it is still possible to modify their location by performing pushing and/or pulling actions on the reinforced power supply cables, as mentioned above, and possibly by rotating the catheter containing them. Control of the temperature detected on the bladder walls and/or within the circulating liquid mass, is obtained by changing the flowrate of said liquid from few cubic centimeters per minute to several tens of cubic centimeters per minute. The circulated fluid circulating system prevents permanence or formation and build-up of possible gas bubbles within the bladder or through the circuit, in that air or other gas bubbles having possibly formed or being already present, are entrained out by the continuous flow and exhausted to the outer environment in an appropriate position of the outer pumping circuit. In addition, the liquid circulation provided as above prevents the antenna and the environment thereof from overheating, therefore from causing undesirable reactions within the circulating liquid.

It is pointed out herein that all the antenna and thermocouple components contacted by the liquid circulating within the bladder are sealingly lined and insulated from the outer environment by a polytetrafluoroethylene layer whereby, after each usage and application they may be sterilized for subsequent further use.

We claim:

1. A radiating device for [urethral] hyperthermia including a catheter provided at its distal end with an inflatable balloon (7) and adapted to receive multiple injected liquid flows (2,5,8) passing therethrough, a radiofrequency radiating antenna (1) and multiple thermocouples (6,6', 6"), the radiating antenna [being] adapted to be submerged within said liquid flow, characterized in that

said radiating antenna (1) [is] adapted to be submerged within a liquid flow which proceeds through a central channel (2) surrounding said radiating antenna (1) towards the distal end of said catheter and passes from said catheter through a first opening (3) into the bladder to be treated, while flowing back into said catheter towards [the] a proximal end thereof through a second separate opening (4) of a side channel (5) surrounding [the] power supply cables of said thermocouples (6,6', 6"),

[the] ends of said thermocouples (6,6', 6") are adapted to project out of said second opening (4), being thus



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deflected outwards into the bladder when said balloon (7) is inflated by injecting a fluid therein through a second side channel (8) and third opening (9), whereby [the] outwardly deflected ends of said thermocouples (6,6', 6'') are adapted to come into tangential engagement with the bladder wall (32) irradiated by said antenna (1).

2. A radiating device including a catheter provided at its distal end with an inflatable balloon and adapted to receive multiple injected liquid fluid flows passing therethrough, a radiofrequency radiating antenna and multiple thermocouples, the radiating antenna being submerged within a fluid flow, characterized in that

said radiating antenna is adapted to be submerged within a flow which proceeds through a central channel surrounding said radiating antenna towards a distal end of said catheter and passes from said catheter through a first opening into an organ to be treated, while flowing back into said catheter towards a proximal end thereof through a second separate opening of a side channel surrounding power supply cables of said thermocouples,

ends of said thermocouples are adapted to project out of said second opening, being thus deflected outwards into the organ when said balloon is inflated by injecting a fluid through a second side channel and third opening, whereby the outwardly deflected ends of said thermocouples are adapted to come into tangential engagement with a wall of the organ irradiated by said antenna.

3. A radiating device including a catheter provided at its distal end with an inflatable balloon and adapted to receive multiple injected liquid fluid flows passing therethrough, a radiofrequency radiating antenna and multiple thermocouples, the radiating antenna being submerged within a fluid flow, characterized in that

said radiating antenna is adapted to be submerged within a flow which proceeds through a central channel surrounding said radiating antenna towards a distal end of said catheter and passes from said catheter through a first opening into an organ to be treated, while flowing back into said catheter towards a proximal end thereof through a second separate opening of a side channel surrounding power supply cables of said thermocouples,

ends of said thermocouples are adapted to project out of said second opening, being thus deflected outwards into the organ when said balloon is inflated by injecting a fluid through a second side channel and third opening, whereby outwardly deflected ends of said thermocouples are adapted to come into engagement with a wall of the organ irradiated by said antenna.

4. A radiating device for irradiating an organ comprising: a catheter provided with an inflatable balloon and including a central channel, first and second side channels, and first, second, and third openings;

an antenna, situated at a first end portion of the catheter, the antenna adapted for being submerged in a first fluid that flows through the central channel surrounding the antenna towards the first end portion of the catheter, passes from the catheter through the first opening, and flows back into the catheter towards a second end portion thereof through the second opening; and

a plurality of thermocouples, having ends, the plurality of thermocouples extending along the first side channel of the catheter, each of the ends of the plurality of ther-

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mocouples adapted to project out of the second opening and to be deflected outwards when the balloon is inflated by injecting a second fluid through the second side channel and the third opening,

wherein the deflected ends of the plurality of thermocouples adapted to contact a wall of the organ irradiated by the antenna.

5. A radiating device for irradiating an organ comprising: a catheter provided with an inflatable balloon and including first and second channels and a first opening;

an antenna, situated at an end portion of the catheter, the antenna adapted for being submerged in a fluid that flows through the first channel surrounding the antenna and into the organ; and

a plurality of thermocouples, having ends, the plurality of thermocouples extending along the second channel each of the ends of the plurality of thermocouples projecting out of the first opening and being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of thermocouples are adapted to contact a wall of the hollow organ irradiated by the antenna.

6. A radiating device for irradiating an organ comprising: a catheter provided with an inflatable balloon;

an antenna, situated at an end portion of the catheter, adapted for irradiating the organ;

a channel for providing a fluid to the organ; and

a plurality of thermocouples, having ends, the plurality of thermocouples extending along the catheter, each of the ends of the plurality of thermocouples being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of thermocouples are adapted to contact a wall of the organ irradiated by the antenna.

7. A radiating device for irradiating an organ comprising: a catheter provided with an inflatable balloon and including first and second channels and a first opening;

an antenna situated at an end portion of the catheter, the antenna adapted for being submerged in a fluid that flows through the first channel surrounding the antenna and into the organ; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter each of the ends of the plurality of temperature sensing devices being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of temperature sensing devices are adapted to contact a wall of the organ irradiated by the antenna.

8. A radiating device for irradiating an organ comprising: a catheter provided with an inflatable balloon;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a channel for providing a fluid to the organ; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of temperature sensing devices are adapted to contact a wall of the organ irradiated by the antenna.

9. A radiating device for irradiating an organ comprising: a catheter;



- an antenna, situated at an end portion of the catheter, adapted for irradiating the organ;*  
*a channel, within the catheter, adapted for providing a fluid comprising a cytotoxic substance to the organ; and*  
*a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices adapted for being deflected outwards after the catheter is inserted into the organ,*  
*wherein the deflected ends of the plurality of temperature sensing devices are adapted to contact a wall of the organ irradiated by the antenna.*  
 10. A radiating device for irradiating an organ comprising:  
*a catheter, including a channel adapted for providing a fluid to the organ;*  
*an antenna, situated at an end portion of the catheter, adapted for irradiating the organ; and*  
*a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards after the catheter is inserted into the organ,*  
*wherein the deflected ends of the plurality of temperature sensing devices are adapted to contact a wall of the organ irradiated by the antenna.*  
 11. A radiating device for irradiating a cavity comprising:  
*a catheter;*  
*an antenna, situated at an end portion of the catheter, for irradiating the cavity;*  
*channel extending along the catheter and adapted for providing fluid to the cavity; and*  
*a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards after the catheter is inserted into the cavity,*  
*wherein the deflected ends of the plurality of temperature sensing devices are adapted to contact a wall of the cavity irradiated by the antenna.*  
 12. The radiating device as recited in claim 11, wherein the channel is within the catheter.  
 13. The radiating device as recited in claim 12, wherein the antenna is within the channel.  
 14. The radiating device as recited in claim 13, adapted for fluid flow by the antenna and into the cavity.  
 15. The radiating device as recited in claim 11, further comprising a shielded cable coupled to the antenna.  
 16. The radiating device as recited in claim 15, adapted for fluid flow by the shielded cable and the antenna and into the cavity.  
 17. The radiating device as recited in claim 11, further comprising means for providing a second fluid around the antenna.  
 18. The radiating device as recited in claim 11, adapted for flow of a conditioning liquid.  
 19. The radiating device as recited in claim 11, adapted for flow of a solution of a selective cytotoxicity substance.  
 20. The radiating device as recited in claim 11, wherein the antenna is adapted for a frequency range of 900–1000 MHZ.  
 21. The radiating device according to claim 11, wherein the antenna comprises a linear dipole antenna.

22. The radiating device according to claim 21, wherein the linear dipole antenna comprises a coil-shaped segment and a linear conductor.  
 23. The radiating device according to claim 22, further comprising:  
*a first plastic sleeve surrounding a portion of the linear conductor;*  
*a metal braiding surrounding the first plastic sleeve;*  
*a second plastic sleeve surrounding the metal braiding;*  
*a metal cylinder surrounding the second plastic sleeve and electrically coupled to the metal braiding; and*  
*a third plastic sleeve surrounding the metal cylinder.*  
 24. The radiating device as recited in claim 11, further comprising a stainless steel wire coupled to each of the plurality of temperature sensing devices.  
 25. The radiating device as recited in claim 11, further comprising means for retaining the plurality of temperature sensing devices prior to deflection.  
 26. The radiating device according to claim 25, wherein the retaining means comprises at least one notch.  
 27. The radiating device according to claim 11, further comprising a sealing member for sealing the antenna.  
 28. The radiating device according to claim 27, further comprising a sealing member for each of the plurality of temperature sensing devices.  
 29. The radiating device according to claim 27, wherein the sealing member comprises a polytetrafluoroethylene layer.  
 30. The radiating device according to claim 11, further comprising a second plurality of temperature sensing devices for detecting temperatures at predetermined positions along the antenna.  
 31. The radiating device according to claim 30, wherein each of the second plurality of temperature sensing devices is coupled to a power supply cable.  
 32. The radiating device according to claim 31, wherein each of the power supply cables is wound into a helical coil.  
 33. The radiating device according to claim 11, wherein the deflected ends of the plurality of temperature sensing devices tangentially contact the wall of the cavity.  
 34. The radiating device according to claim 11, wherein the catheter further comprises an inflatable balloon.  
 35. The radiating device according to claim 34, wherein the balloon is adapted to be inflated by a second fluid.  
 36. The radiating device according to claim 35, wherein the second fluid is a liquid.  
 37. The radiating device according to claim 35, wherein the second fluid is a gas.  
 38. The radiating device according to claim 34, wherein the catheter comprises a second channel in communication with the balloon for providing a second fluid to inflate the balloon.  
 39. The radiating device according to claim 34, wherein each of the ends of the plurality of temperature sensing devices is deflected outwards when the balloon is inflated.  
 40. The radiating device according to claim 11, wherein the catheter comprises a first opening adapted to provide the fluid into the cavity and a second opening adapted to allow for circulation out of the cavity.  
 41. The radiating device according to claim 34, wherein the catheter comprises a first opening adapted to provide the fluid into the cavity and a second opening adapted to allow for circulation out of the cavity.  
 42. The radiating device according to claim 41, wherein the catheter comprises a third opening adapted to provide a second fluid to inflate the balloon.



43. The radiating device according to claim 11, adapted to contact a cavity that is an organ.

44. The radiating device according to claim 11, adapted to contact a cavity that is a hollow organ.

45. The radiating device according to claim 11, adapted to contact a cavity that is a bladder.

46. The radiating device according to claim 11, further comprising means for protecting the cavity wall from excess heat from the antenna.

47. The radiating device according to claim 11, further comprising means for preventing the catheter from being displaced from the cavity.

48. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an inflatable balloon, an antenna and a plurality of thermocouples, into an organ;

providing a supply of a first fluid such that the first fluid flows through a first channel of the catheter and circulates out a first opening in the catheter through the organ and into a second opening in the catheter and through a second channel of the catheter; and

inflating the balloon by passing a second fluid through a third channel of the catheter and out a third hole in the catheter and into the balloon, such that the plurality of thermocouples are deflected by the inflated balloon and contact a wall of the organ.

49. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an inflatable balloon, an antenna, and a plurality of temperature sensing devices, into an organ;

providing a supply of a first fluid such that the first fluid flows through a first channel of the catheter and circulates out a first opening in the catheter through the organ and into a second opening in the catheter and through a second channel of the catheter; and

inflating the balloon by passing a second fluid through a third channel of the catheter and out a third hole in the catheter and into the balloon, such that the plurality of temperature sensing devices, carried in the second channel, are deflected by the inflated balloon and contact a wall of the organ.

50. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter including an inflatable balloon, an antenna, and a plurality thermocouples, into an organ; irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid through the catheter and into the organ; and

inflating the balloon such that the plurality of thermocouples are deflected by the inflated balloon and contact a wall of the organ.

51. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter including an inflatable balloon, an antenna and a plurality of temperature sensing devices into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid through the catheter and into the organ; and

inflating the balloon such that the plurality of temperature sensing devices are deflected by the inflated balloon and contact a wall of the organ.

52. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an antenna and a plurality of temperature sensing devices, into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid comprising a cytotoxic substance through the catheter and into the organ; and

deflecting the plurality of temperature sensing devices to contact a wall of the organ.

53. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an antenna and a plurality of temperature sensing devices, into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid through the catheter and into the organ; and

deflecting the plurality of temperature sensing devices to contact a wall of the organ.

54. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an antenna and a plurality of temperature sensing devices, into a cavity;

irradiating the tin radiation using the antenna;

providing a supply of a fluid into the cavity; and

deflecting the plurality of temperature sensing devices to contact a wall of the cavity.

55. The method of performing hyperthermal therapy according to claim 54, wherein the providing step comprises the step of providing the fluid through the catheter and into the cavity.

56. The method of performing hyperthermal therapy according to claim 55, wherein the step of providing comprises the step of flowing the fluid past the antenna.

57. The method of performing hyperthermal therapy according to claim 54, wherein the fluid comprises a conditioning liquid.

58. The method of performing hyperthermal therapy according to claim 54, wherein the fluid comprises a solution of a selective cytotoxicity substance.

59. The method of performing hyperthermal therapy according to claim 54, wherein the catheter includes a balloon.

60. The method of performing hyperthermal therapy according to claim 59, further comprising the step of:

inflating the balloon such that the plurality of temperature sensing devices are deflected by the inflated balloon and contact the wall of the cavity.

61. The method of performing hyperthermal therapy according to claim 60, wherein the inflating step comprises the step of inflating the balloon with a liquid.

62. The method of performing hyperthermal therapy according to claim 60, wherein the inflating step comprises the step of inflating the balloon with a gas.

63. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a volume of the fluid in the cavity.

64. The method of performing hyperthermal therapy according to claim 54, further comprising the step of evacuating gas introduced by the providing step to prevent irradiation non-uniformities.

65. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a temperature of the fluid.



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66. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a flowrate of the fluid.

67. The method of performing hyperthermal therapy according to claim 54, further comprising the step of sensing temperatures at different locations by modifying a location of the temperature sensing devices.

68. The method of performing hyperthermal therapy according to claim 54, further comprising the step of generating therapeutically active radiation using the antenna to achieve a temperature within the cavity lethal for cancer cells.

69. The method of performing hyperthermal therapy according to claim 54, further comprising sensing a temperature at various positions along the antenna with a second plurality of temperature sensing devices.

70. The method of performing hyperthermal therapy according to claim 54, further comprising sensing a temperature at various positions along the antenna and a shielded cable coupled to the antenna with a second plurality of temperature sensing devices.

71. The method of performing hyperthermal therapy according to claim 54, wherein the plurality of temperature sensing devices come into tangential contact with the wall of the cavity.

72. The method of performing hyperthermal therapy according to claim 54, wherein a second plurality of temperature sensing devices come into tangential contact with the wall of the cavity.

73. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a temperature of the wall of the cavity.

74. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a temperature of the antenna.

75. The method of performing hyperthermal therapy according to claim 54, wherein the inserting step comprises inserting the catheter into an organ.

76. The method of performing hyperthermal therapy according to claim 54, wherein the inserting step comprises inserting the catheter into a hollow organ.

77. The method of performing hyperthermal therapy according to claim 54, wherein the inserting step comprises inserting the catheter into a bladder.

78. The method of performing hyperthermal therapy according to claim 54, further comprising the step of protecting the cavity wall from excess heat from the antenna.

79. The method of hyperthermal therapy according to claim 54, further comprising the step of preventing the catheter from being displaced from the cavity.

80. A radiating device for irradiating a cavity comprising:  
a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the cavity;

a first channel adapted to provide a fluid to the cavity;  
a second channel adapted to receive the fluid from the cavity; and

at least one temperature sensing device, having an end, the end of the at least one temperature sensing device extending outward from the catheter after the catheter is inserted into the cavity,

wherein the end of the at least one temperature sensing device is adapted to detect a temperature of a wall of the cavity irradiated by the antenna.

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81. A radiating device for irradiating a cavity comprising:  
a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the cavity;

a first channel adapted to provide a fluid to the cavity;  
a second channel adapted to receive the fluid from the cavity; and

at least one temperature sensing device, having an end, the end of the at least one temperature sensing device extending outward from the catheter after the catheter is inserted into the cavity,

wherein the end of the at least one temperature sensing device is adapted to detect a temperature of the cavity irradiated by the antenna.

82. The radiating device as claimed in claim 81, wherein the at least one temperature sensing device is released from the catheter after the catheter is inserted into the cavity.

83. A radiating device for irradiating an organ comprising:

a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a channel, within the catheter, adapted to provide a fluid comprising a treatment substance to the organ; and

at least one temperature sensing device, having an end, the end of the at least one temperature sensing device extending outwards from the catheter after the catheter is inserted into the organ,

wherein the end of the at least one temperature sensing device is adapted to contact a wall of the organ irradiated by the antenna and wherein the fluid is adapted to be provided to the organ simultaneously with the irradiation of the organ.

84. The radiating device according to claim 83, wherein the treatment substance comprises a cytotoxic substance.

85. A radiating device for irradiating an organ comprising:

a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a first channel, within the catheter, adapted to provide a fluid comprising a cytotoxic substance to the organ;

a second channel, within the catheter, adapted to receive the fluid from the cavity; and

at least one temperature sensing device, having an end, the end of the at least one temperature sensing device extending outward from the catheter after the catheter is inserted into the organ;

wherein the end of the at least one temperature sensing device is adapted to contact a wall of the organ irradiated by the antenna and wherein the fluid is adapted to be provided to the organ simultaneously with the irradiation of the organ.

86. A radiating device for irradiating an organ comprising:

a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a first channel, within the catheter, adapted to provide a fluid comprising a cytotoxic substance to the organ;

a second channel, within the catheter, adapted to receive the fluid from the cavity; and



at least one temperature sensing device, having an end,  
the end of the at least one temperature sensing device  
extending outward after the catheter is inserted into the  
organ,  
wherein the end of the at least one temperature sensing 5  
device is adapted to detect a temperature of the fluid  
and wherein the fluid is adapted to be provided to the  
organ simultaneously with the irradiation of the organ.  
87. A method of performing hyperthermal therapy com-  
prising the steps of:  
inserting a catheter, including an antenna and at least one  
temperature sensing device, into an organ;  
irradiating the organ by generating radiation using the  
antenna;  
providing a supply of a fluid through the catheter and into 10  
the organ;  
extracting the fluid from the organ through the catheter;  
and  
extending the at least one temperature sensing device 20  
adapted to detect a temperature of a wall of the organ.  
88. A method of performing hyperthermal therapy com-  
prising the steps of:  
inserting a catheter, including an antenna and at least one 25  
temperature sensing device, into a cavity;  
irradiating the cavity by generating radiation using the  
antenna;  
providing a supply of a fluid through the catheter and into  
the cavity;  
extracting the fluid from the cavity through the catheter;  
and 30

extending the at least one temperature sensing device  
within the cavity; and  
detecting a temperature of the cavity.  
89. The method as recited in claim 88, wherein  
the detecting step comprises detecting a temperature of  
the fluid.  
90. A method of performing hyperthermal therapy com-  
prising the steps of:  
inserting a catheter, including an antenna and at least one  
temperature sensing device, into an organ;  
irradiating the organ by generating radiation using the  
antenna;  
simultaneously with irradiating, providing a supply of a 15  
fluid comprising a cytotoxic substance through the  
catheter and into the organ; and  
extending the at least one temperature sensing device  
adapted to contact a wall of the organ.  
91. A method of performing hyperthermal therapy com-  
prising the steps of:  
inserting a catheter, including an antenna and at least one  
temperature sensing device, into an organ;  
irradiating the organ by generating radiation using the 25  
antenna;  
simultaneously with irradiating, providing a supply of a  
fluid comprising a cytotoxic substance through the  
catheter and into the organ. 30

\* \* \* \* \*



UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : RE 37,315 E  
DATED : August 7, 2001  
INVENTOR(S) : Lev

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,

Line 57, delete "*liquid*".

Line 60, delete "*the*" and insert --*α*--.

Column 7,

Line 35, delete "*being*" and insert -- *adapted to be* --.

Column 8,

Lines 27 and 54, delete "*for providing*" and insert -- *adapted to provide* --.

Column 9,

Line 33, before "*channel*" insert -- *α* --.

Column 11,

Line 16, after "*antenna*" insert a comma.

Column 12,

Line 25, delete "*tin*" and insert -- *cavity by generating* --.

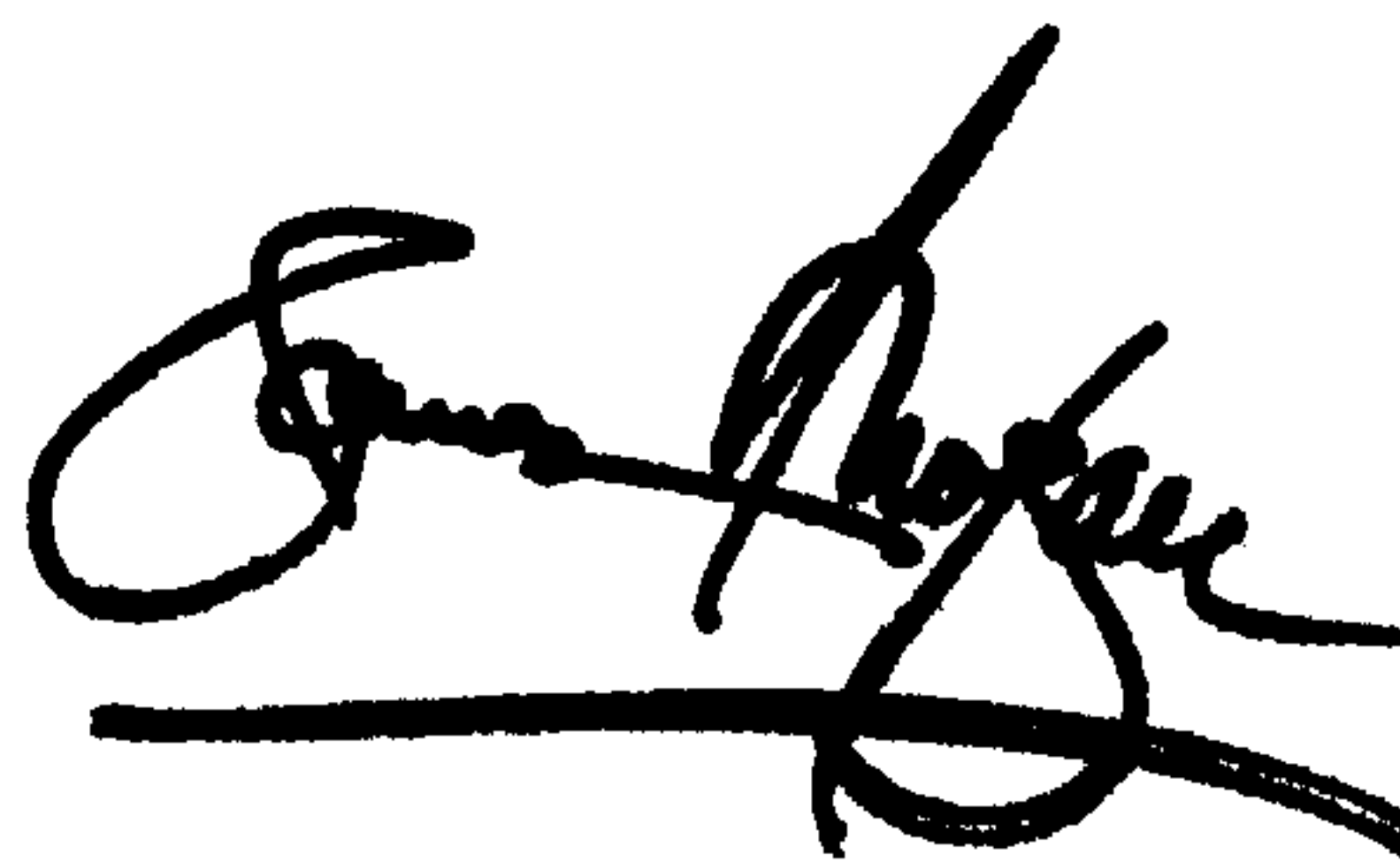
Column 13,

Line 57, delete "Provide" and insert -- *provide* --.

Signed and Sealed this

Eleventh Day of June, 2002

Attest:

A handwritten signature in black ink, appearing to read "James E. Rogan", with a long horizontal stroke underneath.

Attesting Officer

JAMES E. ROGAN  
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : RE 37,315 E  
APPLICATION NO. : 08/889825  
DATED : August 7, 2001  
INVENTOR(S) : Lev

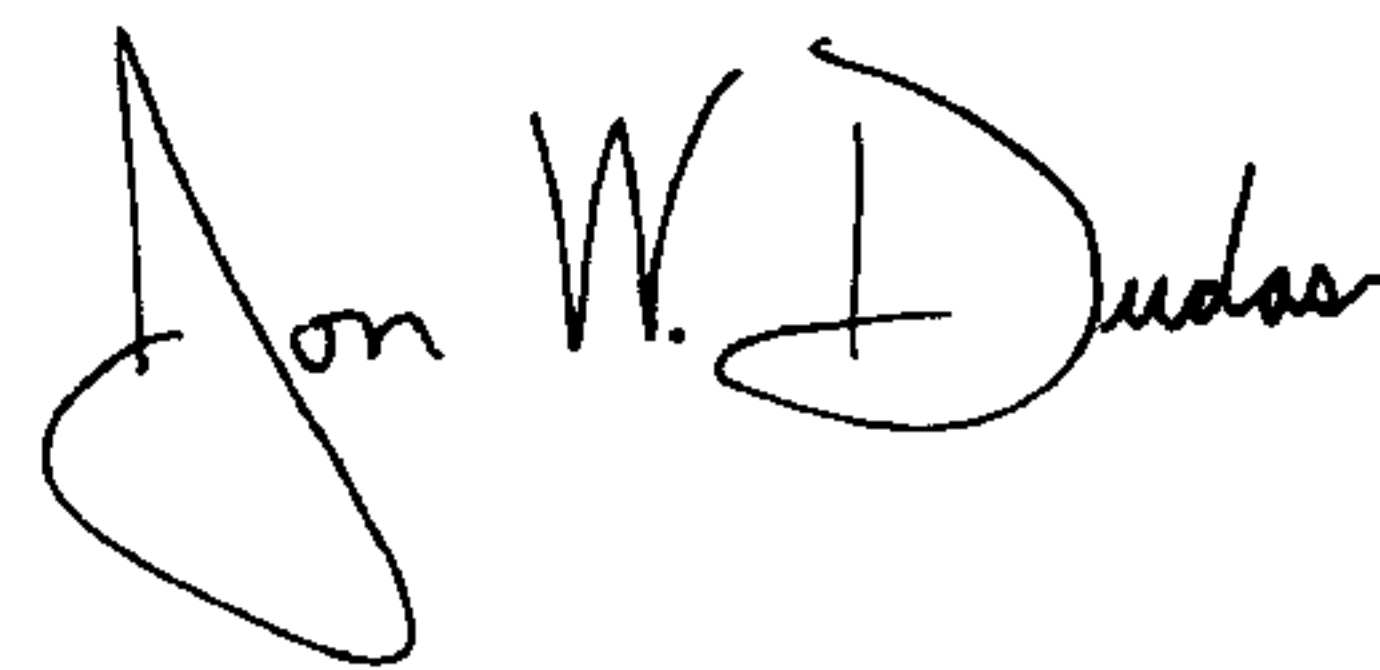
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 6, claim 1, line 57, delete "*liquid*".  
Col. 6, claim 1, line 60, delete "*the*" and insert --*a*--.  
Col. 7, claim 3, line 35, delete "*being*" and insert --*adapted to be*--.  
Col. 8, claim 6, line 27, delete "*for providing*" and insert --*adapted to provide*--.  
Col. 8, claim 8, line 54, delete "*for providing*" and insert --*adapted to provide*--.  
Col. 9, claim 11, line 33, before "*channel*" insert --*a*--.  
Col. 11, claim 28, line 16, after "*antenna*" insert a comma.  
Col. 12, claim 54, line 25, delete "*tin*" and insert --*cavity by generating*--.  
Col. 13, claim 80, line 57, delete "*Providing*" and insert --*providing*--.

Signed and Sealed this

Ninth Day of December, 2008

A handwritten signature in black ink, reading "Jon W. Dudas". The signature is stylized, with a large, looped initial "J" and a cursive "Dudas".

JON W. DUDAS  
*Director of the United States Patent and Trademark Office*