

655262

Section 29

AUSTRALIA
Patents Act 1990

PATENT REQUEST : STANDARD PATENT

The person identified below as the Applicant requests the grant of a patent to the person identified below as the Nominated Person, for an invention described in accompanying standard complete specification.



Applicant: SECTION 113 DIRECTION SEE FOLIO 11
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Invention Title: METHOD AND DEVICE FOR THERMAL ABLATION HAVING
IMPROVED HEAT TRANSFER

Names of Actual
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BASIC CONVENTION APPLICATION DETAILS

Application No	Country	Country Code	Date of Application
07/702,796	United States	US	17 May 1991

DATED this 15th day of May 1992

5029428 15/05/92

INTERVENTIONAL THERMODYNAMICS, INC.
By their Patent Attorney

GRIFFITH HACK & CO

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NOTICE OF ENTITLEMENT

We **INTERVENTIONAL THERMODYNAMICS, INC.**

of **2672 Bayshore Parkway, Suite 700, Mountain View, California 94043, U.S.A.**

being the Applicant and Nominated Person, in respect of Application No. 16346/92,
entitled **METHOD AND DEVICE FOR THERMAL ABLATION HAVING IMPROVED HEAT
TRANSFER** state the following:

Convention priority is claimed from the following basic application(s):

Basic Applicant	Application Number	Application Date	Country	Country Code
Colin J Nichols William R Dubrul Robert S Behl	07/702,796	17 May 1991	U.S.A.	US

Colin J NICHOLS; William R DUBRUL and Robert S BEHL are the actual inventors of the
invention.

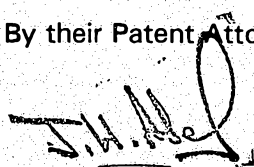
The nominated person is the assignee of the invention from the inventors.

The basic application was the first application made in a Convention country in respect
of the invention the subject of this request.

DATED this 31st day of August 1992

INTERVENTIONAL THERMODYNAMICS, INC.

By their Patent Attorney



GRIFFITH HACK & CO

AU-B-16346/92

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METHOD AND DEVICE FOR THERMAL ABLATION HAVING IMPROVED HEAT TRANSFER

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(56) Prior Art Documents
US 4160455
US 4946440
US 5159925

(57) Claim

1. A thermal ablation system comprising:

a catheter including an elongate member having proximal and distal ends and a lumen for fluid flow, and a resistive heating element mounted on an exterior surface at the distal end of the elongate member, the resistive heating element and/or the exterior surface at the distal end being adapted such as to define a fluid circulation region between the exterior surface and the resistive heating element and allow aspiration and expiration of a thermally conductive medium past the resistive heating element through the fluid circulation region into/from the lumen;

a power supply connected to the resistive heating element; and

means for inducing an oscillatory flow of the thermally conductive medium in the circulation region and past the resistive heating element.

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ORIGINAL
COMPLETE SPECIFICATION
STANDARD PATENT

Invention Title:

METHOD AND DEVICE FOR THERMAL
ABLATION HAVING IMPROVED HEAT
TRANSFER

The following statement is a full description of this invention, including
the best method of performing it known to me/us:

GH&CO REF: 22294-B:RPW:MS



methods and apparatus for the thermal ablation of hollow body organs, such as the gallbladder. In particular, the present invention relates to a method and apparatus for inducing an oscillating flow of a heat transfer fluid past a heating element of a catheter structure to enhance heat transfer to and temperature uniformity throughout the transfer medium.

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In recent years, a variety of "minimally invasive" surgical procedures has been developed as alternatives to conventional "open" surgery. While minimally invasive surgical procedures have no fixed definition, they are generally characterized by use of specialized surgical tools in combination with visual or radiographic imaging techniques. The specialized tool is generally inserted through an open body orifice or a small surgical incision, and the tool is then positioned within the body using the imaging technique to allow manipulation of the organ or structure to be treated. A common example of least-invasive surgery is arthroscopic knee surgery, where penetration of the surgical tools is minimal. Less-accessible body organs, such as the heart and interior blood vessels, may be reached by specialized catheters which may be routed through the vascular system over relatively long distances. Exemplary of such vascular catheters are balloon dilatation catheters which are used to expand regions of stenosis within diseased blood vessels.

Of particular interest to the present invention are least-invasive surgical techniques which rely on a catheter to deliver heat to the interior of a hollow body

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organ. As described in detail in US Patents 5,045,056, 5,100,388 and 5,188,602, the delivery of heat may be used for deactivating or ablating

a diseased body organ, such as a gallbladder, appendix, uterus, kidney, or the like, as well as for blocking other body lumens, such as blood vessels. In each case, the heat is usually delivered by conduction through a thermal conduction medium from a heating element disposed in the organ or blood vessel. The heat destroys the mucosa or endothelial lining of the organ or vessel, resulting eventually in deactivation and eventual resorption of the organ or vessel.

U.S. Patent No. 4,160,455, describes a bidirectional pump and unidirectional valve means for circulating a fluid through a housing containing a heating element. The entire housing is placed within a body cavity for effecting heat treatment of tumors. The device relies on forming a single high-speed outlet jet to agitate the fluid content of the organ. U.S. Patent No. 4,979,948, describes a device having a radio frequency balloon electrode at its distal end for thermally destroying the mucosal layer of a body organ, such as the gallbladder. U.S. Patent Nos. 4,655,744; 4,723,941; 4,755,167; 4,758,596; 4,793,776; and Australian published application A-71786/87, describe improved methods for performing chemical cholecystectomy where a stone dissolving agent is oscillated in and out of a body area.

Coleman, *Non-Surgical Ablation of the Gallbladder*, Proc. 1988 SCVIR, pp 214-219, is a review article discussing various techniques for non-surgical

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externally heated medium to induce fibrosis of the gallbladder. The article further presents data demonstrating thermal ablation of a dog's gallbladder after open surgical injection of hot contrast media. The work of Salomonowitz is described in Salomonowitz et al. (1984) Arch. Surg. 119:725-729. The work of Getrajdman is described in Getrajdman et al. (1985) Invest. Radiol. 20:393-398 and Getrajdman et al. (1986) Invest. Radiol. 21:400-403. The use of sclerosing agents to induce gallbladder fibrosis is described in Remley et al. (1986) Invest. Radiol. 21:396-399. See also Becker et al. (1988) Radiology 167:63-68; Becker et al. (1989) Radiology 171:235-240; and Becker et al. (1989) Work in Progress Paper #1354, RSNA Meeting, November 1989. U.S. Patent No. 4,160,455, describes a device for internally heating a body cavity for therapy, where the heat is intended to inhibit the growth of tumor cells. German Patent 37 25 691 describes a catheter combining a heater at its distal tip and a balloon proximate the heater, where the heater is not directly exposed to the fluid environment surrounding the catheter tip. U.S. Patent No. 4,869,248, describes a thermal ablation catheter having a resistive heating loop at its distal end. Other patent documents describing heated or cooled catheters include U.S. Patent Nos. 4,676,258; 4,638,436; 4,469,103; 4,375,220; 3,901,224; USSR 1329-781-A; and USSR 281489.

The use of catheters having heating elements to deliver heat within a hollow body organ can be problematic in certain respects. First, heat distribution through the thermally conductive medium can be non-uniform, requiring an increase in the total amount of heat delivered in order to assure that the temperature of all portions of the mucosa are raised above the threshold level necessary to induce injury and necrosis. Such an increase in heat delivery, however, may raise the



temperature of the other portions of the mucosa above a desired maximum. Such excessive heating can result in injury to adjacent body organs. A related difficulty arises from the limited heat transfer capacity of the thermally-conductive medium. In order to deliver sufficient heat to remote portions of the mucosal wall, it may be necessary to raise the surface temperature of the heating element above a desired maximum. Excessively hot heating surfaces can result in fouling of the heating element as a result of coagulation and denaturing of blood and other proteins present. Such fouling, of course, further reduces the heat transfer capacity of the heating element.

For these reasons, it would be desirable to provide improved methods and apparatus for delivering heat to the interior of hollow body organs. It would be particularly desirable to provide thermal ablation catheters having improved heat transfer characteristics so that the surface temperature of a heating element can be maintained below a desired maximum level, typically being below about 100°C, preferably being below about 90°C. The methods and apparatus should further provide for improved uniformity of heat distribution throughout the thermally conductive medium used to transfer heat from the catheter to the mucosal lining of the hollow body organ. Such improved heat transfer should even further reduce the surface temperature of the heating element as well as reducing the total amount of heat delivered to the body organ. The reduction in total heat will reduce the likelihood of unintentionally injuring adjacent body organs. The catheters of the present invention should have few or no moving parts and should be simple and reliable in design.

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Accordingly, the present invention provides for an apparatus and method for thermally ablating a hollow body organ, such as a gallbladder, uterus, appendix, kidney, and the like.

5 More specifically, the present invention provides in one aspect thereof a thermal ablation system comprising:

a catheter including an elongate member having proximal and distal ends and a lumen for fluid flow, and a resistive heating element mounted on an exterior
10 surface at the distal end of the elongate member, the resistive heating element and/or the exterior surface at the distal end being adapted such as to define a fluid circulation region between the exterior surface and the resistive heating element and allow aspiration and
15 expiration of a thermally conductive medium past the resistive heating element through the fluid circulation region into/from the lumen;

a power supply connected to the resistive heating element; and
20 means for inducing an oscillatory flow of the thermally conductive medium in the circulation region and past the resistive heating element.

The heating element of the catheter is mounted on the outside at the distal end of the elongate member such
25 as to leave circulation regions in between the heating element and the opposite outside surface of the elongate member; this arrangement can thus also be described in that the heating element is suspended away from the outside surface. Means are provided for distributing a
30 heat transfer from the lumen to the circulation region defined between the heating element and the surface (and extending into the space between adjacent turns of a coiled heating element as described hereinafter). In this way, heat transfer to the medium is improved as the
35 fluid is introduced through the catheter. Heat transfer and uniform temperature distribution is enhanced by



providing the means for inducing oscillatory flow of heat transfer fluid through the heating element during a portion of or all of the thermal ablation procedure.

5 In a preferred aspect, the heating element of the catheter is a coil wrapped over three or more axial ribs formed at the distal end of the elongate member. The individual windings of the coil are usually spaced-apart, preferably by from 0.5 to 2 diameters, in order to permit flow of heat transfer fluid therethrough. Other heating
10 element designs, such as perforate electrodes, meshes, or the like, would also be possible.

Optionally, the system may further include an introducer sheath having an expandable cage at its distal end, where the cage may be expanded within the hollow
15 body organ to open its interior to permit optimal positioning of the heating element of the catheter. For example, the introducer sheath may position the heating element substantially at the center of the hollow body organ in order to enhance uniform temperature
20 distribution to all portions of the mucosal lining.

According to a second aspect of the invention there is provided a method for ablating a hollow body organ, said method comprising:

percutaneously introducing a catheter into the
25 interior of the hollow body organ, the catheter having a resistive heating element and fluid distributing means at its distal end, the resistive heating element being arranged such as to be directly exposed to fluid within the organ;

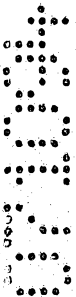
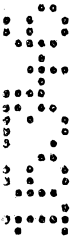
30 introducing a thermally conductive medium into the hollow body organ through the fluid distributing means so that the medium is unconstrained and in direct thermal contact with the interior wall of the organ;

heating the thermally conductive medium within the
35 hollow body organ using the resistive heating element; and



inducing an oscillatory flow of the thermally
conductive medium through the fluid distributing means to
effect mixing of the thermally conductive medium thereby
enhancing uniformity of temperature distribution in the
5 medium, and to induce the thermally conductive medium to
reciprocatingly flow past the resistive heating element
thereby increasing heat flux to the body organ.

Optionally, the catheter is introduced so that the
heating element is within the interior of the hollow body
10 organ using an introducer sheath having an



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expandable cage as described above. The thermally conductive medium is then introduced through the catheter so that it is unconstricted as it enters the hollow body organ. The thermally conductive medium is heated by inducing an oscillatory flow through the circulation region and heater of the catheter. The oscillatory flow comprises alternately aspirating and expelling relatively small volumes of the thermally conductive medium through the catheter, typically in the range from about 0.1 ml to 3 ml. The oscillation will typically be performed at from about 0.1 Hz to 5 Hz with the temperature of the bulk medium being maintained in the range from about 50°C to 60°C. The surface temperature of the heating element will usually be between about 70°C and 90°C, with the minimum differential temperature between the element and medium being possible because of both the element design and oscillatory flow.

The present invention therefore provides the combined advantages of a catheter construction allowing improved heat transfer and a catheter system and method having improved mixing of the thermally conductive medium to enhance both heat transfer and uniformity of temperature distribution. In this way, the surface temperature of the heating element can be reduced while maintaining a desired heat flux to the mucosal or other lining of the hollow body organ. In addition, because of the uniform temperature distribution, the total amount of heat flux delivered to the hollow body organ can be reduced. This is desirable since it reduces the risk of injury to adjacent body organs.



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The subject matter of the present application is related to that of US Patents 5,045,056, 5,100,388 and 5,188,602, assigned to the assignee of the present application, the disclosures of which are incorporated
5 herein by reference.

The above advantages and other features of the invention will be more fully appreciated and understood from the ensuing description of preferred embodiments of the present invention which is provided with reference to
10 the accompanying drawings in which:



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Fig. 1 is a perspective view of a thermal ablation catheter constructed in accordance with the principles of the present invention.

5 Fig. 2 is a cross-sectional view taken along 2-2 of Fig. 1.

Fig. 3 is a cross-sectional view taken along line 3-3 of Fig. 1.

Fig. 4 is a detailed elevational view of the distal end of the catheter of Fig. 1.

10 Figs. 5 and 6 illustrate alternate cross-sections which would be useful in the construction of catheters according to the present invention.

Fig. 7 illustrates an introducer sheath having an expandable cage at its distal end which is useful for
15 introducing the thermal ablation catheter of the present invention, shown with its expandable cage in a collapsed configuration.

Fig. 8 illustrates the introducer sheath of Fig. 7, with its expandable cage in its expanded
20 configuration.

Fig. 9 illustrates the introducer sheath of Fig. 8, shown with the thermal ablation catheter present therein.

Fig. 10 illustrates a system for connecting and
25 operating a preferred thermal ablation catheter according to the present invention.

According to the present invention, apparatus and methods are provided for heating the interior of a wide variety of hollow body organs, cavities, ducts, and
30 passages, particularly including those which have an endothelial lining, mucous membrane, or other internal surface which may be thermally injured to inactivate the organ and usually to induce necrosis and subsequent fibrosis of the organ itself. Alternatively, the present
35 invention may be used to provide thermal therapy where the temperature of the surrounding tissue is raised, particularly in the treatment of solid tumours and other neoplastic diseases. Exemplary hollow body organs and



cavities include the gallbladder, the appendix, the uterus, the kidney, and the like. Exemplary hollow body passages and ducts include blood vessels, fistulas, and the like. When the intent is to inactivate, the hollow body organ will usually be diseased or in some way abnormal prior to treatment according to the present invention. When the desire is to thermally treat surrounding tissue, an organ or passage may serve merely as an access route. In other cases, it may be desirable to ablate and destroy apparently healthy body organs or parts in order to achieve a desired purpose, e.g., blockage of a blood vessel in a varicocele procedure. For convenience hereinafter, the phrase "hollow body organ" is intended to embrace hollow body organs, hollow body passages and hollow body cavities.

The catheter of the present invention comprises an elongate member having proximal and distal ends. The elongate member may be flexible or rigid, although flexible catheters are preferred for most applications. The length of the catheter will vary depending on the application, typically being from about 10cm to 100cm, usually from about 10cm to 50cm, and more usually from about 10cm to 30cm, although longer structures will usually be provided for intravascular applications.

Rigid elongate members may be formed from metals, typically stainless steel, rigid plastics, and the like, while flexible elongate members will typically be formed from extruded organic polymers, such as silicone rubber, polyurethane, polyvinyl chloride, nylon, and the like.

Elongate members will typically include a multiplicity of lumens to provide for fluid communication between the proximal end (which remains outside the patient) to the distal end (present inside the patient during treatment). Normally, a lumen will be provided for delivering and aspirating the thermally conductive medium to the hollow body organ. Additional lumens may

be provided for delivery of the catheter over a movable guide wire, for venting the hollow body organ while the thermally conductive medium is being delivered, for electrical power and signal connections, and the like.

5 A heating means for raising the temperature of the fluid environment surrounding the distal end of the catheter will be provided at or near the distal tip of the elongate member typically being within about 10 cm of the tip, more typically being within about 5 cm. The
10 heating means will provide a heated surface for heating fluid surrounding the catheter tip, usually including a resistive heater element. Preferably, the heated surface of the heating means will be exposed directly to the environment surrounding the catheter, with little or no
15 insulation covering the surface, in order to enhance heat transfer. The heating means will be directly exposed to its surrounding environment and will not be enclosed in a housing or other structure which substantially impedes direct heat exchange with surrounding fluid in the body
20 organ.

The heated surface will be located over an extended axial length at or near the distal tip of the elongated member. The length will usually be from about 1 cm to 8 cm, more usually being about 2 cm to 6 cm, and
25 most usually being about 1.5 to 4 cm. The heated surface will be suspended over or spaced-apart from the exterior surface of the elongate member to define a circulation region therebetween. As described hereinafter, the thermally conductive fluid will usually be passed from
30 the central lumen into the circulation region to enhance heating thereof. In particular, by suspending the heating element, additional heating surface of the element is exposed to the thermally conductive medium as it is distributed from the catheter.

35 The heating element will be a permeable or perforate structure in order to increase the total surface area to enhance heat transfer. For example, a

cylindrical mesh or other perforate cylindrical structure may find use as a heating element, where the thermally conductive fluid can pass through the interstices or apertures of the structure.

5 A preferred heating element is a coiled structure where an elongate heating element, e.g., a wire, is wrapped in a helix about a supporting structure at the distal end of the elongate member. Successive turns of the helical coil are spaced-apart to permit flow
10 of the thermally conductive medium therethrough and to minimize the thermal effect of adjacent turns on each other. By suspending the heating element away from the elongate member, the exposed surface area of the heating element is maximized, with only the suspension points
15 being blocked. Usually, the heating element will be a resistance heating wire having a diameter in the range from about 0.05 mm to 0.25 mm, usually from about 0.1 mm to 0.15 mm, where spacing between successive windings of the coil are from about 0.5 to 2 diameters. The number
20 of turns in the heating element may vary, typically being from about 3 to 8 turns/mm, more typically being from about 4.5 to 5.5 turns/mm, depending in part on the total length which is to be covered, the linear electrical resistance of the wire, and the desired heat transfer rate.

25 The means for suspending the heating element from the surface of the elongate member may take a variety of forms. For example, it would be possible to form a plurality of discrete support posts on the surface
30 of the elongate member. Alternatively, the coil heating element could be shaped so that it defines integral support posts in its own structure. Preferably, the suspension means will comprise a plurality of axial ribs formed in the elongate member itself. At least three
35 ribs will be employed, with troughs between adjacent ribs defining the circulation region between the heater and the elongate member. The use of ribs is preferred since

they are relatively easy to fabricate, e.g., by extrusion or other techniques.

5 The thermally conductive medium is introduced through a lumen which extends from the proximal end to distal end of the elongate member. The lumen will open into a plurality of distribution ports at the distal end of the elongate member which permits flow of the thermally conductive medium into and through the recirculation region between the member and the heating
10 element. In this way, heat transfer between the medium being introduced and the heating element can be maximized.

15 The catheter of the present invention will frequently be employed as part of a thermal ablation system comprising, in addition to the catheter, a power supply connected to the heater and a means for inducing an oscillatory flow of thermally conductive medium past the resistive heating element. The power supply will typically include means for controlling the temperature to which the thermally conductive medium is heated by the
20 heating means. Such a temperature control system may comprise a feedback controller where a temperature sensing element (typically one or more thermocouples or thermistors) is mounted on the catheter and/or an
25 associated introducer sheath (as described in more detail hereinbelow) at a location chosen to accurately measure the heated environment surrounding the catheter, and the energy delivered to the heating means is regulated based on the measured temperature of the medium. Preferably,
30 the temperature control system will include temperature sensing element(s) mounted on an expandable cage at the distal end of the introducer sheath. Such element(s) will be in close proximity to the wall of the organ or duct which is being treated, where the temperature is
35 most critical.

The means for inducing an oscillatory flow of thermally conductive medium will typically include a

syringe or other pump mechanism which can be connected to the medium introduction lumen in the catheter. Thus by driving the syringe or pump with a preselected stroke and frequency, a desired volume of the thermally conductive medium can be caused to alternately be aspirated and expelled by the catheter. In this way, heat transfer and uniform heat distribution of the system can be enhanced.

The thermal ablation system optionally includes the introducer sheath having an expandable structure or cage near its distal end. The introducer sheath will be used to introduce the thermal ablation catheter and to expand the portion of the hollow body organ in which the heating element of the catheter is positioned. The expanded cage can thus both protect the organ wall from direct contact with the heating element and position the heating element near the center of the organ so that heat is uniformly distributed to all portions of the organ.

The cage structure on the introducer sheath preferably comprises a plurality of axially aligned fingers which can be introduced in a collapsed configuration and expanded within the hollow body organ or duct in order to provide the desired expanded cage structure. Such a cage, of course, will be substantially open so that the inner wall of the organ or duct will be completely exposed to the thermally conductive medium which is being heated by the catheter. The fingers may be spring-loaded to open when they are released within the body organ or duct, or a separate means may be provided for mechanically causing the opening. Other designs, such as the use of heat memory alloys, may also find use. Regardless of the particular construction, it will be particularly preferred to provide one or more temperature sensing elements on at least some of the finger elements which form the expandable cage. Desirably, the temperature sensing elements will be located at the point(s) of maximum radial expansion on the cage. In this way, the temperature sensing elements

will be located immediately adjacent to the inner wall of the hollow body organ during the thermal treatment procedure and will thus be able to accurately measure the localized temperature at the point of thermal impact.

5 The method of the present invention relies on introducing the thermally conductive medium into the interior of the hollow body organ in such a way that the organ is filled with the medium and the medium is in good thermal contact with substantially the entire interior
10 surface of the organ. The heating element then transfers heat directly to the thermally conductive medium which in turn transfers the heat to the organ wall by convection. In this way, by heating the medium as will be described hereinafter, the temperature of the endothelial lining or
15 mucous membrane of the body organ can be raised to a preselected temperature for a preselected minimum time period in order to permanently injure the lining and deactivate the organ, typically by inducing necrosis. The thermally conductive medium can be virtually any
20 physiologically-compatible liquid, solution, slurry, gel, or the like, which can be percutaneously or directly introduced into the interior of the hollow body organ. Exemplary thermally conductive media include water, normal saline, contrast media, physiological irrigating
25 solution, and the like.

 As used herein, the term "ablation" means any injury or damage to the hollow body organ and/or connecting ducts and body passages which results in deactivation of the function of the organ, usually
30 resulting in necrosis and eventual resorption of the organ. The resorption will typically occur over an extended period of weeks, months, or longer.

 The thermally conductive medium will usually be introduced to the interior of the hollow body organ at a
35 temperature below that which will have a deleterious effect on the tissue and organs surrounding the hollow body organ being treated. The temperature will be below

about 45°C, and more usually being at body temperature (37°C) or room temperature (about 20°C). In some cases, however, it may be desirable to introduce the contrast medium above body temperature, usually in the range from about 37°C to 45°C, in order to shorten the time necessary to raise the temperature of the medium to the treatment temperature, discussed hereinafter.

In order to induce necrosis of the endothelial lining or mucous membrane of the hollow body organ, the temperature of the thermally conductive medium will be raised and maintained above a threshold level which results in injury to the endothelial mucous or membrane. The threshold temperature will generally be above 45°C, usually being in the range from 45°C to 70°C, more usually being in the range from 50°C to 65°C, and preferably being in the range from about 53°C to 60°C. Depending on the precise temperature employed and on the nature of the particular organ being treated, the thermally conductive medium will be maintained above the threshold temperature for a period of time in the range from about 1 to 60 minutes, usually being in the range from about 5 to 40 minutes, and preferably being in the range from about 15 to 35 minutes. Usually, the temperature of the thermally conductive medium will be raised as rapidly as possible and maintained at a substantially constant treatment temperature for the desired treatment period. Alternatively, the treatment temperature may vary or be varied during the treatment period with the total treatment time being adjusted to take the variation in temperature into account.

After the thermally conductive medium has been introduced and heat transfer initiated through the heating element, the method of the present invention relies on alternately aspirating and expelling incremental volumes of the medium through the catheter. Such an oscillatory flow has been found to significantly enhance temperature uniformity (through mixing of the

medium) as well as heat transfer (through continuous reversing flow of medium through and past the heating element). Both the enhanced temperature uniformity and the increased heat transfer rate allow the thermal ablation procedures to reduce the total amount of heat delivered to the organ as well as the temperature of the heating surfaces required to deliver that amount of heat.

The volume which is aspirated will usually be substantially the same as the volume which is expelled. Typically, the aspirated and expelled volumes will be in the range from about 0.1 ml to 3 ml, more usually being from about 0.75 ml to 1.5 ml, and the frequency of oscillation will be in the range from about 0.1 Hz to 5 Hz, typically being in the range from about 0.1 Hz to 1 Hz.

After the hollow body organ has been treated with the heated thermally conductive medium at a temperature and for a time sufficient to deactivate the body organ and/or induce necrosis of the endothelial lining or mucous membrane of the organ, the thermal energy being delivered to the medium will be terminated. The thermally conductive medium may then be aspirated from the hollow body organ, typically using the same catheter which was employed to deliver the medium and raise the temperature of the medium as described above. Usually, however, the thermally conductive medium will not be aspirated until the temperature has decreased sufficiently so that its withdrawal will not expose tissues and organs surrounding the catheter to risk. Normally the withdrawal temperature will be below about 45°C, preferably being below about 40°C. Alternatively, the thermally conductive medium can be left within the hollow body organ where it will be resorbed or eliminated by normal physiological processes.

Referring now to Figs. 1-4, the construction of a catheter 10 constructed in accordance with the principles of the present invention will be described.

The catheter 10 includes an elongate element or body 12 having a proximal end 14 and a distal end 16. The catheter body 12 has a cross-sectional profile including three rib elements 18 separated by three trough regions 20. The elongate body 12 further includes four lumens 22, 24, 26, and 28 extending generally from the proximal end 14 to or close to the distal end 16.

The elongate catheter body 12, as illustrated, is shown to be flexible along substantially its entire length. Optionally, portions of the catheter body 12 may be constructed from rigid or semi-rigid materials, for a desired purpose. For example, it may be necessary or desirable to provide a rigid supporting member for the heater having higher or different heat transfer characteristics than the rest of the elongate catheter body. Metals or other heat conductive materials might find use in such designs. Other reasons for departing from the generally flexible nature of the catheter body 12 may occur to those skilled in the art while remaining within the scope of the present invention.

A pair of temperature sensor leads 30 enter the first lumen 22 near the ^{proximal}~~distal~~ end 14 of the catheter body 12 and terminate at external temperature sensors 32 at the distal end 16. Of course, the temperature sensor leads 30 will not be necessary when temperature sensing elements are provided only on the expandable cage of the introducer sheath, as described in more detail hereinafter. Similarly, a first power lead 34 enters lumen 24 at the ^{proximal}~~distal~~ end of the catheter while a second power lead 36 enters lumen 26 at the ^{proximal}~~distal~~ end of the catheter. The power leads 34 and 36 are connected to a heating coil 40 wrapped about and extended axial length near the distal tip of the catheter 10. When not employed for temperature sensor leads, lumen 22 may be used as an auxiliary perfusion and/or aspiration lumen.

Central lumen 28 is connected to a plurality of radial apertures 42 which open into the three trough



regions 20 which are located beneath the heating coil 40. In this way, the thermally conductive medium can be introduced through a connector 46 at the proximal end of the catheter 10 and in turn be distributed through the various radial apertures 42 which open into a circulation region defined by the trough regions 20 of the catheter body 12. Central lumen 28 terminates in a port 29 located at the distal tip of the catheter body 12. Usually, the diameter of the port 29 will be smaller than that of the lumen 28 so that there will be a close fit about the center wire (not illustrated) which is used for introducing the catheter 10. Such a close fit inhibits flow of the thermally conductive medium through the port 29, which flow is generally undesirable since it bypasses the heating element 40. Flow through the port 29, however, does contribute to the mixing capability of the catheter 10 and to a limited extent may be acceptable or desirable.

Referring now in particular to Fig. 3, the heating coil 40 is wrapped around the catheter body 10 so that it is suspended on the axial ribs 18. Portions of the heating coil 40 which are between the axial ribs 18 are thus completely exposed to the surrounding environment. In particular, the wires are exposed to the thermally conductive medium as it is released or expelled through the axial apertures 42 as well as when it is aspirated back into the catheter through said apertures. Heat transfer or flux from the heating coil 40 will be a compromise between maximizing the total wire length and providing sufficient spacing between adjacent turns of the wire to increase exposure and permit free flow of thermally conductive medium therethrough. That is, the total wire length (which increases the total surface area of the wire) is increased by having a higher number of turns on the catheter. Too high a turn density, however, limits both the effective exposed area of each turn and limits the flow of thermally conductive medium through

the coil 40. An optimum compromise heat transfer can be achieved when the spacing s (Fig. 4) between adjacent turns of the coil 40 is equal to from about 0.5 to 2 times the wire diameter d . For catheters having diameters in the range from about 1.5 mm to 3 mm, the wire diameter will usually be in the range from about 0.05 mm to 0.75 mm, with the spacing between adjacent turns of the coil being from about 0.025 mm to 0.25 mm.

Referring now to Figs. 5 and 6, alternate catheter body cross sections having different numbers of axial ribs are illustrated. The number of axial ribs is not critical, but it will be appreciated that at least three ribs will usually be required.

Referring now to Fig. 7, an introducer sheath 50 useful for inserting the thermal ablation catheter 10 into a variety of hollow body organs, such as the gallbladder, will be illustrated. The introducer sheath 50 includes an outer sheath member 52 and an inner sheath member 54. The inner sheath member 54 includes an expandable cage 56 at its distal end and a centering wire 58 extending throughout its length. The outer sheath 52 and inner sheath 54 will be configured as nested tubes which are capable of sliding relative to each other. The tubes may be rigid or flexible, usually being flexible to facilitate introduction through relatively tortuous paths.

The cage 56 includes a plurality of resilient fingers 57 (only two are illustrated) which are constrained in a collapsed configuration within the distal end of outer sheath member 52. Usually, although not necessarily, the individual fingers 57 will be connected together at their distal ends so that, when released from the outer sheath 52, they will spring into the expanded configuration illustrated in Fig. 8. It would also be possible to leave the individual fingers 57 unconnected at their distal end so that they remain free to expand away from each other. The cage 56 may also be

configured so that it is expanded by pulling proximally on the centering wire 58 to axially compress the cage, forcing its radial expansion. A variety of other specific designs will be apparent to those skilled in the art. It is critical only that the cage 56 be expandable within the target body organ and that, when expanded, it cover or block a minimum area of the inner surface of the body organ.

The introducer sheath 50 will be inserted into a hollow body organ, typically through adjacent passages and ducts in a conventional manner, with the expandable cage 56 in a collapsed configuration held within the outer sheath 52. Once the introducer sheath is in position, the outer sheath member 52 will be retracted rearwardly so that the cage 56 is freed to assume its expanded configuration, as illustrated in Fig. 8. Usually, a seal member 60 will be provided to seal against the outer sheath member.

Temperature sensors 61 may be disposed on at least some of the fingers 57 of the expandable cage 56. Preferably, at least two fingers 57 will include at least one temperature sensor 61. More preferably, at least one sensor will be located at the point of maximum expansion as illustrated for sensors 61 in Figs. 8 and 9. In this way, the temperature sensors 61 will be located immediately adjacent to the endothelium or mucosa of the hollow body organ during treatment.

Once in position with the cage 56 expanded, the thermal ablation catheter 10 can be introduced over the centering wire 58 so that the heating element 40 is positioned within the expanded cage 56. In this way, the heating element 40 can be optimally positioned within the hollow body organ and direct contact between the heating element and the interior surfaces of the organ prevented. Usually, a second seal 62 will be provided on the catheter 10 in order to seal against the proximal end of the inner sheath 54.

Referring now to Fig. 10, a system for connecting and operating the thermal ablation catheter 10 is illustrated. The system includes a power supply and controller 70 which is connected to the sensor leads 30 and power leads 34 and 36. The power supply and controller may be connected to a mechanical actuator 72 which drives a syringe assembly 74 to create a reciprocating pump mechanism. Alternatively, the mechanical drive may be separately actuated and controlled. The syringe 74, in turn, is connected to a three-way valve 76 which permits the introduction of the thermally conductive medium into connecting tube 78. Connecting tube 78, in turn, is connected to the hub connector 46 on the thermal ablation catheter 10. In this way, after filling the hollow body organ with thermally conductive fluid, the valve 76 can be switched to connect the syringe mechanism 74 and the desired oscillating flow of medium induced by starting the actuator 72. The desired volume, frequency, and the like, can be controlled through the power supply and control system 70 or by independent controls within the actuator 72 itself.

The power to the heating coil 40 will be controlled to achieve a desired temperature, based on the temperature sensors 32 and/or 61. Usually, the fluid temperature will be in the range from about 53°C to 60°C.

The catheter 10 may be introduced to a hollow body organ, such as the gallbladder, by techniques described in ^{US patents 5,045,056, 5,100,388 and 5,188,602,} ~~copending application nos. 07/407,859, 07/529,077, and 07/551,971,~~ the disclosures of which have previously been incorporated herein by reference.

For thermal ablation of the gallbladder, the optimum temperature of the medium will be from about 53°C to 60°C (usually corresponding to a heating element surface temperature of from about 70°C to 90°C), the optimum oscillation frequency will be from about 0.1 Hz to 5 Hz the oscillation volume from about 0.1 ml to 3 ml,



and the total treatment time from about 15 minutes to 45 minutes.

Although the foregoing invention has been described in detail for purposes of clarity of understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claims.

1. A thermal ablation system comprising:

5 a catheter including an elongate member having proximal and distal ends and a lumen for fluid flow, and a resistive heating element mounted on an exterior surface at the distal end of the elongate member, the resistive heating element and/or the exterior surface at the distal end being adapted such as to define a fluid circulation region between the exterior surface and the resistive heating element and allow aspiration and expiration of a thermally conductive medium past the resistive heating element through the fluid circulation region into/from the lumen;

10 a power supply connected to the resistive heating element; and

means for inducing an oscillatory flow of the thermally conductive medium in the circulation region and past the resistive heating element.

20 2. A thermal ablation system as in claim 1, further comprising:

an introducer sheath having a proximal end, a distal end, and an expandable cage at its distal end, the sheath being disposed over the catheter so that the expandable cage is arranged over the resistive heating element.

25 3. A thermal ablation system as in claim 2, further comprising at least one temperature sensing element on the expandable cage.

30 4. A thermal ablation system as in claim 2, wherein the temperature sensing element is at a point of maximum radial expansion on the expandable cage.



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5 6. A thermal ablation system as in any one of claims 1 to 5, wherein the means for inducing an oscillatory flow includes:

the lumen extending from the proximal end to the distal end of the elongate member;

10 an oscillatory pump connected to the proximal end of the lumen; and

a plurality of ports in the elongate member opening from the lumen into the circulation region between the exterior surface of the elongate member and the resistive heating element.

15 7. A thermal ablation system as in claim 6, wherein the oscillatory pump is a syringe connected to the lumen of the elongate member.

20 8. A thermal ablation system as in any one of claims 1 to 7, wherein the resistive heating element comprises a coil having spaced-apart windings and the catheter further includes means for suspending the coil away from the exterior surface of the elongate member to form the circulation region between the exterior surface and the coil.

25 9. A thermal ablation system as in claim 8, wherein the means for suspending the coil comprises three or more axial ribs formed along the distal end of the elongate member with trough regions between adjacent ribs defining the circulation regions.

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11. A thermal ablation system as in any one of claims 7
5 to 10, wherein the resistive heating element is a coiled
wire having a diameter in the range from about 0.05 mm to
0.25 mm, wherein adjacent windings of the coil are
spaced-apart by from 0.5 to 2 wire diameters to permit
10 free flow of the heat transfer fluid through the heating
element.

12. A thermal ablation system as in any one of claims 1
to 11, wherein the catheter further comprises a thermally
conductive supporting member disposed on the distal end
of the elongate member beneath the resistive heating
15 element.

13. A thermal ablation system as in any one of claims 2
to 12, further comprising means for expanding the cage
structure.

14. A thermal ablation system as in claim 12, wherein
20 the means for expanding the cage structure is the
introducer sheath.

15. A method for ablating a hollow body organ, said
method comprising:

percutaneously introducing a catheter into the
25 interior of the hollow body organ, the catheter having a
resistive heating element and fluid distributing means at
its distal end, the resistive heating element being
arranged such as to be directly exposed to fluid within
the organ;

30 introducing a thermally conductive medium into the
hollow body organ through the fluid distributing means so



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that the medium is unconstrained and in direct thermal contact with the interior wall of the organ;

heating the thermally conductive medium within the hollow body organ using the resistive heating element; and

- 5 inducing an oscillatory flow of the thermally conductive medium through the fluid distributing means to effect mixing of the thermally conductive medium thereby enhancing uniformity of temperature distribution in the medium, and to induce the thermally conductive medium to
10 reciprocatingly flow past the resistive heating element thereby increasing heat flux to the body organ.

16. A method as in claim 15, further comprising:

expanding a cage structure within the hollow body organ; and

- 15 positioning the heating element of the catheter within the expanded cage structure prior to heating the thermally conductive medium.

17. A method as in claim 16, further comprising sensing the temperature of the thermally conductive medium using
20 at least one sensor disposed on the expandable cage structure.

18. A method as in claim 15, wherein the oscillatory flow is effected with a syringe connected to a proximal end of a central lumen of the fluid distributing means.

- 25 19. A method as in claim 15, wherein the volumes which are aspirated and expelled during the oscillatory flow are in the range from 0.1 ml to 3 ml.

20. A method as in claim 15, wherein the oscillatory flow is effected at a frequency in the range from 0.1 to
30 5 Hz.



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21. A method as in claim 15, wherein the thermally conductive medium is heated to a preselected temperature in the range from 45°C to 70°C.

22. A method as in claim 15, wherein the hollow body organ is the gallbladder, the thermally conductive medium is heated to a temperature in the range from 50°C to 65°C, the oscillory flow frequency is from 0.1 Hz to 5 Hz, the volumes aspirated and expelled during oscillatory flow are in the range from 0.1 ml to 3 ml, and the total treatment time is from 15 minutes to 45 minutes.

23. A thermal ablation system substantially as herein described with reference to Figure 10 of the accompanying drawings.

24. A method for ablating a hollow body organ substantially as herein described with reference to the accompanying drawings.

DATED this 4th day of October 1994

INNERDYNE MEDICAL, INC

By their Patent Attorneys

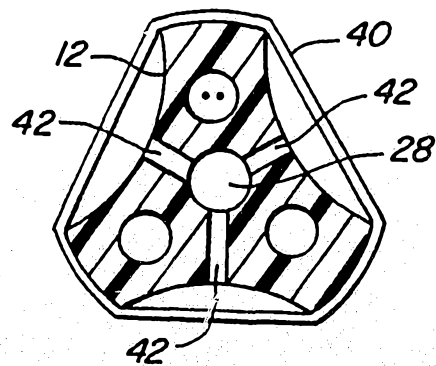
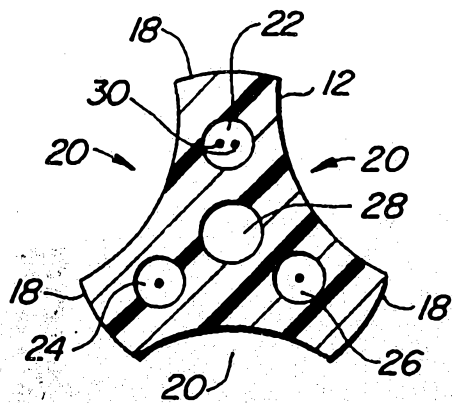
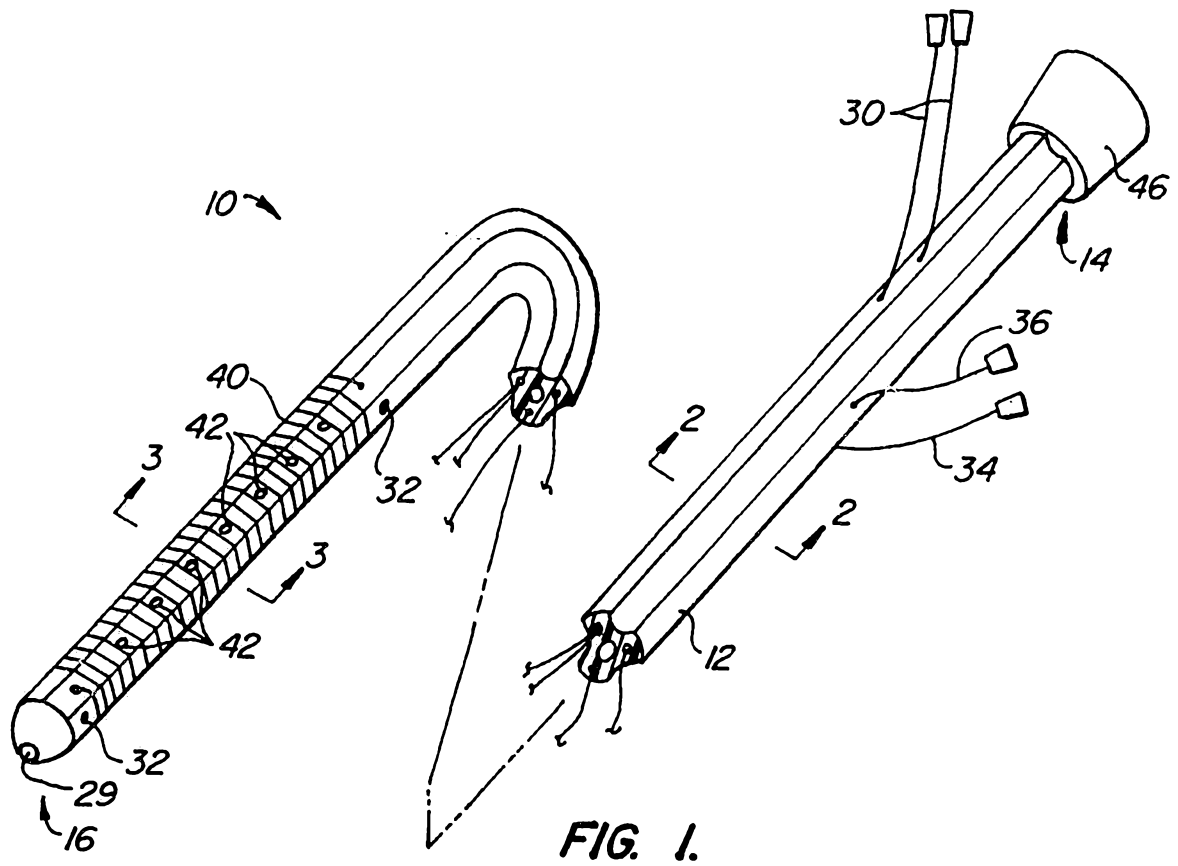
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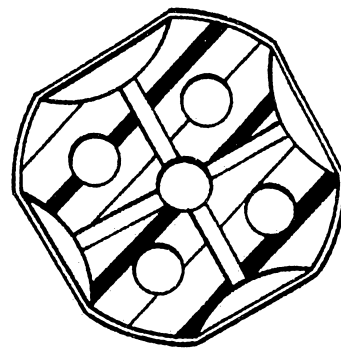
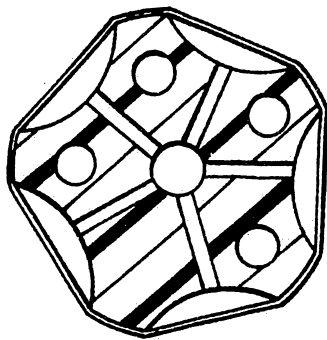
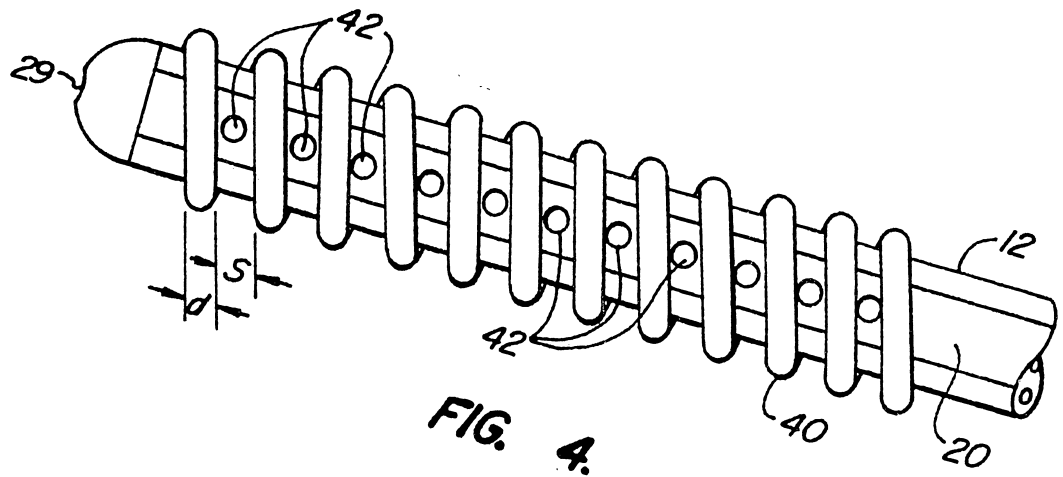


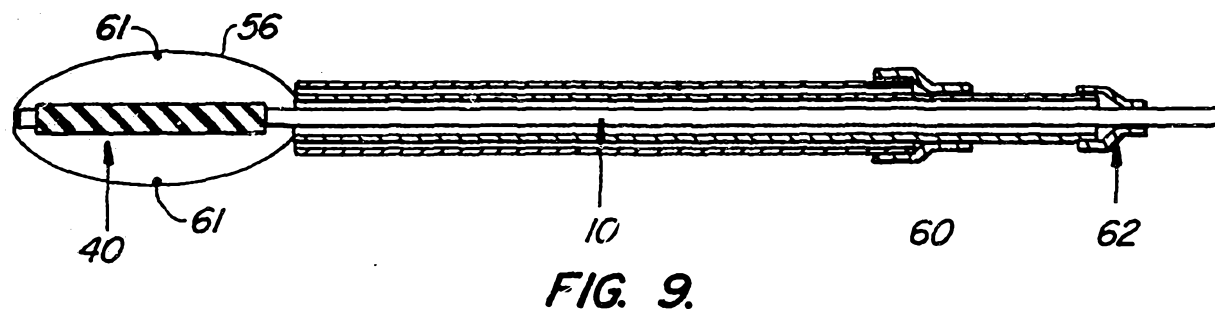
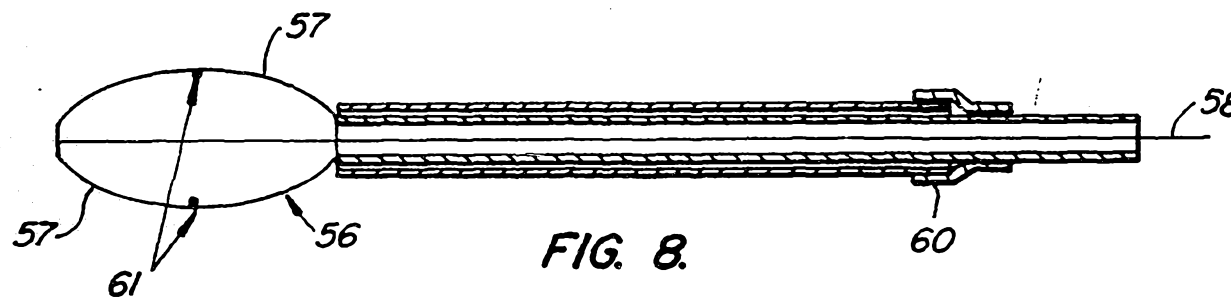
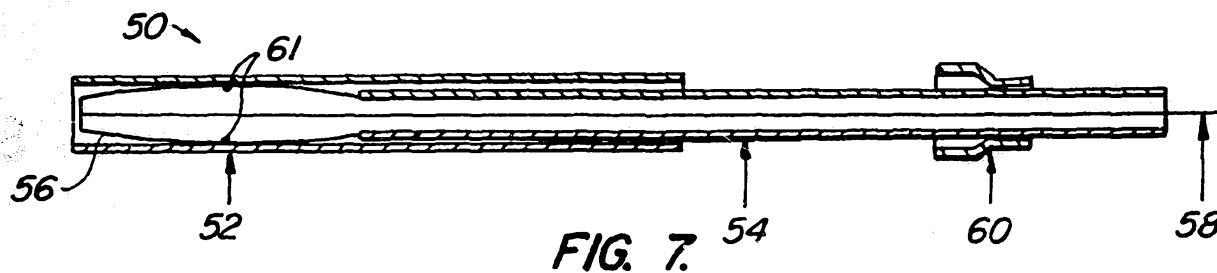
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**METHOD AND DEVICE FOR THERMAL
ABLATION HAVING IMPROVED HEAT TRANSFER
ABSTRACT OF THE DISCLOSURE**

5 A thermal ablation catheter includes an
elongate body member having a heating element disposed
over a predetermined length of its distal end. The
heating element is suspended away from an exterior
surface of the elongate member to form a circulation
10 region thereunder. Thermally conductive fluid can be
introduced through a lumen in the elongate member and
distributed within the circulation region to improve heat
transfer. The catheter is used to introduce the
thermally conductive medium to a hollow body organ where
15 the heating element raises the temperature of the medium
sufficiently to induce injury to the lining of the organ.
Optionally, an introducer sheath having an expandable
cage at its distal end may be used in combination with a
thermal ablation catheter. The expandable cage helps
20 center the heating element on the catheter within the
body organ and prevents direct contact between the
heating element and the wall of the organ. Heat transfer
and temperature uniformity can be enhanced by inducing an
oscillatory flow of the heat transfer medium through the
catheter while heat is being applied.
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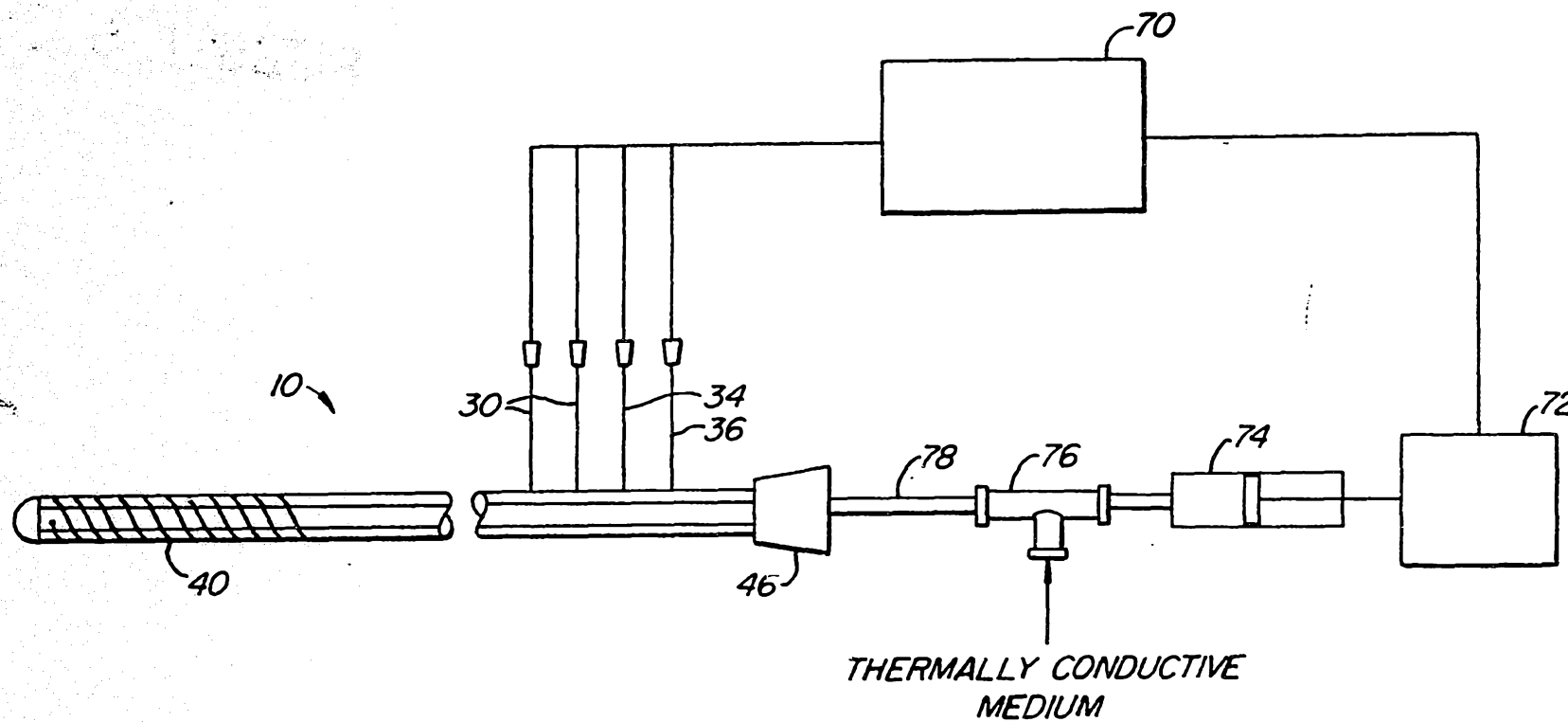


FIG. 10.