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(54) Title: HEATING AND COOLING OF CRYOSURGICAL INSTRUMENT USING A SINGLE CRYOGEN

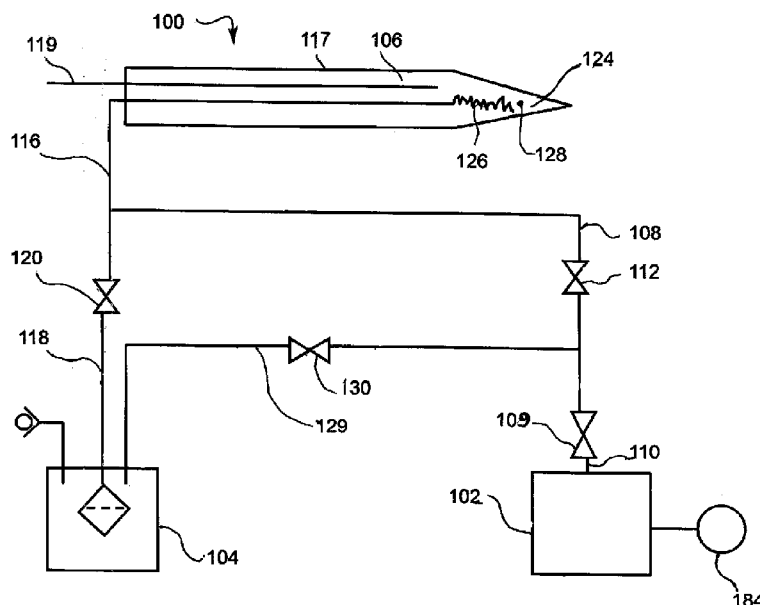


FIG. 1

(57) Abstract: A cryosurgical system featuring both cooling and heating utilizing a single type of cryogen but from two different sources. The liquid cryogen cools the tip of a cryosurgical instrument in the cryosurgical system, such as a cryoprobe or cryocatheter. The gaseous cryogen is further heated by a heating element, preferably an electrical heating element, supplying the heating needed for the thaw and release parts of the cryo treatment procedure. Thus, the cryosurgical system supports the freeze/thaw cycle of the operation of the cryosurgical instrument.



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Title: Heating and Cooling of Cryosurgical Instrument Using A Single Cryogen

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BACKGROUND

1. Technical Field

[0001] Embodiments of the present invention relate generally to cryosurgical equipment, and, more particularly, to the heating and cooling of cryoprobes or cryocatheters.

2. Description of Related Art

[0002] Cryoprobes that utilize a change of phase of a fluid cryogen, when this liquid cryogen is supplied from an external source into the cryoprobe tip, are known for performing cryosurgical procedures. Generally, a cryogen is delivered into a cryoprobe in the form of either a liquid and or two-phase fluid. The liquid phase of the delivered cryogen then cools the tip (distal section of the cryoprobe), by total or partial evaporation.

[0003] It can be advantageous to be able to both heat and cool the cryoprobe, in order to increase the efficacy of ablation. Most cryoablation treatments feature two cycles of cooling, separated by a thawing cycle, for increased efficacy, because the greatest damage to the tissue occurs during either a rapid decrease or a rapid increase in temperature, when the tissue goes through a phase change. A heating cycle therefore improves this phenomenon during thawing. The need for heating at the end of the treatment is twofold, the rapid heating improves the efficiency of the treatment, and the probe can be easily released from the tissue shortening the total procedure time.

[0004] Some compressed gases, such as helium, heat upon expansion. That is why helium is extensively used in Joules-Thomson processes.

[0005] U.S. Patent Publication No. 20060122590 discloses a device for both heating and cooling a cryoprobe, using a single source of gas, in Joules-Thomson process. This device, however, is based on the use of adiabatic expansion of high pressure Argon for cooling, and reducing the high pressure to reduce this cooling phenomenon to a minimum and heating the low pressure Argon.

BRIEF SUMMARY

[0006] The background art does not provide a solution that overcomes the challenge of providing both efficient and sufficient cooling and heating to the tip.

[0007] Embodiments of the present invention meet this challenge by providing a cryosurgical system featuring both cooling and heating utilizing a single type of cryogen but from two different sources. The liquid cryogen cools the tip of a cryosurgical instrument in the cryosurgical system, such as a cryoprobe or cryocatheter. The gaseous cryogen is further heated by a heating element, preferably an electrical heating element, supplying the heating needed for the thaw and release parts of the cryo treatment procedure. Thus, the cryosurgical system supports the freeze/thaw cycle of the operation of the cryosurgical instrument.

[0008] Illustrative embodiments of the present invention may variously provide a cryosurgical system with cryoprobe tip, which is situated near or in a cryogen supply passage of the cryoprobe and which, among many advantages, solves the above technical problem.

[0009] One aspect of the present invention provides a cryosurgical system, comprising: a cryosurgical instrument including a tip that is cooled by a cryogen in a fluid state and warmed by a same type of cryogen in a heated gaseous state; a fluid cryogen source that supplies a liquid cryogen to the cryosurgical instrument; and a gaseous cryogen source that supplies a gaseous cryogen to the cryosurgical instrument; and a heating element that selectively heats the gaseous cryogen. The gaseous cryogen and the fluid cryogen are not supplied to the cryosurgical instrument simultaneously but rather are supplied sequentially, such that wherein said fluid cryogen source is in fluid communication with the cryosurgical instrument, said gaseous cryogen source is not in fluid communication with the cryosurgical instrument; and such that wherein said gaseous cryogen source is in fluid communication with the cryosurgical instrument, said fluid cryogen source is not in fluid communication with the cryosurgical instrument. The gaseous cryogen source and the liquid cryogen source supply a same type of cryogen.

[0010] Another aspect of the present invention provides a cryosurgical system, comprising: a first source of a cryogen, the first source providing the cryogen is a gaseous phase; a second source of the cryogen, the second source providing the

cryogen in a liquid phase; a cryogen heating section that selectively heats provided gaseous phase cryogen; and a cryosurgical instrument having a tip and receiving provided cryogen in a two-phase state. The provided cryogen in the liquid phase cools the tip. The provided cryogen, after being heated by the heating section, warms the tip. The heating and cooling of the tip are achieved using only the provided cryogen.

[0011] Yet another aspect of the present invention provides a system, comprising: a cryosurgical instrument having a tip; a first container storing a cryogen in a gaseous state; a second container storing the cryogen in a liquid state; and a gaseous cryogen heater that selectively heats the gaseous cryogen as it travels from the first container to the cryosurgical device. The heated gaseous cryogen is joined with liquid cryogen as it travels to the cryosurgical device. The liquid cryogen and heated gaseous cryogen cooperate to selectively heat and/or cool the tip.

[0012] Still another aspect of the present invention provides a cryosurgical system, comprising: a cryosurgical instrument having a tip that is warmed by heated gaseous cryogen and cooled by liquid cryogen; means for supplying a cryogen in a gaseous phase; means for supplying the cryogen in a liquid phase; means for mixing together supplied gaseous cryogen and supplied liquid cryogen so as to deliver to the cryosurgical instrument a two phase cryogen that includes cryogen in both liquid and gaseous phases; and means for selectively heating the gaseous cryogen.

[0013] These, additional, and/or other aspects and/or advantages of the present invention are: set forth in the detailed description which follows; possibly inferable from the detailed description; and/or learnable by practice of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The present invention will be more readily understood from the detailed description of embodiments thereof made in conjunction with the accompanying drawings of which:

FIG. 1 is a schematic diagram of a cryosurgical system with cryosurgical instrument, consistent with an embodiment of the present invention , in which the heating element is inside of the cryosurgical instrument;

FIG. 2 is a schematic diagram of a cryosurgical system with cryosurgical instrument consistent with an embodiment of the present invention, in which the heating element is outside of the cryosurgical instrument;

FIG. 3 is a schematic diagram of a system consistent with an embodiment of the present invention, in which the gaseous phase from the two phase "liquid" cryogen source is shifted to the gas cryogen source and or the liquid phase is heated to fill the gaseous source;

FIG. 4 is a schematic illustration of a cryosurgical system consistent with an embodiment of the present invention, in which the gaseous phase of the cryogen is recycled by transferring the return cryogen to either the liquid/two phase cryogen source, or the gas cryogen source;

FIG. 5a is a longitudinal cross-sectional view of a first exemplary cryosurgical instrument usable in the system of FIG. 1;

FIG. 5b is a cross-sectional view of the first exemplary cryosurgical instrument of FIG. 5a take along line I-I of FIG. 5a;

FIG. 5c is a perspective view of a heat exchanging element of the cryosurgical instrument of FIG. 5a;

FIG. 6a is a longitudinal cross-sectional view of a second exemplary cryosurgical instrument usable in the system of FIG. 1;

FIG. 6b is a cross-sectional view of the first exemplary cryosurgical instrument of FIG. 6a take along line II-II of FIG. 6a;

FIG. 6c is a perspective view of a heat exchanging element of the cryosurgical instrument of FIG. 6A;

FIG. 7a is a longitudinal cross-sectional view of a third exemplary cryosurgical instrument usable in the system of FIG. 1;

FIG. 7b is a cross-sectional view of the third exemplary cryosurgical instrument of FIG. 7a take along line III-III of FIG. 7a;

FIG. 7c is a perspective view of a heat exchanging element of the cryosurgical instrument of FIG. 7a; and

FIG. 8 is a flowchart of an exemplary, illustrative method of treatment using the system of FIG. 1.

DETAILED DESCRIPTION

[0015] Reference will now be made in detail to embodiments of the present invention, examples of which are illustrated in the accompanying drawings, wherein like reference numerals refer to the like elements throughout. The embodiments are described below to explain the present invention by referring to the figures.

[0016] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods and materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

[0017] The term "cryosurgical system" refers herein to any type of cryosystem consist of a source of cryogenic material, and including but not limited to cryoprobes and cryocatheters, for the purpose of cryoablation procedure. Although the description centers on cryoprobes, this is for the purpose of illustration only and is without any intention of being limiting.

[0018] Referring to FIG. 1, there is illustrated a system 100 comprising a gaseous cryogen source 102, a liquid cryogen source 104, and a cryosurgical instrument 106.

[0019] A salient feature of the system 100 is a heating element 126 disposed in the tip 124 that warms cryogen gas flowing in the tip, during thawing part of the procedure. One particularly advantageous type of heating element is an electrical heating element.

[0020] The cryosurgical instrument 106 includes an outer shaft 117 surrounding both inlet lumen 116 and an exhaust lumen 119. Inlet lumen 116 preferably includes two

separated portions (shown in FIGS. 5a, 6a, and 7a). A first separated portion is a gas portion that is preferably located adjacent an exhaust lumen 119, which is preferably located between an outer wall of inlet lumen 116 and an inner wall of outer shaft 117. A second separated portion is an exhaust lumen 119 that may optionally be defined by the outer wall of inlet lumen 116 and the inner wall of outer shaft 117, or alternatively may be defined by a separate wall and/or by an outer wall of the gas portion of inlet lumen 116 (shown in 5a, 6a, and 7a).

[0021] The inlet lumen 116 receives the two-phase cryogen fluid from cryogen source 104. The liquid portion of inlet lumen 116 is in communication with tip 124 of cryosurgical instrument 106, such that cryogen enters through the inlet lumen 116 and then flows to tip 124, thereby cooling tip 124 and causing an ice ball to form.

[0022] Each cryogen source 102 and 104 uses the same type of cryogen such as, for example, nitrogen. Also, each cryogen source 102 and 104 is in fluid communication with a cryosurgical instrument 106.

[0023] Gaseous cryogen source 102 may be a cylinder that is connected to the cryosurgical instrument 106 by a first liquid gas pathway that includes, in series, a fluid gas connector line 110 connected to a first two-way gas valve 109, and a gas connector 108 featuring a second two-way gas valve 112, and which is then in fluid communication with an inlet lumen 116 of cryosurgical instrument 106.

[0024] Liquid cryogen source 104 is connected to the cryosurgical instrument 106 through a second gas pathway that includes, in series, a fluid liquid connector line 118 a liquid two-way valve 120 and which is then in fluid communication with inlet lumen 116 of cryosurgical instrument 106. These components in fluid communication with liquid cryogen source 104 transport a two phase fluid, having both liquid and gas components.

[0025] Cryogen sources 102 and 104 do not supply cryogen to the tip 124 of the cryoprobe 106 simultaneously. The selection of the appropriate source 102 or 104 is achieved by selective operation of two-way valves 112 and 120.

[0026] To heat the tip 124, gaseous cryogen from cryogen source 102 is delivered to and enters the inlet lumen 116 and flows to and is warmed by a heating element 126. The temperature of heating element 126, and hence of the gaseous cryogen, is preferably controlled by a thermocouple 128, which senses the temperature of the gaseous cryogen and which is in electrical communication with heating element 126.

In more detail, the thermocouple 128 provides feedback as to the temperature of the heated cryogen, which can be used to regulate operation of the heating element 126. For example, when the heating element is of an electrically resistive type, feedback from the thermocouple may be used to regulate the amount of current flowing to the heating element. Other ways to control the heating, not shown, can be achieved either by placing the thermocouple at the exhaust lumen 119 outside the cryosurgical probe, or measuring the resistance of the electrical element.

[0027] Since the cryogenic fluid is the same in sources 104 and 102, the gaseous phase from the top of the liquid phase from source 104 can fill source 102 through connecting line 129 and valve 130.

[0028] For safety reasons, optionally gas cryogen source 102 also features a pressure meter 184 for determining internal pressure.

[0029] Thus, as illustrated, there are two discrete sources of the same cryogen, one source supplying the cryogen in a liquid state (104) and the other source supplying the cryogen in a gaseous state (102). In operation, these cryogen sources, in cooperation with the heating element 126, provide both selective cooling and heating of the cryosurgical instrument 106. In more detail, gaseous cryogen from gaseous source 102 is selectively heated by the heating element 126 when heating of the cryosurgical instrument 106 is desired.

[0030] Referring to FIG. 2, there is illustrated a system 200 comprising a gaseous cryogen source 202, a liquid cryogen source 204, and a cryosurgical instrument 206. Much of the arrangement of system 100 is shared by system 200.

[0031] Each cryogen source 202 and 204 uses the same cryogen such as, for example, nitrogen. Also, each cryogen source 202 and 204 is in fluid communication with a cryosurgical instrument 206.

[0032] One difference between systems 100 and 200, however, is that a heating element 226 is located outside of cryosurgical instrument 206. As illustrated, the heating element 226 may be located in-line to gas connector 208 downstream from the gaseous cryogen source 202. For example, heating element 226 is optionally located before the fluid connection to inlet lumen 216. Again, heating element 226 may be an electrical (resistance) heating element. Other heating arrangements are both possible and contemplated. For example, additionally and/or alternatively, the heating element 226 may be a piezoelectric element sensitive to a user's grip.

[0033] In system 200, a thermocouple 228 may also be located in-line to gas connector 208. As illustrated in FIG. 2, the thermocouple 228 may be located after heating element 226. This thermocouple 228 may, however, be located in other locations upstream of the inlet lumen 216.

[0034] Optionally, one or more additional thermocouples may be provided. For example there may optionally be two such additional thermocouples as shown, including a thermocouple 231 at tip 224 and also a thermocouple 232 at exhaust lumen 219.

[0035] Thus, as illustrated, there are two discrete sources of the same cryogen, one source supplying the cryogen in a liquid state (204) and the other source supplying the cryogen in a gaseous state (202). In operation, these cryogen sources, in cooperation with the heating element 226, provide both selective cooling and heating of the cryosurgical instrument 206. In more detail, gaseous cryogen from gaseous source 202 is selectively heated by the heating element 226 when heating of the cryosurgical instrument 206 is desired. The gas is heated upstream of the inlet lumen 216.

[0036] Referring to FIG. 3, there is illustrated a system 300 comprising a gaseous cryogen source 302, a liquid cryogen source 304, and a cryosurgical instrument 306. Much of the arrangement of system 200 is shared by system 300.

[0037] Each cryogen source 302 and 304 uses the same cryogen such as, for example, nitrogen. Also, each cryogen source 302 and 304 is in fluid communication with a cryosurgical instrument 306.

[0038] One difference between systems 200 and 300 is the transfer of the gaseous phase from the liquid cryogen source 304 to the gaseous cryogen source 302. This gaseous phase is generated by heating the gaseous phase with an electrical heater 331 in or adjacent to the liquid cryogen source 304. As illustrated, the electrical heater 331 is preferably placed within liquid cryogen source 304. Additionally and/or alternatively, the heating element 331 may be either immersed in the liquid phase in direct contact with the general volume of the liquid cryogen, or inserted into small vessel (not shown) within the liquid cryogen source 304. This small vessel may be connected by line 329 to the gaseous cryogen source 302. Optionally and preferably, electrical heater 331 does not surround fluid liquid connector line 318, nor is electrical heater 331 placed in-line with fluid liquid connector line 318.

[0039] Advantageously, the electrical heater 331 may be selectively activated and/or deactivated according to detected performance/operational parameters such as, by way of non-limiting examples, pressure, as recorded by pressure meter 384, temperature, timing (for example according to those periods that the cryogen flows from liquid cryogen source 304) or a combination thereof.

[0040] In operation, the heating element 331, in the liquid cryogen source 304 heats a portion of the liquid cryogen therein and transforms it to gas. The additional heat energy results in increasing the pressure in the liquid cryogen source 304, which encourages the transfer of the gaseous phase to the gaseous cryogen source 302. The generated gaseous phase is transmitted between the cryogen sources 302 and 304 via line 329 and line 309 by selective operation of valves 330 and 322.

[0041] The size and type of the heating element 331 may depend on the speed of obtaining the desire pressure. One advantageous example for implementation of heating element 331 is an insulated electrical type heating element that uses between 250-1000 watts.

[0042] Without wishing to be limited by a closed list, the inventors have found that such an element effectively increases the pressure in the liquid cryogen source 304 to up to 100psi in reasonably short time, on the order of minutes. The increase in pressure generally elevates the boiling temperature of the cryogen. A benefit of using electrical heater 331 to increase the pressure in the liquid cryogen source 304 is the simplicity of the use of available power source, which directly transforms energy into pressure. Another requirement is that less time is required, as well as the ease of control versus a pump for the same purpose. Pumping gaseous cryogen between the cryogen sources 302 and 304 would require a pump and additional piping, which is avoided by using the heating element 331.

[0043] In more detail, the heater 331 in system 300 is used to raise the pressure in the liquid cryogen sources 304 and 302 by boiling the liquid cryogen stored therein, until the pressure reaches a specified threshold as measured by pressure gauge 384. It is done by keeping valves 330 and 309 open, and valves 312 and 320 closed. A particularly advantageous threshold may be, for example, between about 40-100psi.

[0044] For thawing mode of operation, another heating element 326 is located outside of cryosurgical instrument 306 and also outside of gaseous cryogen source

302. As illustrated, the heating element 326 may be located in-line to gas connector 308 downstream from the gaseous cryogen source 302. For example, heating element 326 is optionally located after one way valve 314. Again, heating element 326 may be an electrical (resistance) heating element. Other heating arrangements are both possible and contemplated. For example, additionally and/or alternatively, the heating element 326 may be a piezoelectric element sensitive to a user's grip.

[0045] In system 300, to monitor the heating of the gaseous phase during active thawing, a thermocouple 328 may also be located in-line to gas connector 308. As illustrated in FIG. 3, the thermocouple 328 may be located after heating element 326. This thermocouple 328 may, however, be located in other locations upstream of the inlet lumen 316. The location of the thermocouple 328 monitoring the heating may also optionally be located, at the tip 330, while the position of thermocouple 332 may also optionally be located at the return/exhaust line 319.

[0046] Thus, as illustrated, there are two discrete sources of the same cryogen, one source supplying the cryogen in a liquid state (304) and the other source supplying the cryogen in a gaseous state (302). In operation, these cryogen sources, in cooperation with the heating element 326, provide both selective cooling and heating of the cryosurgical instrument 306. In more detail, gaseous cryogen from gaseous source 302 is selectively heated by the heating element 326 when heating of the cryosurgical instrument 306 is desired. The gas is heated upstream of the inlet lumen 316. To provide additional gaseous cryogen and to assist with this process, the transfer of the gaseous phase from the liquid cryogen source 304 to the gaseous cryogen source 302 is optionally and preferably generated by heating the gaseous phase with an electrical heater 331 in or adjacent to the liquid cryogen source 304.

[0047] Referring to FIG. 4, there is illustrated a system 400 comprising a gaseous cryogen source 402, a liquid cryogen source 404, and a cryosurgical instrument 406. Much of the arrangement of system 100 is shared by system 400. The freeze/thawing cycles provided through alternating application of liquid cryogen and gaseous cryogen as described for the system of Figure 1 is also provided by system 400. However, system 400 also features, as described below, a recycling solution to enable additional gaseous cryogen to be returned to gaseous cryogen source 402, thereby advantageously "topping up" the supply of gaseous cryogen in gaseous cryogen source 402.

[0048] One difference between system 100 and 400 is an exhaust lumen 419 through which the gas phase is returned after the liquid (two phase) cryogen has boiled to cool the tip 424. The returned gas phase is used to fill the gaseous cryogen in gas cryogen source 402 by pumping the returned gas phase with a pump 434 through a pump connector line 433 and another pump connector line 431, as regulated by a two way valve 432.

[0049] In system 400, the pump 434 compresses the return cryogen from line 419 and returns it to the liquid cryogen source 404 via lines 433, 431 and 429 by opening the valves 432 and 430. This operation increases the pressure in the liquid cryogen source 404. Additionally and/or alternatively the pump 434 of system 400 increases the pressure in the gaseous cryogen source 402 by compressing the return fluid in line 419, and transferring it to the gaseous cryogen source 402 via lines 433 and 431, and 410, by opening valves 432 and 420.

[0050] A pressure gauge 409 preferably controls the activity of the pump 434, for example by turning the pump 434 off and on, so that if pressure at liquid cryogen source 404 reaches a certain threshold, pump 434 is turned off and/or relief valve 491 is opened. As a non-limiting example, the preferred pressure range is 40psi to 100psi for liquid nitrogen, but this range is preferably adjusted for other types of cryogens.

[0051] A complete recycling solution, for active thawing is provided by system 400. During this mode of operation, valves 432 and 412 are open and valves 430 and 420 are closed. The gaseous cryogen is circulated by the pump through the lines 433, 431, 408, 416, and 419.

[0052] Turning to FIGS. 5a-5c, there is illustrated an example of a cryosurgical instrument 500 usable with any of the systems 100, 200, 300, or 400. Cryosurgical instrument 500 includes an outer shaft 508 that features insulation 504 and an inlet 509 through which fluid and gaseous cryogen flows, according to the source from which cryogen is flowing as previously described, to an inner shaft 509. The cryogen is then reflected by a reflecting surface 510, which is preferably located at, but spacedly separated from, a tip 505, which is a closed and preferably a solid tip. The reflected cryogen then rapidly enters and flows through a plurality of exhaust grooves 507 (shown in Figures 5B and 5C) of a heat exchange enhancing element 501. Grooves 507 are preferably straight grooves and function as a plurality of return channels for receiving the expanded return cryogen. Grooves 507 are preferably in

communication with an outlet 503 for then exhausting the cryogen out of cryosurgical instrument 500. Grooves 507 may be circumferentially disposed about the longitudinal axis of heat exchange enhancing element 501.

[0053] During the freezing part of the operation, the liquid cryogen enters inlet 509 and travels through inner shaft 509. The liquid cryogen is then reflected by reflecting source 510 and travels through exhaust grooves 507. A heat transfer zone 511, shown by arrows, is defined by the boundaries of thermal insulation 504. Heat transfer zone 511 causes tip 505 to be chilled and hence an ice ball to form.

[0054] During the thawing part of the operation, the gaseous cryogen enters inlet 509 and travels as for the liquid cryogen. While flowing through the exhaust grooves 507, a heating element 515 heats the gaseous cryogen that, in turn, heats the shaft 508 (in contact with the tissue) and increases the rate of flow through grooves 507. The gaseous cryogen then exits through outlet 503.

[0055] As FIGS. 5b and 5c show, the heating element 515 may be an electrical heating coil element with a plurality of coils disposed within the grooves 507 of heat exchange enhancing element 501. As shown, grooves 507 are disposed about the exterior of heat exchange enhancing element 501. Power may be supplied to the heating element 515 through electrical lines 512 (shown also in FIG. 5a). Coils 513 are preferably covered such that only heat is transferred therethrough.

[0056] As described above thermal insulation 504 terminates the heat transfer from the cryosurgical instrument 500, thereby defining the end of heat transfer zone 511, in which heat is absorbed from the external environment at heat exchange zone 511.

[0057] As explained above, the above construction increases the speed of the return flow. By increasing the speed of the return flow, heat exchange between the shaft 508 at the heat exchanging zone 511 is improved. The heating coils placed in the grooves 507 heat the gaseous cryogen transmitting the heat directly to the shaft 508, and indirectly by conducting the heat through the surface in contact of heat exchange enhancing element 501, resulting in defreezing of an ice ball generated at the heat exchanging zone 511.

[0058] Turning to FIGS. 6a-6c, there are illustrated an example of a cryosurgical instrument 600 usable with any of the systems 100, 200, 300 or 400. Cryosurgical instrument 600 has many of the same features as the cryosurgical instrument of Figures 5a-5c, and elements with the same or similar function have the same number

plus 100. The function of cryosurgical instrument 600 is also highly similar to that of cryosurgical instrument 500. However, preferably wires 613 are arranged such that a plurality of wires 613 run in parallel in each groove 607, to create one long resisting electrical element, which is heated by electrical current.

[0059] As FIG. 6c illustrates, the wire 613 is shown laid along grooves 607, wrapping the heat exchange enhancing element 615 like the rotor of an electrical engine.

[0060] Turning to FIGS. 7a-7c, there is illustrated an example of a cryosurgical instrument 700 usable with any of the systems 100, 200, 300 or 400. Cryosurgical instrument 700 has many of the same features as the cryosurgical instrument of Figures 5a-5c, and elements with the same or similar function have the same number plus 200. The function of cryosurgical instrument 700 is also highly similar to that of cryosurgical instrument 500. However, preferably grooves 707 are located in the interior of heat exchange enhancing element 701, but external to the internal cryogen supply passage. Wires 713 are preferably located as coils within grooves 707.

[0061] Figure 8 illustrates a method 800 of performing cryosurgical ablation. In the description of method 800 that follows, concurrent reference is made to the system 100 of FIG. 1. This concurrent reference is merely to facilitate understanding of the method 800. It is to be understood that the method need not be used with system 100 and is usable by systems with other configurations.

[0062] In operation 810, a cryogen, in liquid state, fills a liquid cryogen source/reservoir (104). In operation 820, the cryogen, in a gaseous state, is delivered to a gaseous cryogen source/reservoir (102). Next, in operation 830, a tip (124) of the cryosurgical instrument, which is in communication with the cryogen sources/reservoirs, is inserted into target tissue in preparation for cryoablation. The cryoablation process of method 800 consists of one or more two-step cycles of freezing and thawing. In operation 840, the tip is cooled by a flow of cold liquid cryogen. In operation 850, the tip is warmed by a flow of warmed gaseous cryogen.

[0063] In operation 860, it is determined whether the two-step freezing/thawing cycle should be repeated. When it is determined that the two-step cycle should be repeated, the method returns to operation 830. When it is determined that the two step cycle should not be repeated, the method continues to operation 860, in which the cryosurgical instrument is warmed by a flow of warm gaseous cryogen so as to facilitate release from the target tissue.

[0064] Operations 840 – 860 may be repeated until a desired cryoablation result is achieved.

[0065] As the foregoing illustrates, the embodiment(s) provide a cooling and heating options utilizing a single cryogen delivered from a source of liquid cryogen and a source of gaseous cryogen. The liquid cryogen cools the tip of a cryosurgical instrument, such as a cryosurgical instrument or cryocatheter. The gaseous cryogen is heated by a heating element, preferably an electrical heating element, heating the tip.

[0066] Examples of various features/aspects/components/operations have been provided to facilitate understanding of the disclosed embodiments of the present invention. In addition, various preferences have been discussed to facilitate understanding of the disclosed embodiments of the present invention. It is to be understood that all examples and preferences disclosed herein are intended to be non-limiting.

[0067] Although selected embodiments of the present invention have been shown and described individually, it is to be understood that at least aspects of the described embodiments may be combined.

[0068] Also although selected embodiments of the present invention have been shown and described, it is to be understood the present invention is not limited to the described embodiments. Instead, it is to be appreciated that changes may be made to these embodiments without departing from the principles and spirit of the invention, the scope of which is defined by the claims and the equivalents thereof.

What is claimed is:

1. A cryosurgical system, comprising:

a cryosurgical instrument including a tip that is cooled by a cryogen in a fluid state and warmed by a same type of cryogen in a heated gaseous state;

a fluid cryogen source that supplies a liquid cryogen to the cryosurgical instrument;

a gaseous cryogen source that supplies a gaseous cryogen to the cryosurgical instrument; and

a heating element that selectively heats the gaseous cryogen,

wherein the gaseous cryogen and the fluid cryogen are not supplied to the cryosurgical instrument simultaneously but rather are supplied sequentially, such that wherein said fluid cryogen source is in fluid communication with the cryosurgical instrument, said gaseous cryogen source is not in fluid communication with the cryosurgical instrument; and such that wherein said gaseous cryogen source is in fluid communication with the cryosurgical instrument, said fluid cryogen source is not in fluid communication with the cryosurgical instrument, and

wherein the gaseous cryogen source and the liquid cryogen source supply a same type of cryogen.

2. The system of claim 1, wherein the cryosurgical instrument, the fluid cryogen source and the gaseous cryogen source comprise a closed system.

3. The system of claim 2, wherein the fluid cryogen source is in gaseous communication with the gaseous cryogen source and cryogen in a gaseous

phase in the liquid cryogen source is delivered to the gaseous cryogen source.

4. The system of claim 3, wherein the fluid cryogen source includes a cryogen heater that heats and converts liquid cryogen into gaseous cryogen.

5. The system of claim 1, wherein a gas phase of cryogen exhausted from the cryosurgical instrument is delivered to the gaseous cryogen source.

6. The system of claim 1, wherein the heating element is upstream of the cryosurgical instrument.

7. The system of claim 7, wherein the heating element is upstream of a section at which the gaseous cryogen and the liquid cryogen come together before being supplied to the cryosurgical instrument.

8. The system of claim 1, further comprising a heat exchange enhancing element disposed in the cryosurgical instrument near the tip and in a heat exchange zone, the enhancing element having a plurality of external cryogen return grooves circumferentially disposed lengthwise along the enhancing element.

9. The system of claim 8, further comprising a heating element disposed in the grooves.

10. The system of claim 9, wherein the heating element is an electrical heating coil element with (i) a plurality of coils disposed in the grooves or (ii) a plurality of wires disposed in the grooves and running several times in each groove so as to create one long resisting electrical element.

11. The system of claim 10, wherein said coils are insulated.

12. The system of claim 9, wherein said grooves are disposed lengthwise along an internal passage of the enhancing element, or lengthwise along an external passage of the enhancing element.

13. A cryosurgical system, comprising:

a first source of a cryogen, the first source providing the cryogen is a gaseous phase;

a second source of the cryogen, the second source providing the cryogen in a liquid phase;

a cryogen heating section that selectively heats provided gaseous phase cryogen; and

a cryosurgical instrument having a tip and receiving provided cryogen in a two-phase state,

wherein the provided cryogen in the liquid phase cools the tip,

wherein the provided cryogen, after being heated by the heating section, warms the tip, and

wherein the heating and cooling of the tip are achieved using only the provided cryogen.

14. A system, comprising:

a cryosurgical instrument having a tip;

a first container storing a cryogen in a gaseous state;

a second container storing the cryogen in a liquid state; and

a gaseous cryogen heater that selectively heats the gaseous cryogen as it travels from the first container to the cryosurgical device,

wherein the heated gaseous cryogen is joined with liquid cryogen as it travels to the cryosurgical device, and

wherein the liquid cryogen and heated gaseous cryogen cooperate to selectively heat and/or cool the tip.

15. A cryosurgical system, comprising:

a cryosurgical instrument having a tip that is warmed by heated gaseous cryogen and cooled by liquid cryogen;

means for supplying a cryogen in a gaseous phase;

means for supplying the cryogen in a liquid phase;

means for mixing together supplied gaseous cryogen and supplied liquid cryogen so as to deliver to the cryosurgical instrument a two phase cryogen that includes cryogen in both liquid and gaseous phases; and

means for selectively heating the gaseous cryogen.

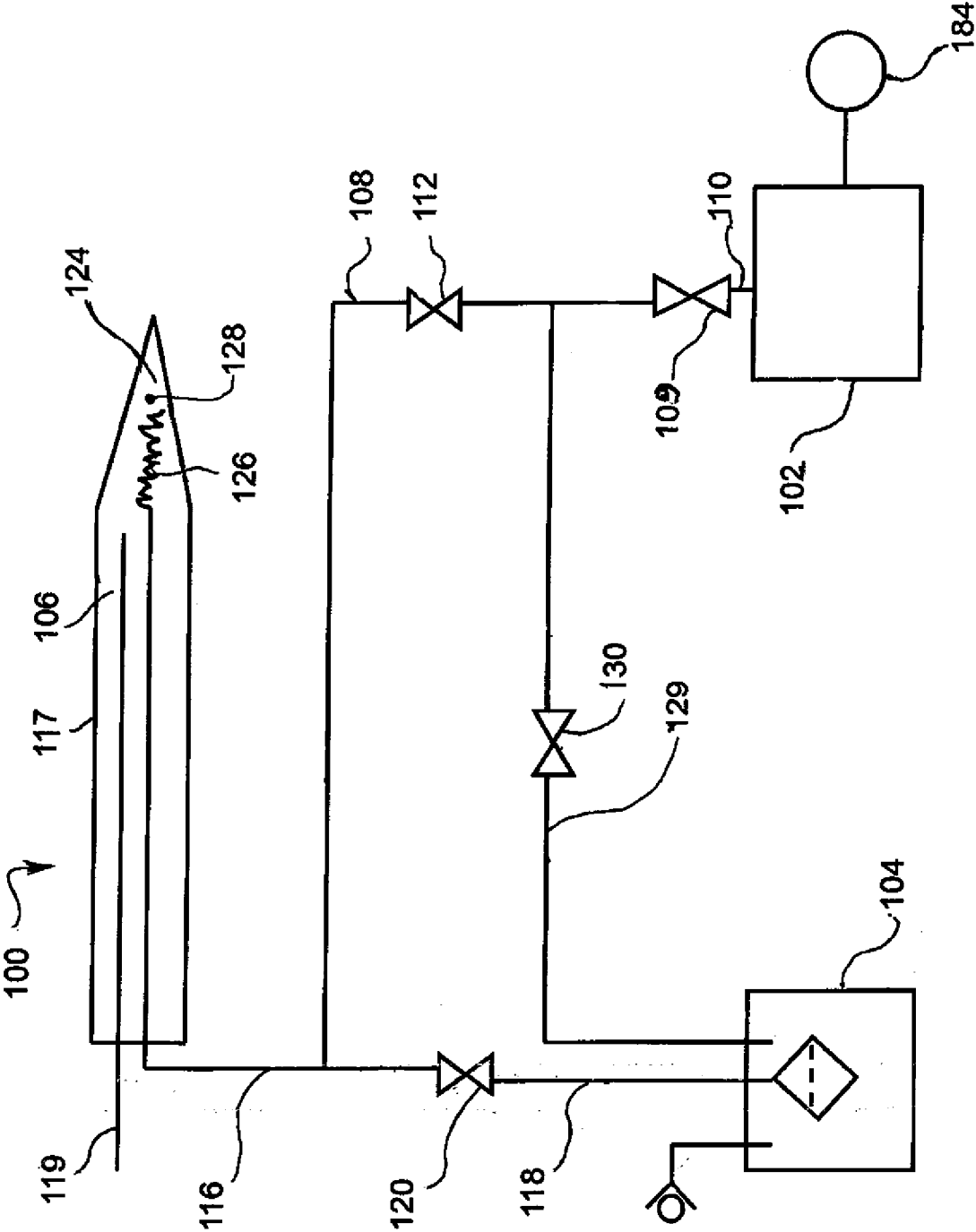


FIG. 1

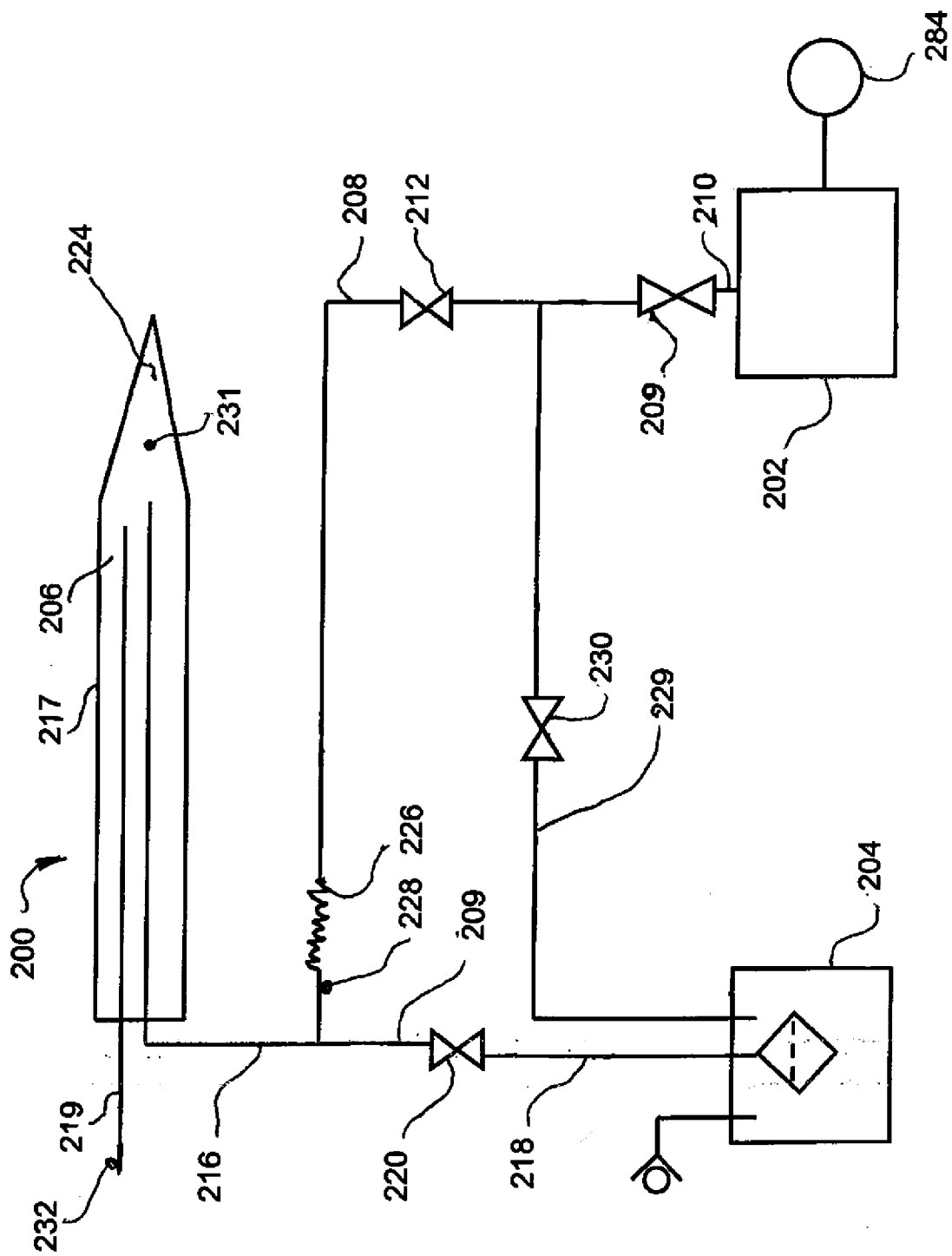


FIG. 2

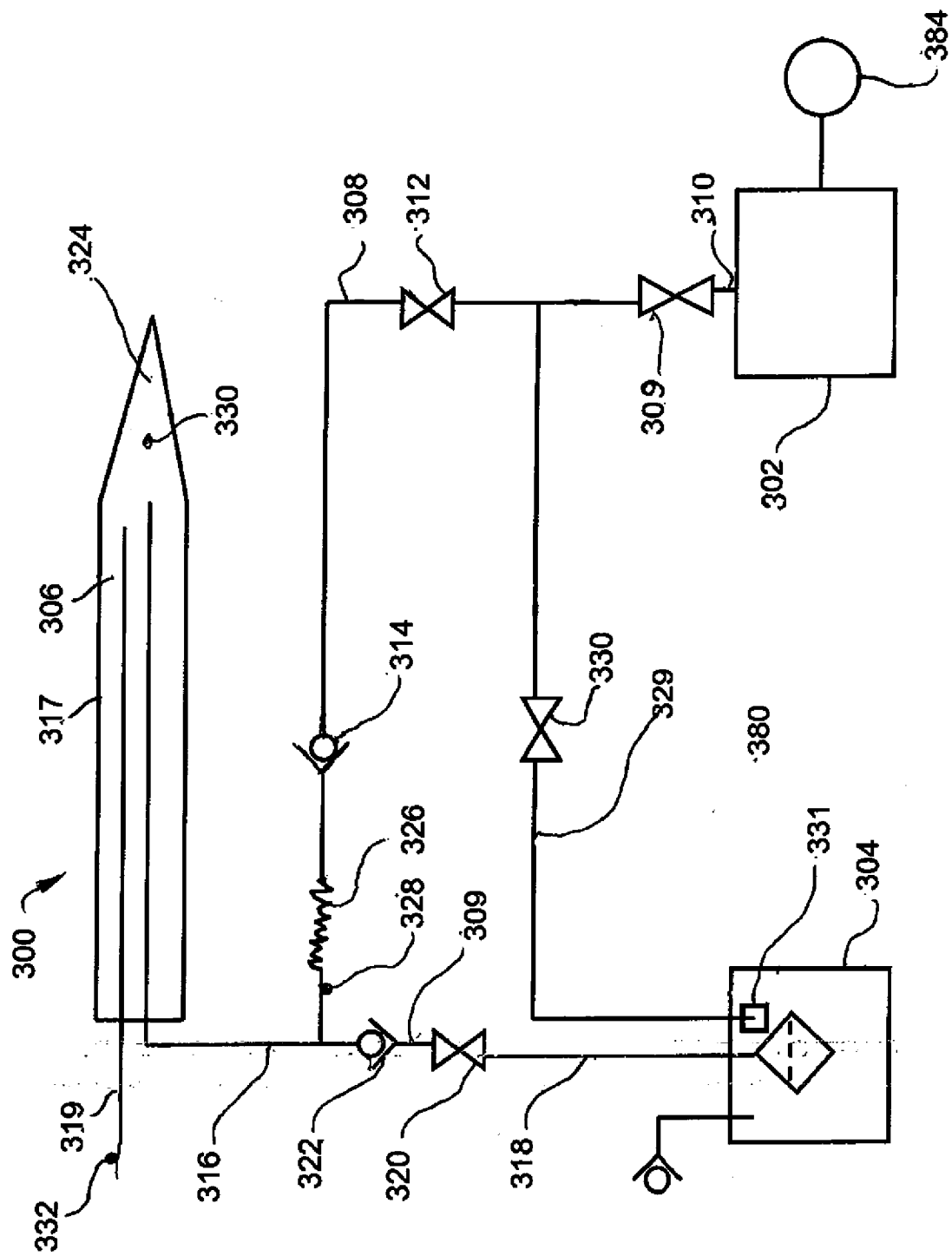


FIG. 3

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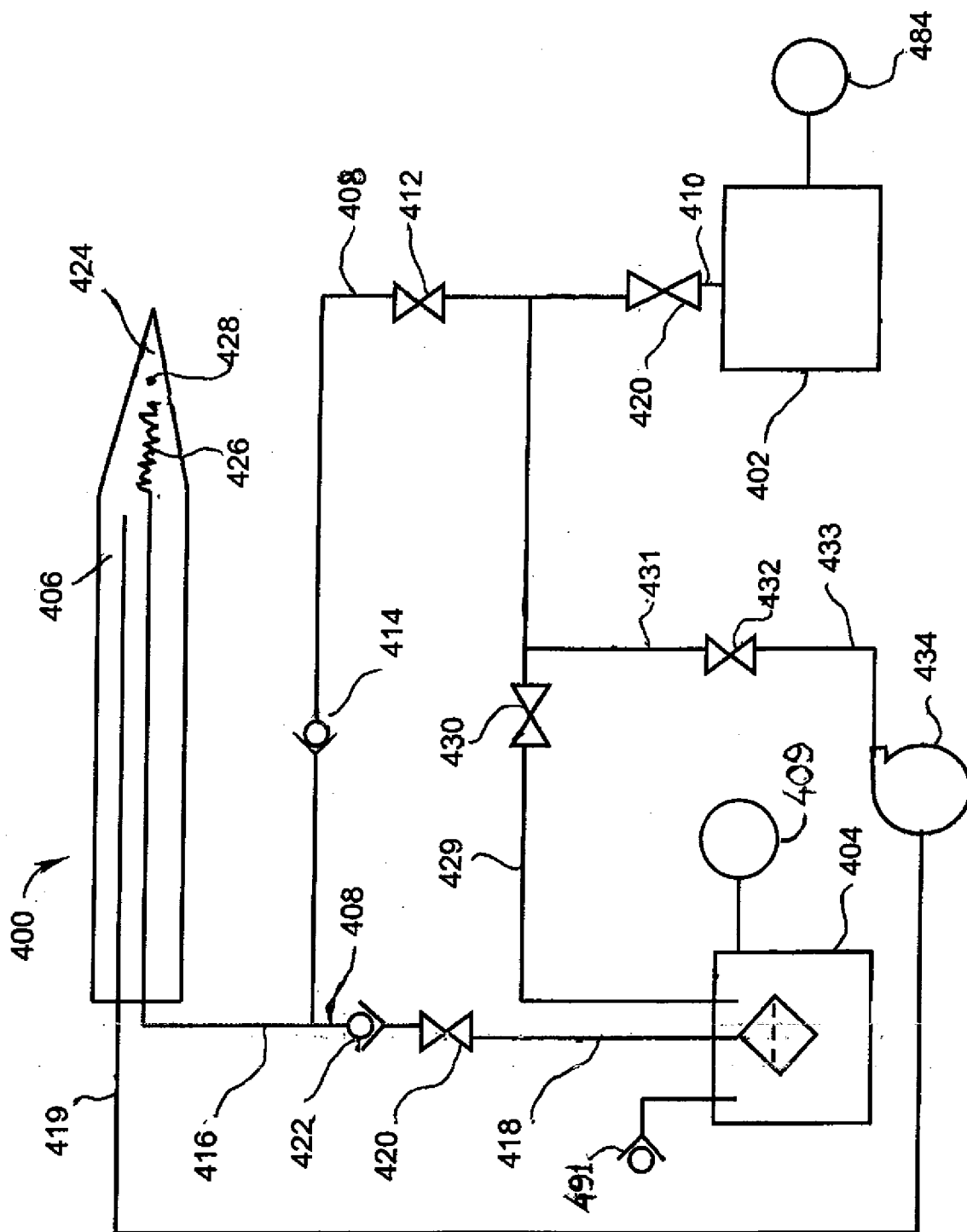


FIG. 4

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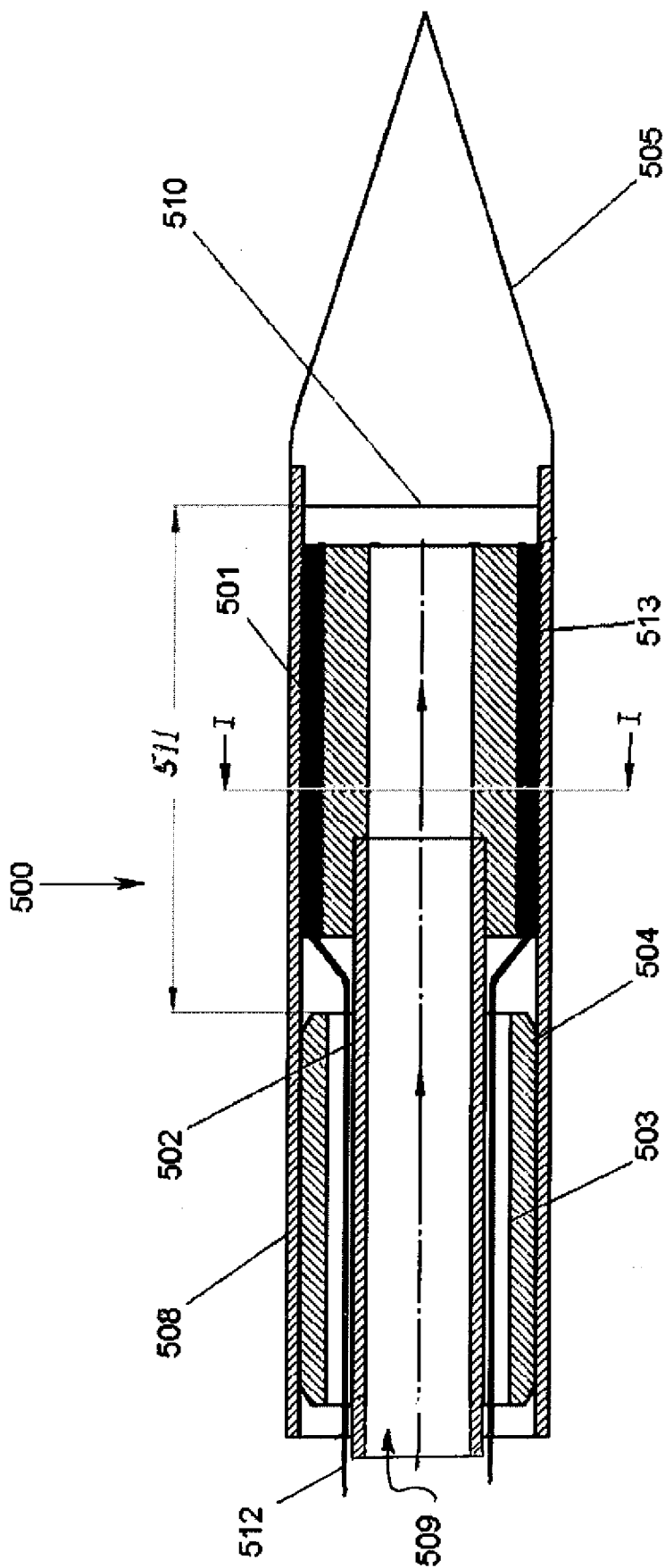


FIG. 5a

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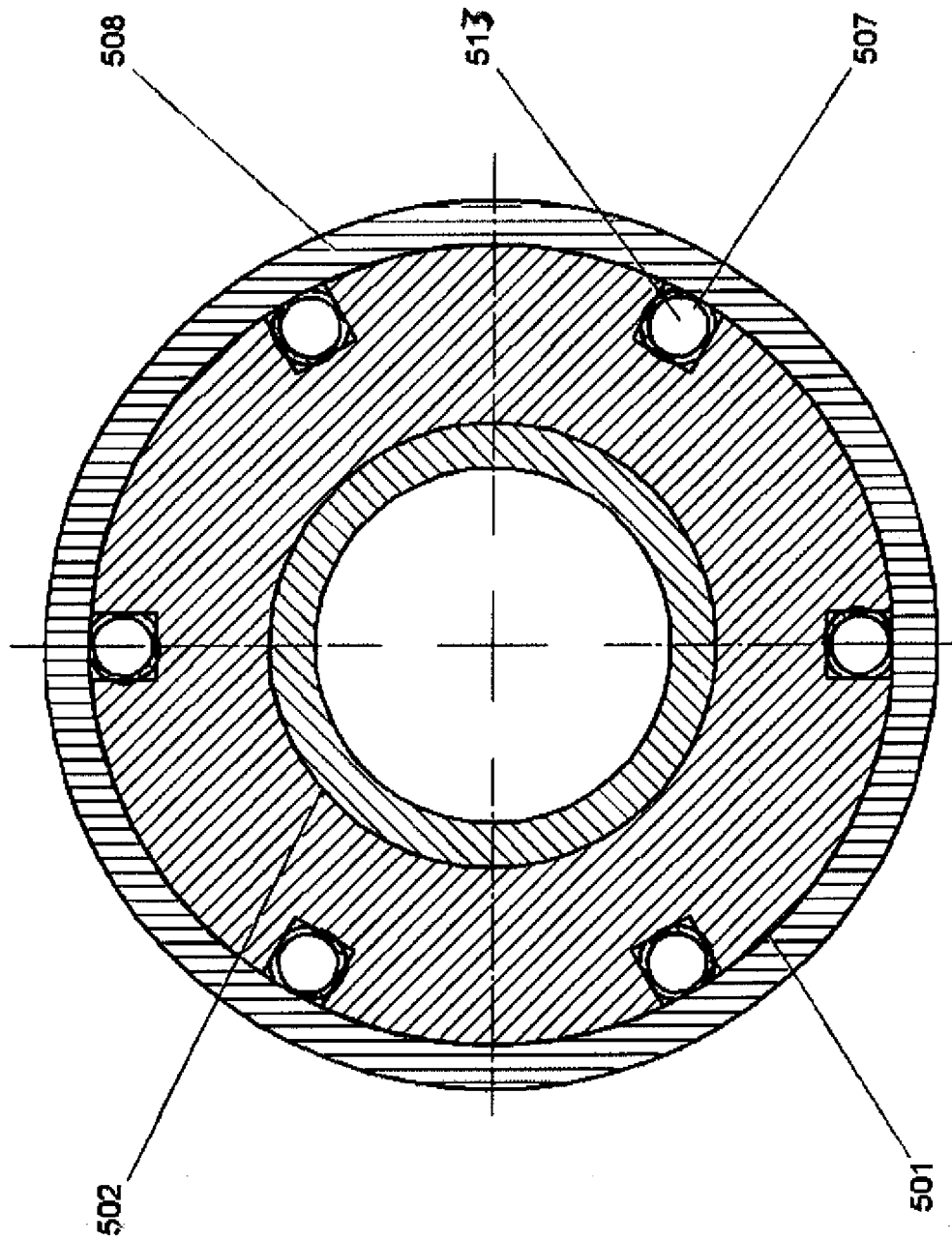


FIG. 5b

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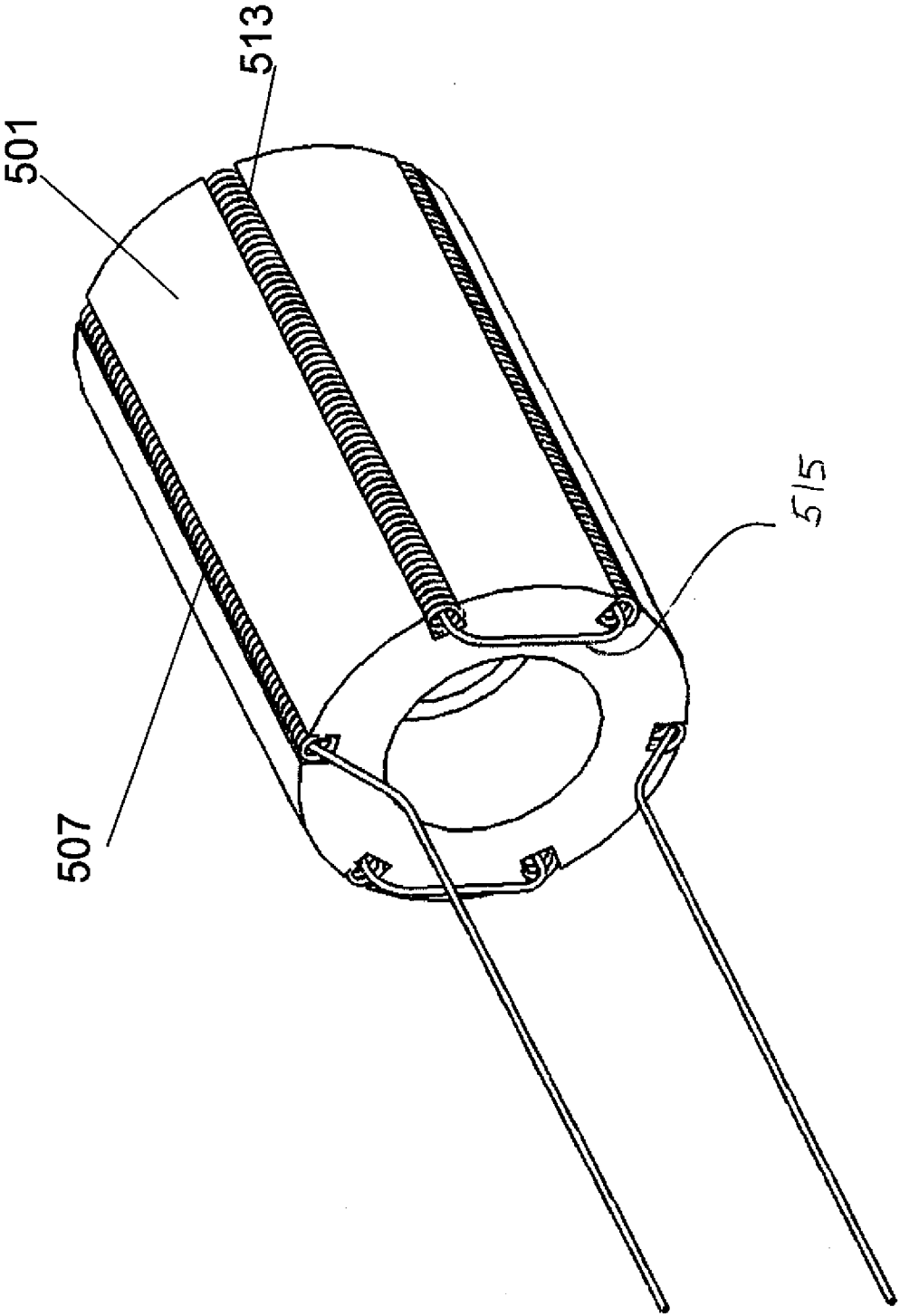


FIG. 5c

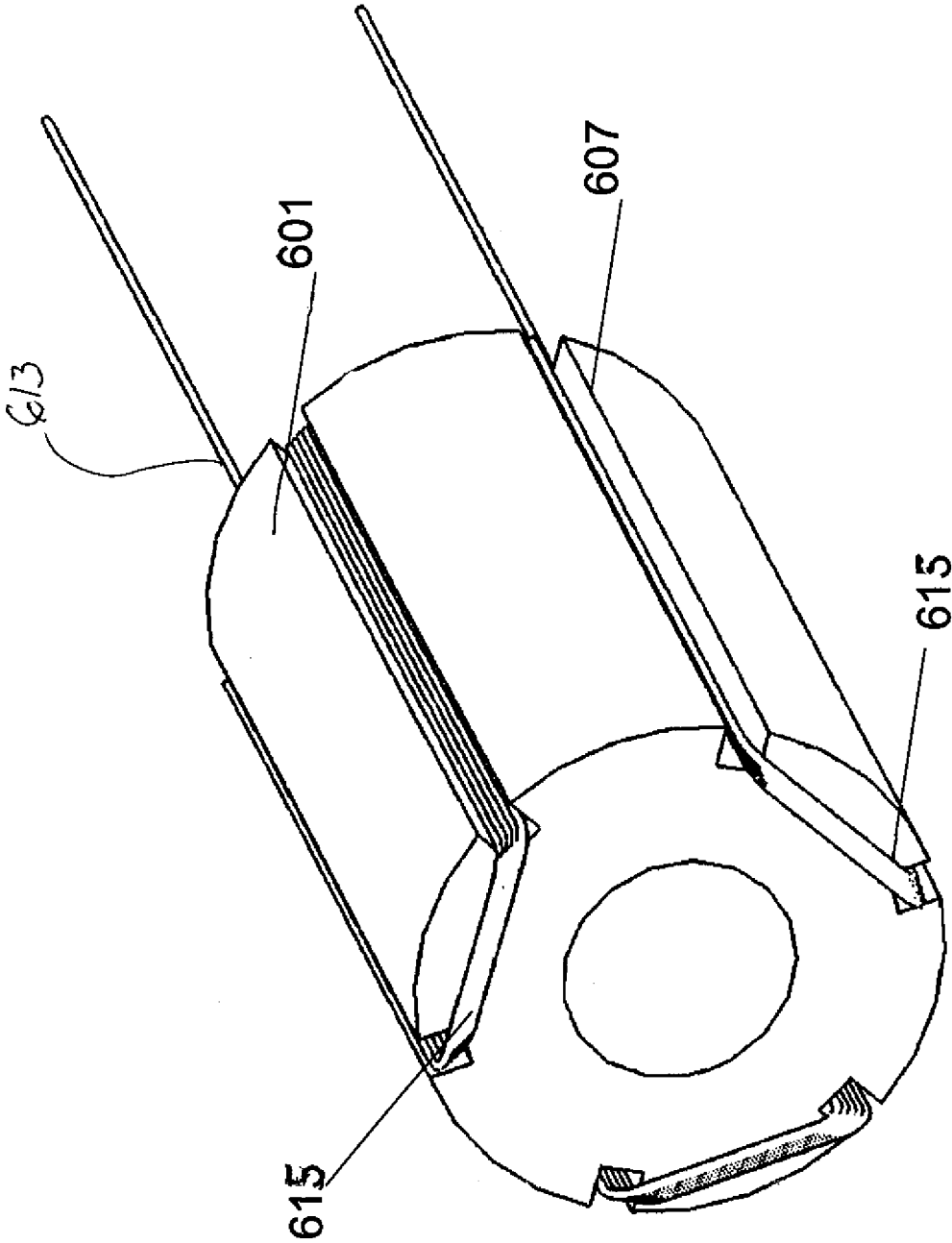


FIG. 6c

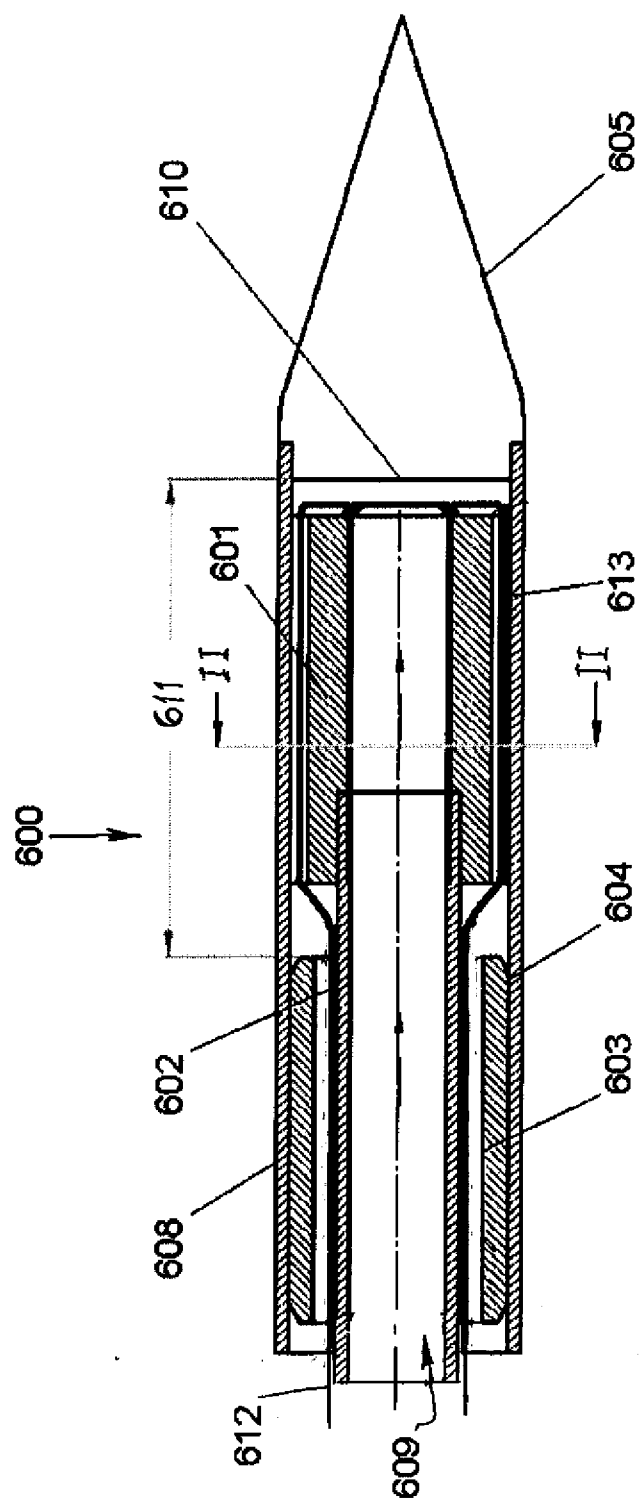


FIG. 6a

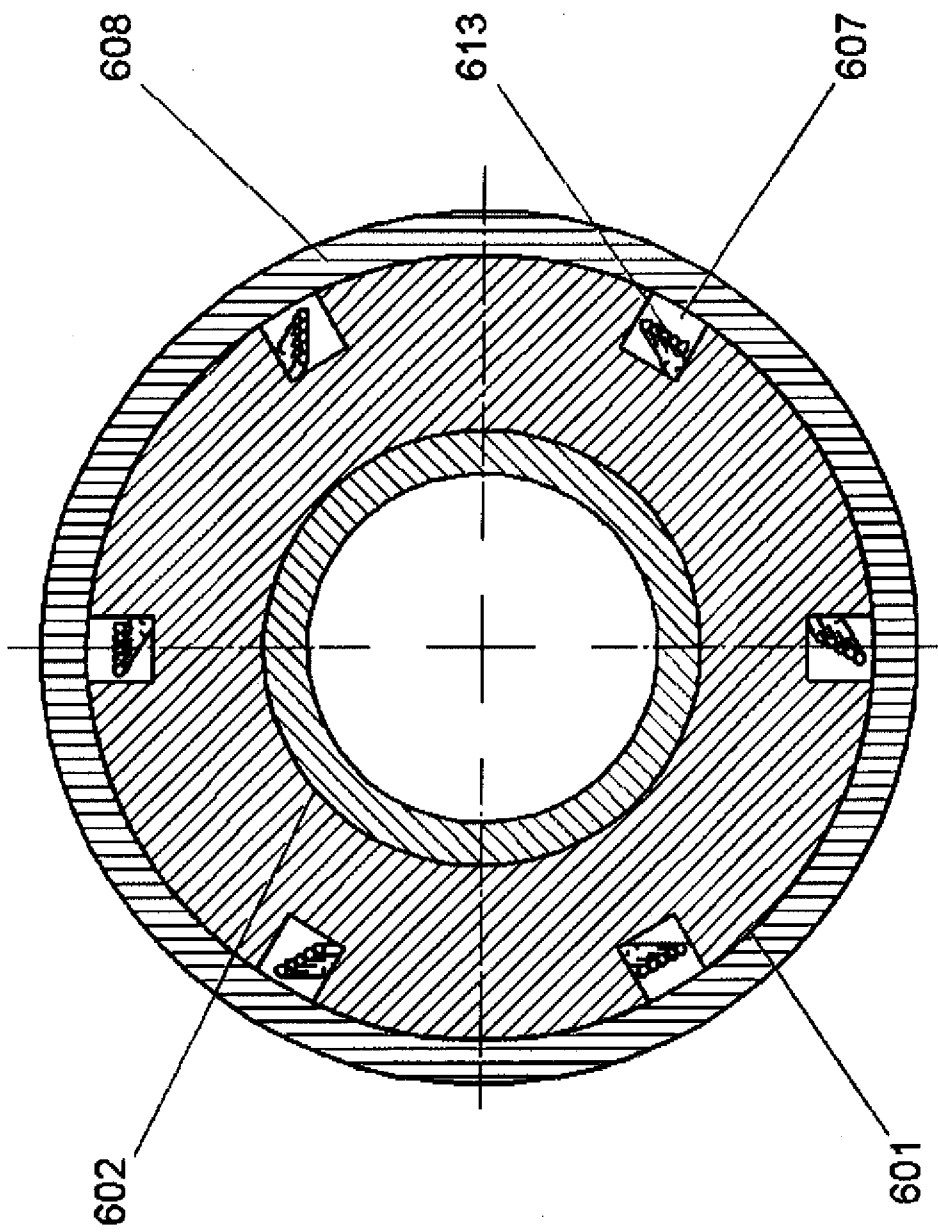


FIG. 6b

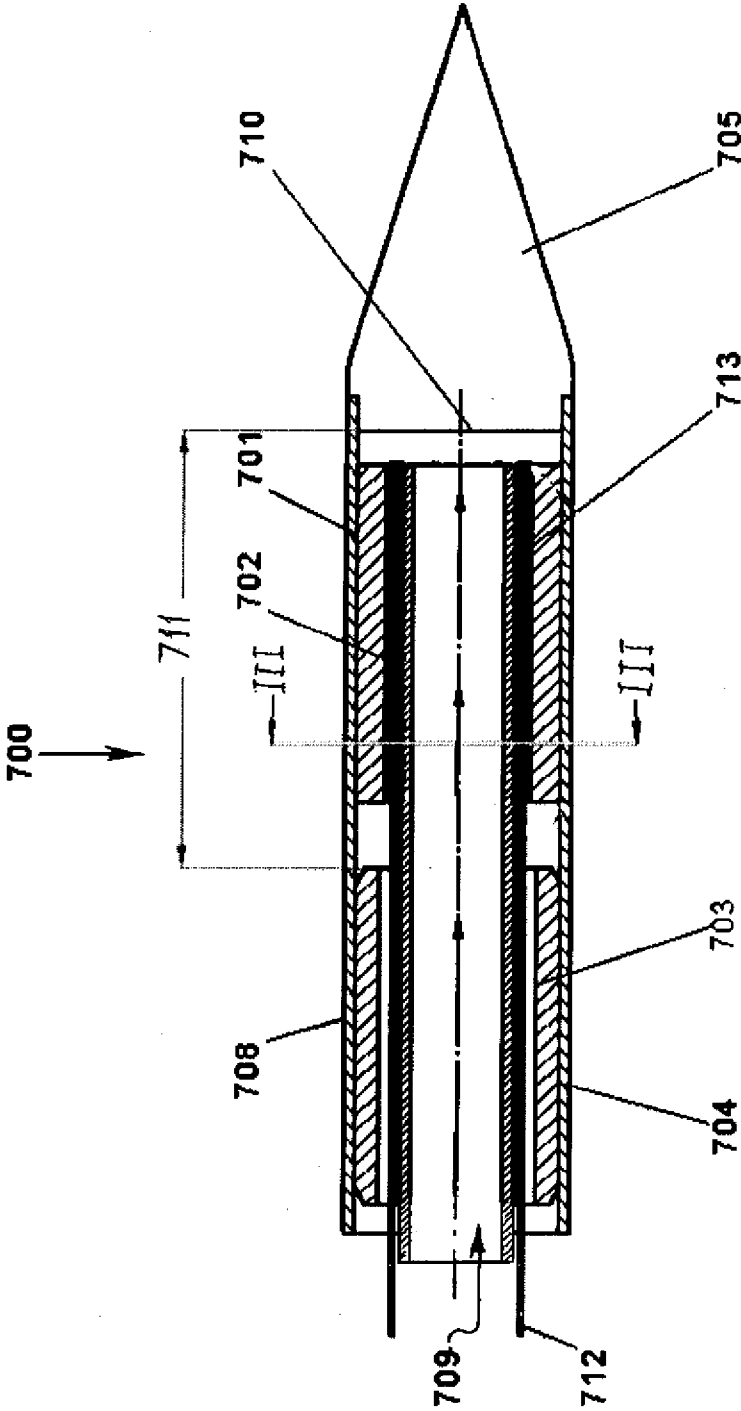


FIG. 7a

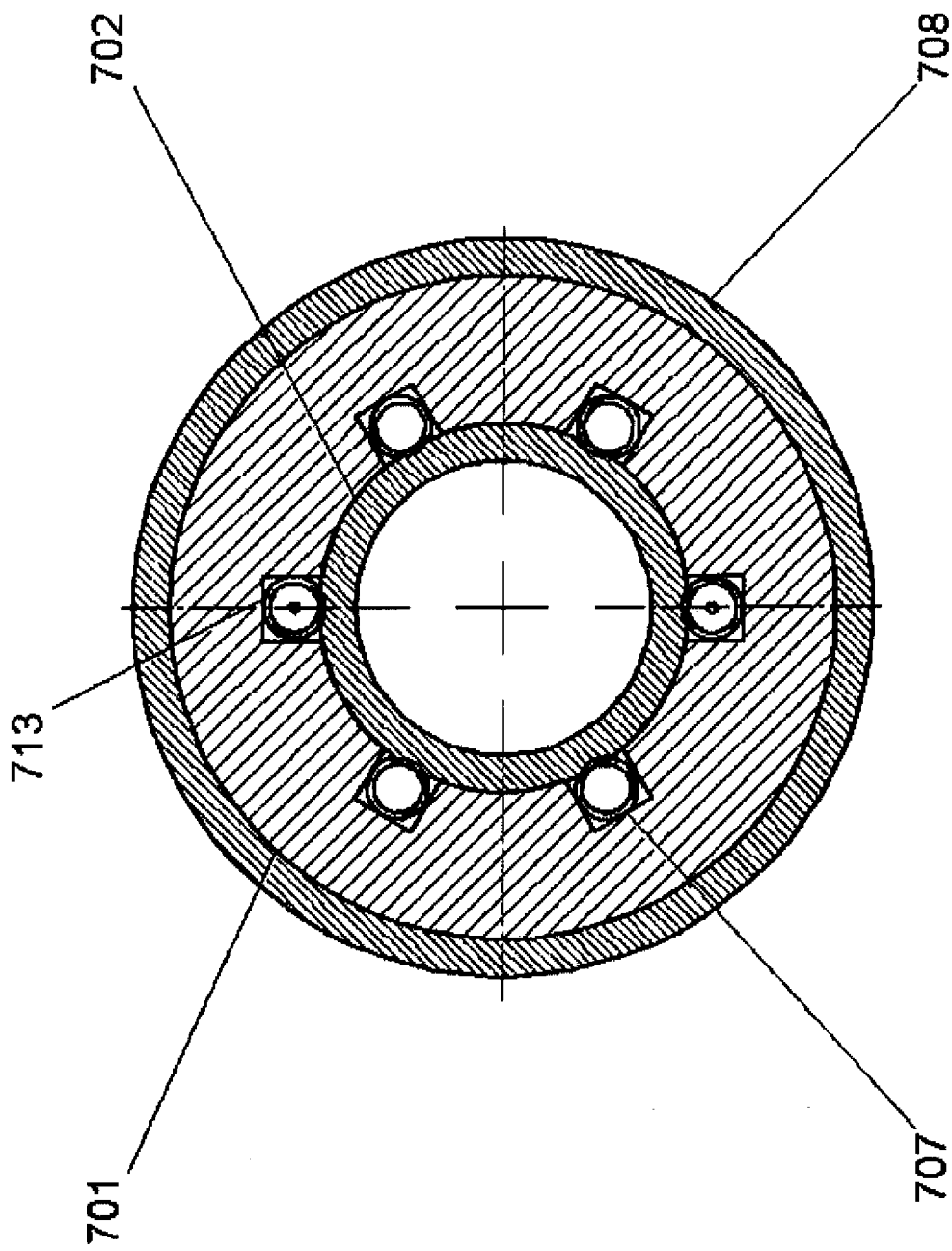


FIG. 7b

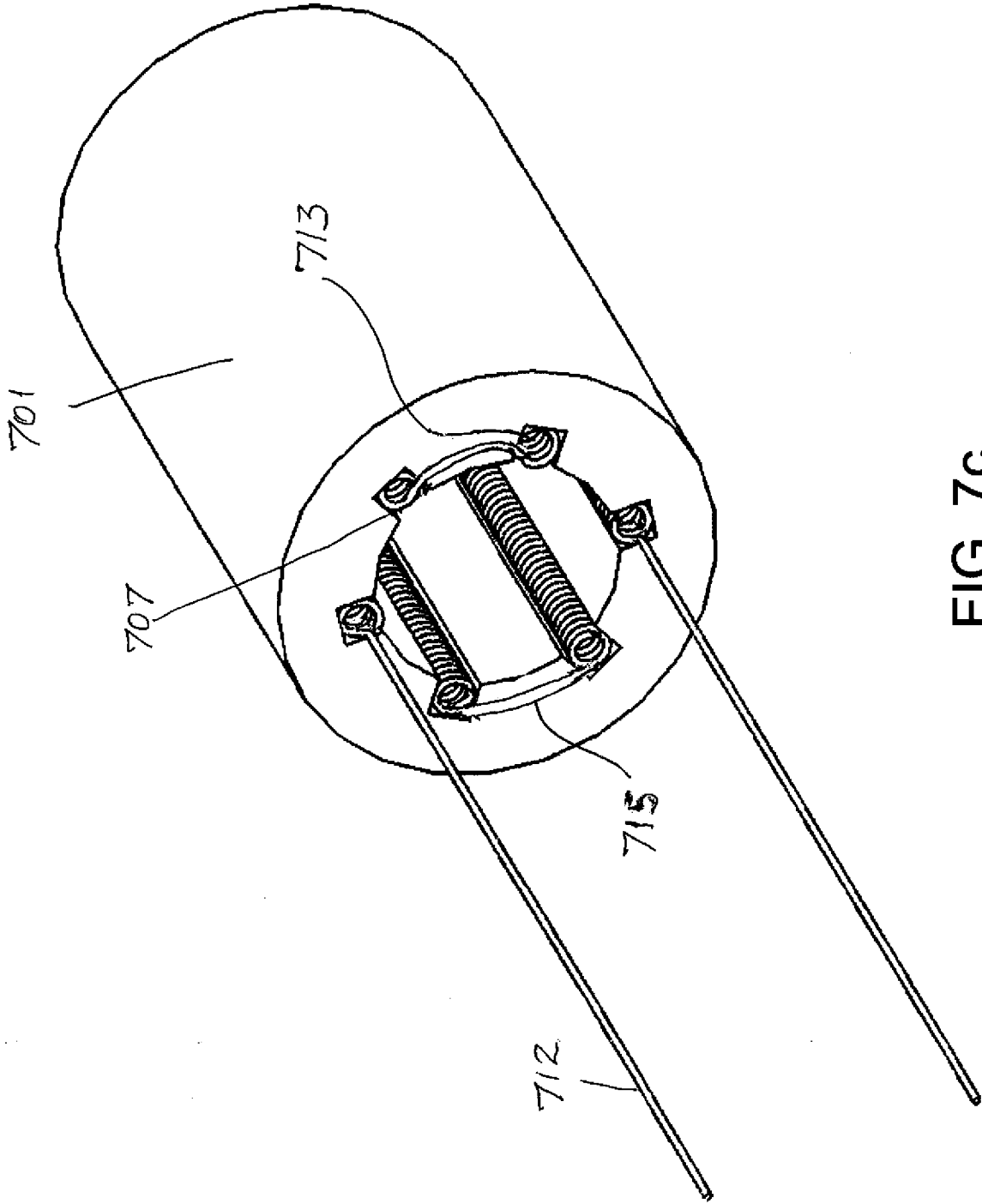


FIG. 7c

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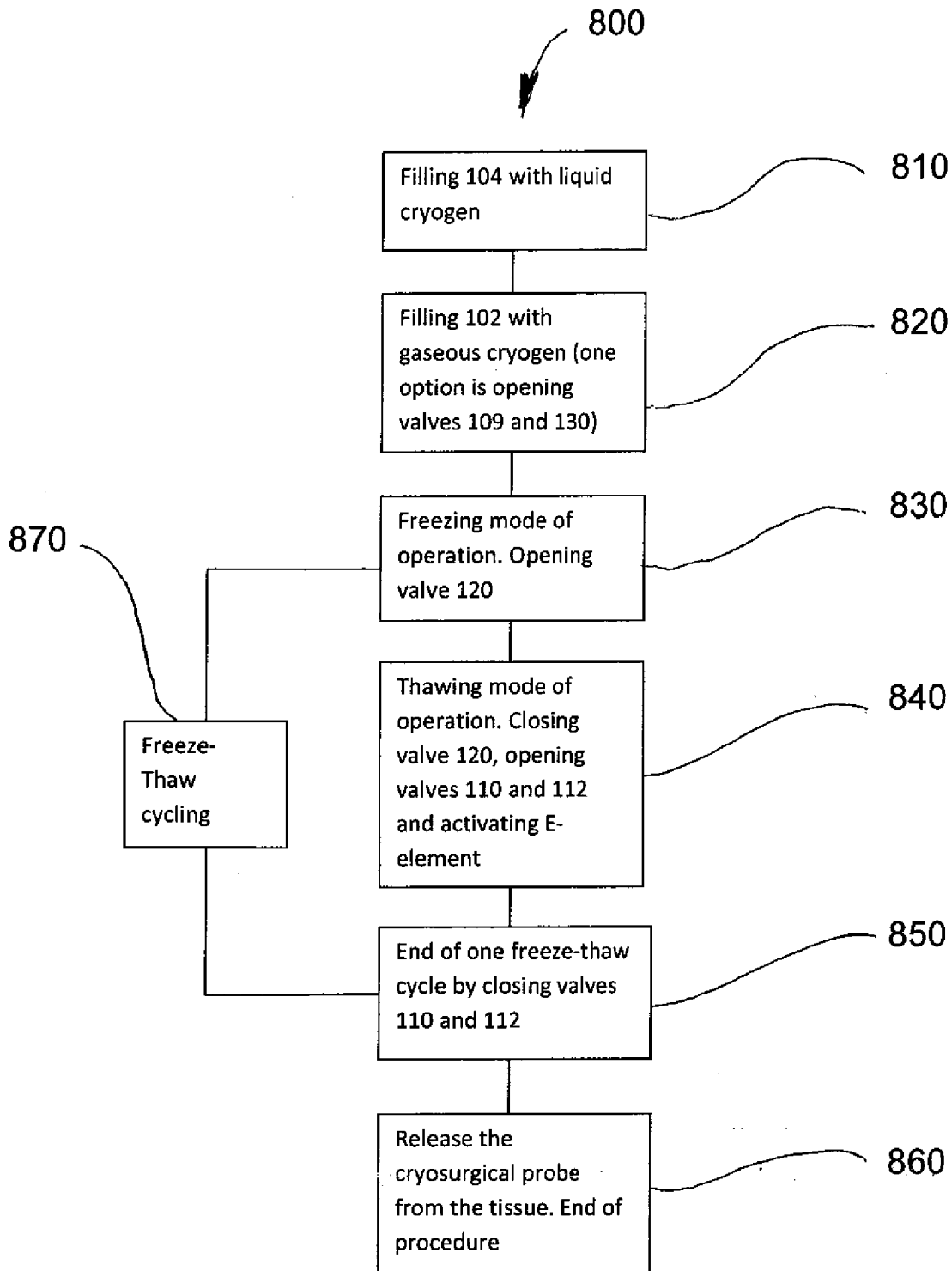


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/031722

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/02
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 860 971 A (CLARKE BRIAN KEVIN RODERICK [GB]) 19 January 1999 (1999-01-19) figures 1-5	1,6,7
X	US 5 674 218 A (RUBINSKY BORIS [US] ET AL) 7 October 1997 (1997-10-07) column 34, line 24 - line 41; figures 5a,5b	1,2,6,7
A	US 2006/122590 A1 (BLIWEIS MORDECHAI [IL] ET AL) 8 June 2006 (2006-06-08) figures 1-3	1-12
A	GB 1 443 069 A (DRAEGERWERK AG) 21 July 1976 (1976-07-21) figure 1	1-12
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

10 August 2011

Date of mailing of the international search report

10/10/2011

Name and mailing address of the ISA/

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Authorized officer

Cornelissen, P

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/031722

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-12

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/031722

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 2007/149959 A1 (DELONZOR RUSSELL L [US] ET AL) 28 June 2007 (2007-06-28) figures 2-8</p> <p>-----</p>	8-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/031722

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5860971	A	19-01-1999	NONE	

US 5674218	A	07-10-1997	NONE	

US 2006122590	A1	08-06-2006	CA 2589475 A1	15-06-2006
			EP 1833396 A2	19-09-2007
			WO 2006061831 A2	15-06-2006

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			FR 2207731 A1	21-06-1974
			IT 1005539 B	30-09-1976

US 2007149959	A1	28-06-2007	US 2011112521 A1	12-05-2011
			WO 2007075930 A2	05-07-2007

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12

a cryosurgical system for freezing and thawing sequentially

2. claims: 13-15

a cryosurgical system in which liquid cryogen and heated gaseous cryogen are mixed
