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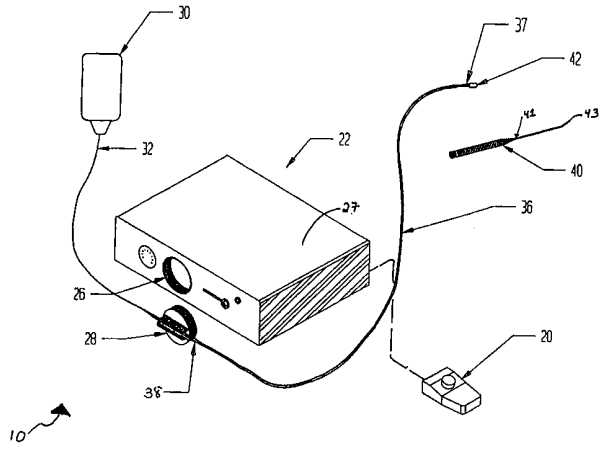

(57) Abstract

The present invention is directed to a system (10) and method for generating a high pressure fluid jet for cutting or drilling into the heart, particularly during TMR/PMR procedures. When used in TMR/PMR procedures, the system (10) preferably includes a variable pressure pump (24) for creating a high–pressure fluid jet which drills channels in the heart at predetermined depths corresponding to the pressure and the duration of the jet, with multiple pulses, increased duration, and/or increased pressure increasing the depth of the channel. The size or diameter of the hole is determined by the stand–off distance of the nozzle (40) from the surgical site, the design of the nozzle (40) and the diameter of the nozzle's orifice (43). The system also preferably includes a console (22) for housing the pump (24) and other control mechanisms which allow the surgeon to input information into the system (10), for example to selectively vary the diameter of the jet stream, the pressure of the jet, the desired depth of the cut into the heart, and the like, thereby allowing the system to be customized by the surgeon depending upon the details of the application. In one embodiment, the drilling solution may contain additives to achieve certain functional purposes.

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FLUID JET CUTTING SYSTEM FOR CARDIAC APPLICATIONS

Field of the Invention

The present application relates to a fluid jet system and method for use in cardiac surgical applications.

Background of the Invention

Fluid jet cutting systems which employ high pressure streams of liquid, such as water, have been utilized in various surgical applications, for example, to disintegrate eye lens tissue (see U.S. pat. no. 3,930,505), to break down and remove tumors (see U.S. pat. no. 5,037,432), and to dislodge, emulsify and remove deposits from a vein or artery (see U.S. pat. no. 5,370,609). The use of waterjets in surgical procedures offers a cost-effective, precise tool which delivers the stream of liquid to the surgical site. As the use of waterjets in surgical applications gains increasing acceptance in the medical community, new instrumentation and techniques are being developed to utilize water jets in new procedures in place of more conventional surgical instrumentation.

Transmyocardial revascularization (TMR) is a procedure used to restore blood flow in patients with vascularization deficiencies in the heart muscle (myocardium). In this experimental procedure, a surgeon cuts or drills a network of holes (channels) through the myocardium of the left ventricle which allows the blood inside the heart to enter the myocardium. Typically, between six to twenty channels, about 1 mm in diameter each, are drilled though the myocardium using a high-powered laser. The channels may either be drilled from the outside of the heart into the ventricle (thoracotomy approach), or from the ventricle outward (percutaneous approach, hereinafter, "PMR"). In the thoracotomy approach, the holes in the surface of the heart are closed by clotting which is promoted either by applying external digital pressure, or by placing epicardial purse-string sutures over the opening. In the percutaneous approach the channel does not penetrate the outer surface of the ventricle.

In the thoracotomy approach (the most common approach to date), in order to drill channels into the heart the surgeon first aims the laser at the targeted site, arms the device, and then fires the laser, preferably between heartbeats (when the heart is gorged with blood), so that the blood in the ventricle will act as a backstop, absorbing the energy of the laser and preventing the laser's energy from inadvertently damaging other tissue. Firing between heartbeats also

results in drilling through the myocardium at the point in the cardiac cycle at which the tissue of the myocardium is the thinnest. The firing of the laser is usually computer controlled from the cardiac waveform to insure that the laser is fired at the appropriate time. Once a channel has been drilled in the heart, it quickly fills with blood from the ventricle. The current view of many researchers is that angiogenic factors, which stimulate the formation of new blood vessels, are released as the blood fills and rapidly coagulates in the drilled channels. Thus, new blood vessels are formed which results in collateral circulation in the previously unhealthy, underperfused myocardium.

Although this procedure is still experimental, it has offered many patients who are not candidates for bypass or angioplasty procedures a viable alternative to medications alone. Currently, however, the use of lasers is the only known effective method with which to drill the holes into the heart. Alternative methods of forming the channels, such as by the use of needles, to date have not met with success. While generally acceptable, the laser equipment is very expensive and generates heat which may adversely affect the surrounding heart tissue (for example, by inadvertently damaging other tissue such as the tissue of a heart valve), beyond the desired channel length.

Summary

The present invention is directed to a system and method for generating a high pressure fluid jet for cutting or drilling into the heart, particularly during TMR/PMR procedures, to provide controlled, accurate and fast drilling with little or no dissipation of heat to surrounding tissue. When used in TMR/PMR procedures, the system preferably includes a variable pressure pump for creating a high-pressure fluid jet which drills channels in the heart at predetermined depths corresponding to the pressure and duration of the jet, with multiple pulses, increased duration, and/or increased pressure increasing the depth of the channel. The size or diameter of the hole is determined by the stand-off distance of the nozzle from the surgical site, the design of the nozzle and the diameter of the nozzle's orifice. The system also preferably includes a console for housing the pump and other control mechanisms which allows the surgeon to input information into the system, for example to selectively vary the diameter of the jet stream, the pressure of the jet, the desired depth of the cut into the heart, and the like, thereby allowing the system to be customized by the surgeon depending upon the details of the application.

The configuration and pressure of the fluid jet may be adjusted according to the particular procedure and desired cut, with the effective diameter of the jet preferably being up to approximately 1 mm in diameter for TMR/PMR procedures. The jet may be delivered as a coherent, hair-thin jet, or may assume other configurations, such as an outwardly spreading spray, or a plurality of jet streams which may converge on a focal point, depending upon the desired orientation and shape of the jet channels. In addition, several inter-changeable instruments or catheters may be provided to allow the surgeon to choose a particular instrument depending upon the particular application. The drilling solution may include water, physiological saline, a liquefied gas such as carbon dioxide, or other drilling media. In one embodiment, the drilling solution may contain additives to achieve certain functional purposes. For example, in TMR/PMR procedures it is believed that angiogenic factors stimulate the formation of new blood vessels, therefore the fluid jet may contain angiogenic factors for inducing vascularization. Other functional additives may include, but are not limited to, contrast agents for image visualization, denaturing agents for strengthening holes drilled in tissues, anti-infectives for treating or preventing infections, drugs to prevent myocardial shock, vasoconstricting compounds to reduce bleeding, anesthetic compounds to reduce pain, solutions of various salts to achieve an electrolyte balance with the blood, and/or other functional additives.

The system also preferably includes a high pressure fluid delivery tube for conducting the pressurized stream to a distal end of the system, to deliver the drilling jet to the myocardium. The delivery tube may be flexible for ease of manipulation by the user, allowing the user to position the fluid jet relative to the heart and also may include means for guiding the tube, such as by a guidewire or a guiding catheter. If the procedure is performed with the thoracotomy or thoroscopic approach (TMR), the distal end of the tube is preferably in the form of an instrument dimensioned to fit through a port of an endoscope. When utilized percutaneously (PMR), the distal end preferably is in the form of a flexible, guidable catheter, preferably with an articulated or movable nozzle, and may also include a metallic tip or marker, so as to be visible by angioscopy.

The variable pressure pump which drives the cutting fluid may preferably include a reusable component and a disposable or limited use component, which allows the portion of the pump which directly contacts the drilling fluid to be separate from the other components. In this manner, the pumped fluid communicates only with the disposable component, allowing for contamination-free reuse of the pumping system by simply replacing a spent disposable

component with a fresh, sterile one. The pump preferably operates in the range of 10 to 50,000 psi, so that the pressure and velocity of the fluid jet can be selectively controlled between a pin-pointing pressure (about 10-500 psi) having no significant drilling affect on the heart, before increasing the pressure to within the drilling range (about 700-50,000 psi) after the target has been pin-pointed by the non-drilling jet. During the TMR/PMR procedure, pinpointing may optionally be utilized to selectively space the channels drilled into the heart, but it is not necessary to pinpoint the target before drilling.

In one embodiment, the pump is designed so that for a given pressure, a single pulse of liquid will drill into the heart at a predetermined depth, for example one pulse may equal a 2 mm deep hole. Multiple pulses are utilized to increase the depth of the cut, for example two pulses in the above example would drill a 4 mm deep hole. In another embodiment, the pump is designed so that the flow of liquid through the pump is continuous with the flow being "gated" or diverted to the surgical site for a controlled duration of time in order to drill into the heart at a predetermined depth, the longer the flow is diverted, the deeper the cut. Both embodiments allow for precise drilling into the heart with the flexibility of increasing the depth of the holes, if necessary.

In one embodiment, the fluid jet system is designed for use in a TMR procedure to drill one or more channels into the myocardium of the heart.

In another embodiment, the fluid jet system is designed for use in a PMR procedure to drill one or more channels into the myocardium of the heart.

In another embodiment, the fluid jet system utilizes a drilling solution containing additives to achieve certain functional purposes.

In another embodiment, the components of the system are detachable allowing for the interchange of various components, as desired.

It is an object of the present invention to provide a fluid jet drilling system for cardiac applications which is operable at high pressures and which may be utilized in TMR and/or PMR procedures.

Brief Description of the Drawings

Various embodiments are described herein with reference to the drawings, wherein:

Fig. 1 is a schematic of a fluid jet drilling system according to the present invention specifically configured for use in surgical applications;

Fig. 2 is an illustration of the variable high pressure pump illustrated in Fig 1;

Fig. 3 is a sectional illustration of the disposable pump cartridge component of the variable high pressure pump; and,

Fig 4 is a top view of a latching mechanism which secures the cartridge to a reusable component of the variable high pressure pump.

Detailed Description of the Preferred Embodiment

A fluid jet cutting system **10** for use in cardiac surgical procedures, for example TMR and/or PMR procedures, is illustrated in Fig. 1. When used in TMR/PMR procedures, the system **10** preferably includes a variable pressure pump **24** (Fig. 2) for creating a high pressure fluid jet which drills channels in the heart at predetermined depths corresponding to the pressure and duration of the jet, with multiple pulses, increased duration, and/or increased pressure increasing the depth of the cut. The system **10** also preferably includes a console **22** for housing the pump and other control mechanisms which allows the surgeon to vary the parameters of the system by inputting information to the control circuitry, for example by the use of dials or buttons on the console. Such parameters may include, for example, the desired pressure and size of the jet, the desired depth of the cut into the heart, or the inclusion of functional additives to the jet, thereby allowing the system to be customized by the surgeon depending upon the details of the application. When utilized in TMR/PMR procedures this allows the surgeon, in one example, to vary the diameter and/or depth of the channels cut into the heart, and allows the surgeon to vary other parameters during the procedure. The system **10** also preferably includes a high pressure fluid delivery tube **36** for conducting the pressurized stream to a distal end of the system adjacent the heart to deliver the fluid jet to the surgical site (heart).

As illustrated in Fig. 1, high pressure delivery tube **36** may be connected at one end **37** to a surgical jet instrument **40**. Surgical instrument **40** preferably includes a body **41** defining a lumen in communication with delivery tube **36**, and further includes one or more jet orifices **43** in communication with the lumen. In one embodiment, the instrument **40** may be designed for thoroscopic use, and as such may preferably be dimensioned to fit through a port of an endoscope. When utilized percutaneously, the instrument **40** may preferably be in the form of a flexible, guidable catheter for ease of manipulation through the arteries leading to the heart thereby allowing the user to manually position the fluid jet relative to the heart. The catheter may preferably include an articulated or movable nozzle, and may be made of a medical-grade plastic

or metal (for example, a shape memory alloy) and may also include a metallic tip or marker, so as to be visible by angioscopy.

Various configurations may be employed for the distal tip **44** of the surgical instrument **40**, depending upon the desired use for the instrument. Preferably, the tip is selectively moldable allowing a surgeon to reshape or bend the jet tip **44** into variable configurations, including angular orientations, to facilitate positioning of the nozzle relative to the surgical site. This feature is especially attractive where the operative field is difficult to reach, allowing the tip of the instrument to reach around obstructions. The surgical instrument, and more particularly the tip of the instrument, preferably has a low-profile, slender configuration to facilitate use of the instrument in small openings and narrow spaces which may confine the operative field. The one or more jet orifice(s) may be disposed axially or transverse with respect to the lumen of the instrument and may be dimensioned as a small diameter opening, in order to produce a hair-thin fluid jet. In the present embodiment, the diameter of the orifice may be in the tenths of millimeters to drill holes up to about 1 mm in diameter. The size or diameter of the hole is determined by the stand-off distance of the nozzle from the surgical site (i.e. the distance between the nozzle and the surgical site), the design of the nozzle and the diameter of the nozzle's orifice. The stand-off distance in the present embodiment is preferably in the range of approximately 0-5 mm and is most preferably approximately 2mm. The surgical instrument may be releasably secured to delivery tube **36** to allow varying instruments to be utilized with the system. For example, instruments having varying diameter orifices, or having different pre-shaped tips may be utilized. Alternatively, the tip of the surgical instrument may be releasably secured to the body of the instrument to allow the tip to be changed.

The surgical instrument delivers the high-pressure fluid jet to the surgical site in a precise manner. The fluid may include water, physiological saline, or a liquefied gas such as carbon dioxide, or other cutting media. In addition, the fluid may be delivered at lower drilling pressures to pinpoint the target and irrigate the surgical site, if desired. The fluid may also contain additives for achieving certain functional purposes. For example, the fluid may contain a contrast agent for image visualization, angiogenic factors for inducing vascularization, denaturing agents for strengthening holes drilled in tissues, anti-infectives for treating or preventing infections, drugs to prevent myocardial shock, vasoconstricting compounds to reduce bleeding, anesthetic compounds to reduce pain, solutions of various salts to achieve an electrolyte balance with the blood, and/or other functional additives. The high pressure delivery tube **36** is connected at a

second end **38** to a pumping system **24** which provides the high pressure cutting fluid to the delivery tube **36** and the instrument **40**.

Fig. 2 illustrates, in detail, the two component pumping system **24** which is preferably housed in console **22,** and which may include both a reusable component **57** and a disposable component **59**. In one embodiment, the pump is designed so that for a given pressure, a single pulse of liquid is delivered which will drill into the heart at a predetermined depth, for example one pulse may equal a 2 mm deep hole. Multiple pulses are utilized to increase the depth of the cut, for example two pulses in the above example would drill a 4 mm deep hole. In another embodiment, the pump is designed so that the flow of liquid through the pump is continuous with the flow being "gated" or diverted to the surgical site for a controlled duration of time in order to drill into the heart at a predetermined depth, the longer the flow is diverted, the deeper the cut. Both embodiments allow for precise drilling into the heart with the flexibility of increasing the depth of the holes, if necessary.

The reusable component preferably includes a reciprocating plunger **60** which pushes against a flexible, disposable diaphragm **86** (Fig. 3) which is part of the disposable pump cartridge **28**. Although a positive displacement, motor-driven plunger is illustrated as the reusable component, other pumping mechanisms, such as an air intensifier, are contemplated as would be apparent to one of ordinary skill in the art. In the present embodiment, the console **22** may also house shaft **52**, driven by a motor **29** which is connected to an eccentric crank **56** mounted on shaft **52**, and which is engaged to one end of an elongated linkage rod **58**. The other end of linkage rod **58** is preferably connected to plunger **60** by pin **62**. Bearings **34** may additionally be provided at each linkage connection to minimize friction between the respective moving parts. The plunger **60** is preferably made of a carbide-containing material or other wear-resistant material as would be apparent to one of skill in the art.

A cylindrical chamber **64**, preferably including a carbide-containing insert, is dimensioned to receive plunger **60**. In the present embodiment, the clearance between the chamber **64** and the plunger **60** is about 0.0002 inches, with the diameter of the plunger being about 0.50 inches. Rotation of shaft **52** causes the eccentric crank **56** to move the linkage rod **58**, thereby reciprocating the plunger within the chamber **64**. The distance between the plunger in an extended position and a retracted position is the length of the stroke. In the present embodiment, the stroke is about 0.1 inches.

The disposable component of pump **24** preferably includes disposable diaphragm cartridge **28,** or piston pump, which is illustrated in Fig. 3. The cartridge **28** preferably includes flexible diaphragm **86**, supported by a semi-rigid cone **87** which is mounted in a conical recess disposed in the lower surface **88** of cartridge **28**. A variable sized pumping chamber **89** is defined by the deformable diaphragm for receiving cutting fluid therein. When disposed within console **22**, the diaphragm is preferably seated against the mouth of cylindrical chamber **64** so that retraction and extension of the plunger will cause the diaphragm to flex between a fill and an ejection stroke to pump the fluid from the fluid source, into the pumping chamber and to the delivery tube **36**, as described in greater detail below. The diaphragm is preferably made from a medical grade polyurethane, while the semi-rigid cone may be made of type 304 or 316 stainless steel, or a polymer such as fiber-filled hard plastic, the cone preferably being bonded or press fit into position.

The pump cartridge **28** may be mounted into a compatible socket or opening **26** (Fig. 1) in the console housing **27** and may be securely retained in the console by a locking lever **140** and latch **148**, side views of which are shown in Fig. 2. A safety switch (not shown) may also be provided on the lever to prevent the operation of the pump when the lever is in the unlocked position. Fig. 4 shows a top view of an exemplary latching mechanism.

The cartridge further includes an inlet passage **100** which preferably extends between an inlet port **101** communicable with a sterile source of fluid and the flexible pumping chamber **89,** and also includes an outlet passage **112** which preferably extends between an outlet port connected to one end of high pressure delivery tube **36**, and the pumping chamber **89**. In the present embodiment, the inlet port **101** is connected to one end a fluid delivery tube **32**. Delivery tube **32** is connected at its other end to the source of cutting fluid, such as a saline bag **30** suspended from an IV pole (Fig. 1). A one way valve **98** may preferably control the flow of fluid into the chamber during the fill stroke, while preferably preventing backflow into the sterile fluid source. A one-way valve **114** may, likewise, control the flow of pumped fluid out of the pumping chamber during the ejection stroke.

The operation of the system will now be described. The system is first prepared by the user who inserts the pump cartridge **28** into the console housing prior to surgery, with the cartridge aligned so that the diaphragm **86** drapes over the chamber **64**. The user then secures the cartridge to the console by engaging the locking lever **140** with the latch **148** which also acts to deactivate the safety switch and compresses the seal between the diaphragm **86** and cone **87** in

a leaktight fashion. A tube **32** running from a fluid bag may then be connected to the inlet of the cartridge and the burst-resistant delivery tube **36** may be attached to the outlet of the cartridge.

For TMR/PMR procedures, the drilling site on the heart muscle (myocardium) is identified and the patient is anesthetized and prepped in a conventional manner. If the procedure is thoroscopic, a trocar is inserted through the rib cage of the patient, and an endoscope is place through the trocar to provide visualization of the heart muscle through the endoscope. The desired surgical jet instrument is chosen and may then be inserted through a port on the endoscope. Alternatively, if the procedure is percutaneous, the surgical jet instrument is provided in the form of a flexible, guidable catheter, preferably with an articulated or movable nozzle. To deliver the surgical jet catheter percutaneously, it is typically inserted through the femoral artery, into the aorta and then into the left ventricle. The catheter preferably includes a metallic tip or metallic marker so that the catheter is visible by angioscopy as it is inserted into the femoral artery and advanced to the surgical site.

In either case, upon delivering the instrument to the surgical site, the user may pre-select either a non-drilling or drilling pressure, depending upon whether pinpointing the target prior to drilling is desired. If pinpointing is desired, the jet beam is introduced at a low, non-drilling pressure while the drilling site is pin-pointed. When the jet beam and target coincide, the pressure of the stream may be increased to within the drilling range of pressure to drill a hole in the myocardium.

The drilling pressure is pre-selected to drill a hole only through the wall intended for drilling, so as to not injure other parts of the heart. The depth of the hole corresponds to the pressure and the pulse duration of the of the fluid jet, with multiple pulses increasing the depth of the hole, or for gating the longer the flow is diverted, the deeper the cut. The user may select the desired depth by turning the appropriate control knob to the desired depth, as indicated on the control console. The size or diameter of the hole is determined by the stand-off distance of the nozzle from the surgical site, the design of the nozzle and the diameter of the nozzle's orifice. The stand-off distance in the present embodiment is preferably between 0-5 mm and is preferably 2mm.

As the user activates the system the plunger will begin to retract, thus reducing the pressure in the pumping chamber. The reduced pressure causes the inlet check-valve to open, allowing sterile fluid to fill the pumping chamber. Extending the plunger increases the pressure

in the pumping chamber, opening the outlet check-valve and driving the pressurized fluid out through the outlet check-valve, into the delivery tube and ultimately, the surgical instrument. In one embodiment, the pressurized fluid flows out of the instrument as a single pulse, while in another embodiment, the flow of liquid is continuous through the pump with the flow being diverted to the surgical site for a controlled duration of time. The pump speed may be selectively controlled by the user via a control dial, a foot **20** or hand switch (not shown), allowing the pressure and cutting strength of the fluid jet to be varied, during the procedure, as desired.

Once the system is ready and the instrument has been delivered to the surgical site, the target is ready to be drilled. To drill the target, the instrument is triggered by the user to deliver the drilling jet to heart. Preferably, blood is entrained in the fluid jet as the hole is drilled. Entraining the blood allows the holes to fill more rapidly with blood, thus promoting the angiogenic factors and the formation of new blood vessels. Other functional additives may also be introduced into the fluid jet at this time, as described above. If the procedure is percutaneous, once in the ventricle the cutting jet is delivered at a pre-selected pressure for drilling only the myocardium, and preferably through most of the myocardium, but not for complete penetration. In the thoroscopic approach, the cutting jet is delivered at a pre-selected pressure for drilling the myocardium, and preferably complete penetration of the myocardium is achieved. Penetration may be timed to occur between heartbeats, if desired, but this is not necessary. Once a hole has been drilled, the surgeon then moves the instrument to the next position to drill the next hole and repeats the process until, preferably, a plurality of holes are drilled according to the needs of the patient.

Upon completion of a surgical procedure, the disposable pump head is detached from the reusable console and discarded or resterilized for reuse. The plunger, which does not contact the sterile fluid, may then be reused with a new, sterile pump cartridge.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the dimensions of the instrument may be readily altered by one of skill in the art. In addition, the system may be utilized in a variety of surgical procedures, other than TMR/PMR. Therefore, the above description should not be construed as limiting, but merely as exemplifications of a preferred embodiment. Those skilled in the art will envision other modifications within the scope spirit of the invention.

Claims

1. A method of drilling into tissue of the heart, comprising the steps of:

providing a fluid jet drilling system for delivering a high-pressure fluid, the system including a pump and a delivery device having at least one orifice configured and dimensioned to deliver the drilling fluid to the heart;

inserting the instrument into a patient;

placing the nozzle of the instrument adjacent to the myocardium at a desired drilling location;

delivering the fluid from a fluid source into the pump;

driving the fluid through the pump;

delivering the high pressure fluid from the pump to the delivery device and through the orifice to the drilling location; and

drilling a hole in the heart by contacting the myocardium with the high-pressure fluid exiting the orifice.

2. The method according to claim 1, wherein the depth of the cut is a function of the fluid pressure and duration of delivery of the high-pressure fluid.

3. The method according to claim 1, wherein the diameter of the drilled hole is a function of the stand-off distance between the nozzle and the surgical site and the diameter of the orifice.

4. The method according to claim 1, further comprising the step of pumping the liquid at a predetermined pulse, wherein the pulse determines the depth of the cut.

5. The method according to claim 1, further comprising the step of diverting the flow of liquid from the pump to the delivery device for a pre-determined duration, wherein the duration determines the depth of the cut.

6. The method according to claim 1, further comprising the step of delivering a low-pressured fluid to pinpoint the drilling location on the heart.

7. The method according to claim 1, further comprising the step of drilling a channel through the myocardium of the heart into the left ventricle.

8. The method according to claim 7, further comprising the step of entraining blood in the cutting fluid and through the channel drilled in the myocardium.

9. The method according to claim 1, further comprising the step of providing a functional additive into the drilling fluid.

10. The method according to claim 9, wherein the functional additive is an angiogenic factor for promoting growth of blood vessels.

11. The method according to claim 9, wherein the functional additive is a contrast agent for image visualization.

12. The method according to claim 9, wherein the functional additive is a denaturing agent for strengthening the drilled hole.

13. The method according to claim 9, wherein the functional additive is an anti-infective for preventing infections.

14. The method according to claim 9, wherein the functional additive is a vasoconstricting compound for reducing bleeding.

15. The method according to claim 9, wherein the functional additive is an anesthetic compound for reducing pain.

16. The method according to claim 9, wherein the functional additive is a salt solution for achieving an electrolyte balance with the blood.

17. The method according to claim 1, wherein the step of inserting the instrument into the patient is achieved percutaneously.

18. The method according to claim 17, wherein the delivery device is in the form of a flexible catheter.

19. The method according to claim 18, wherein at least a portion of the catheter is metallic.

20. The method according to claim 1, wherein the step of inserting the instrument into the patient is achieved thoroscopically.

21. The method according to claim 20, wherein the delivery device is in the form of an instrument configured and dimensioned for insertion through a trocar.

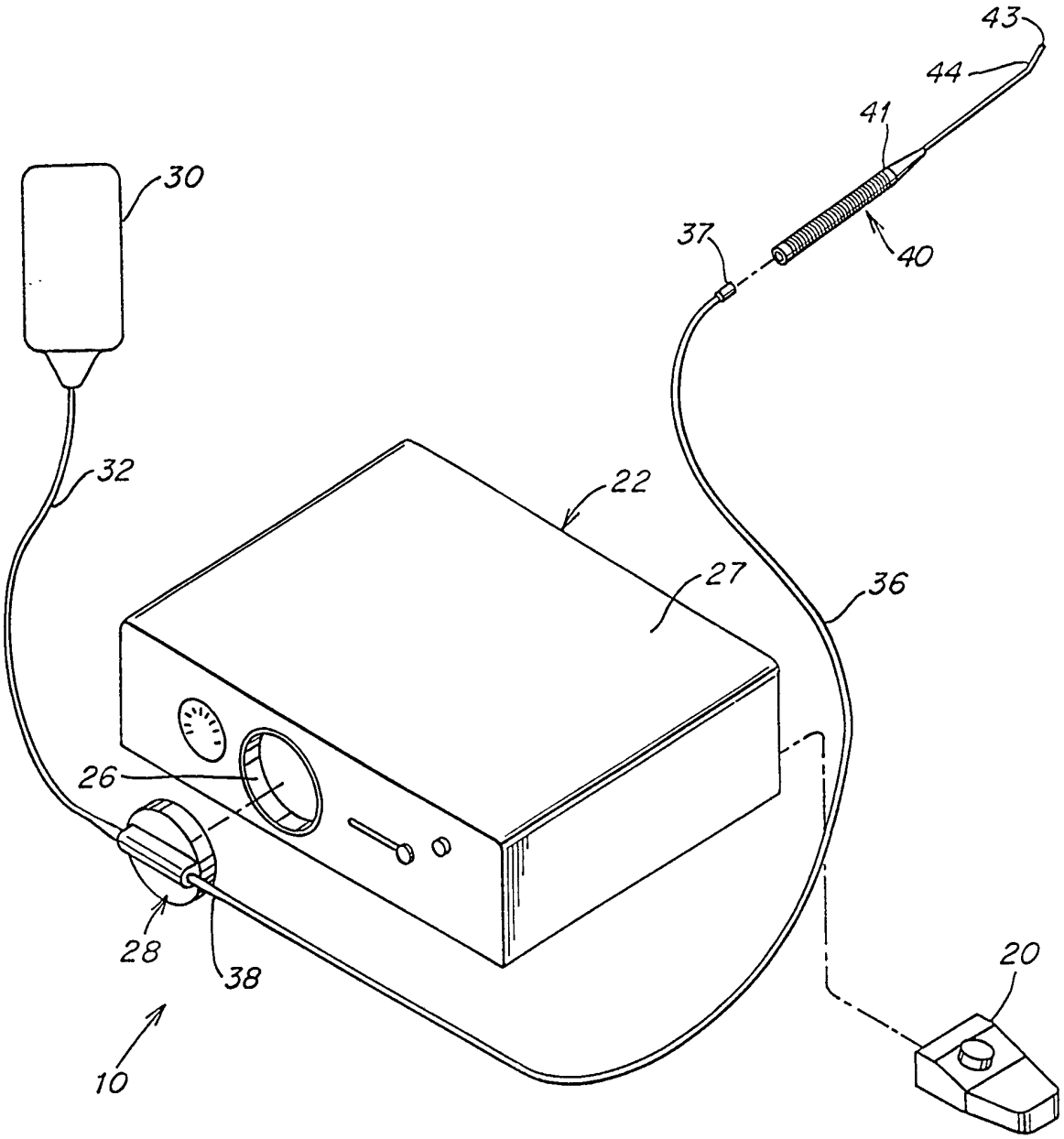

Fig. 1

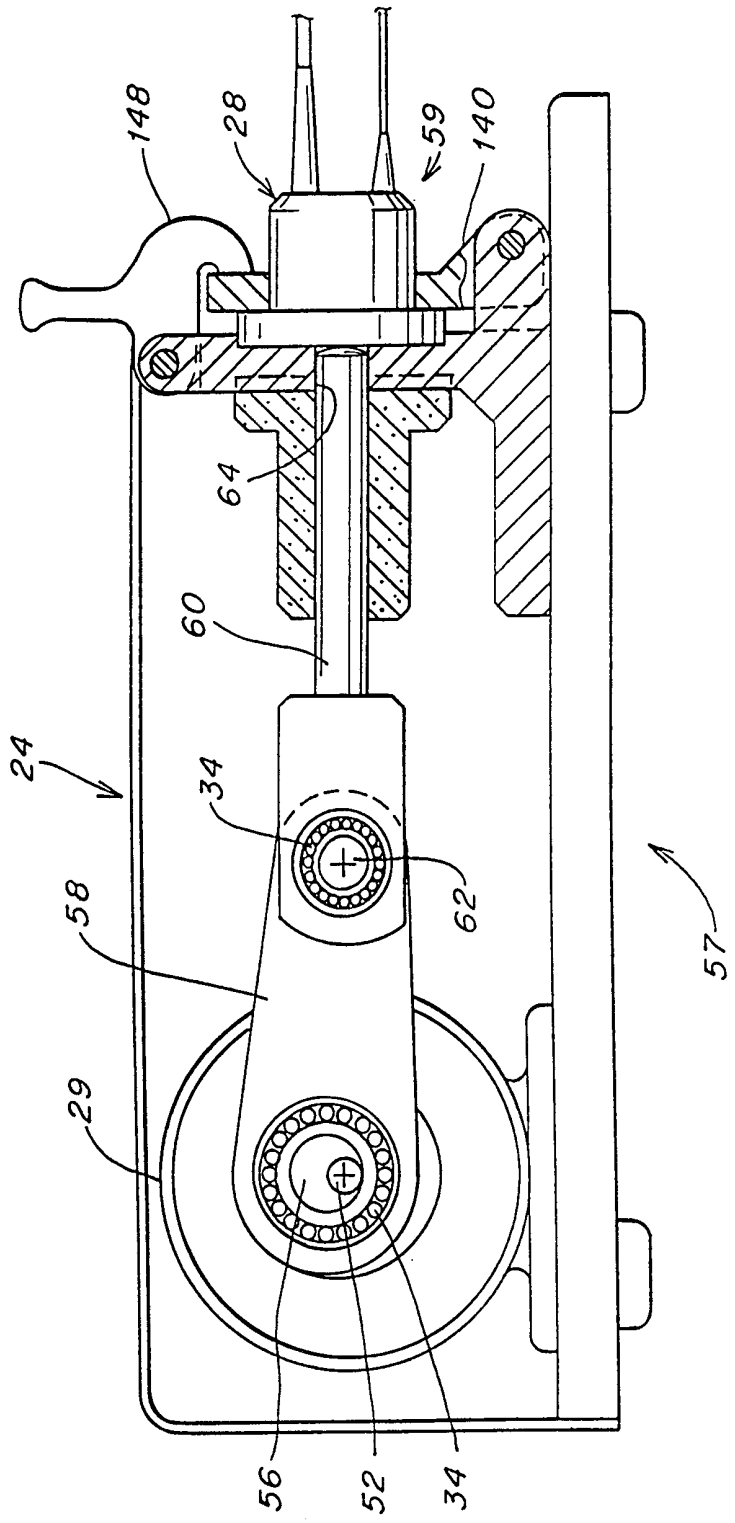

Fig. 2

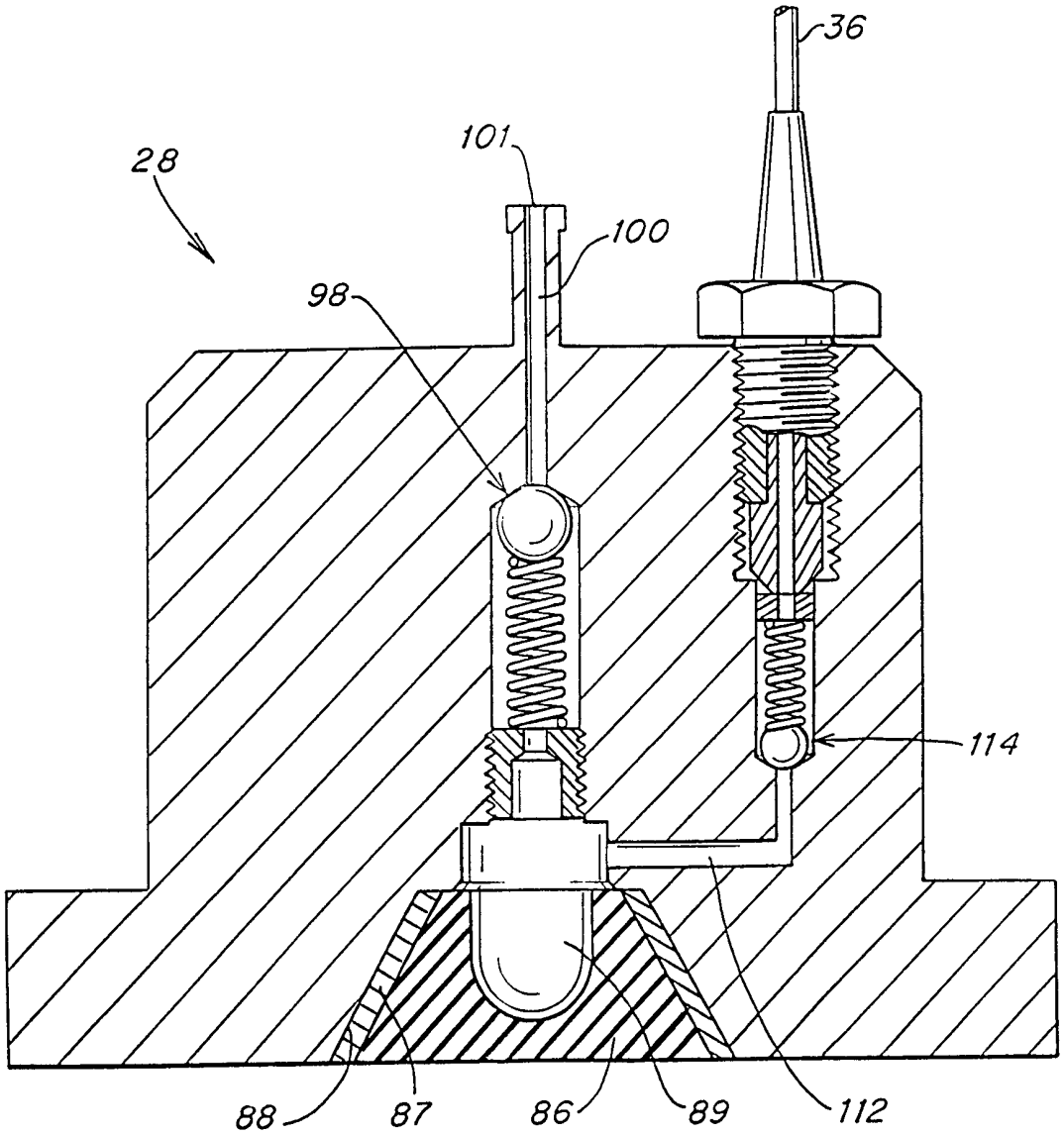

Fig. 3

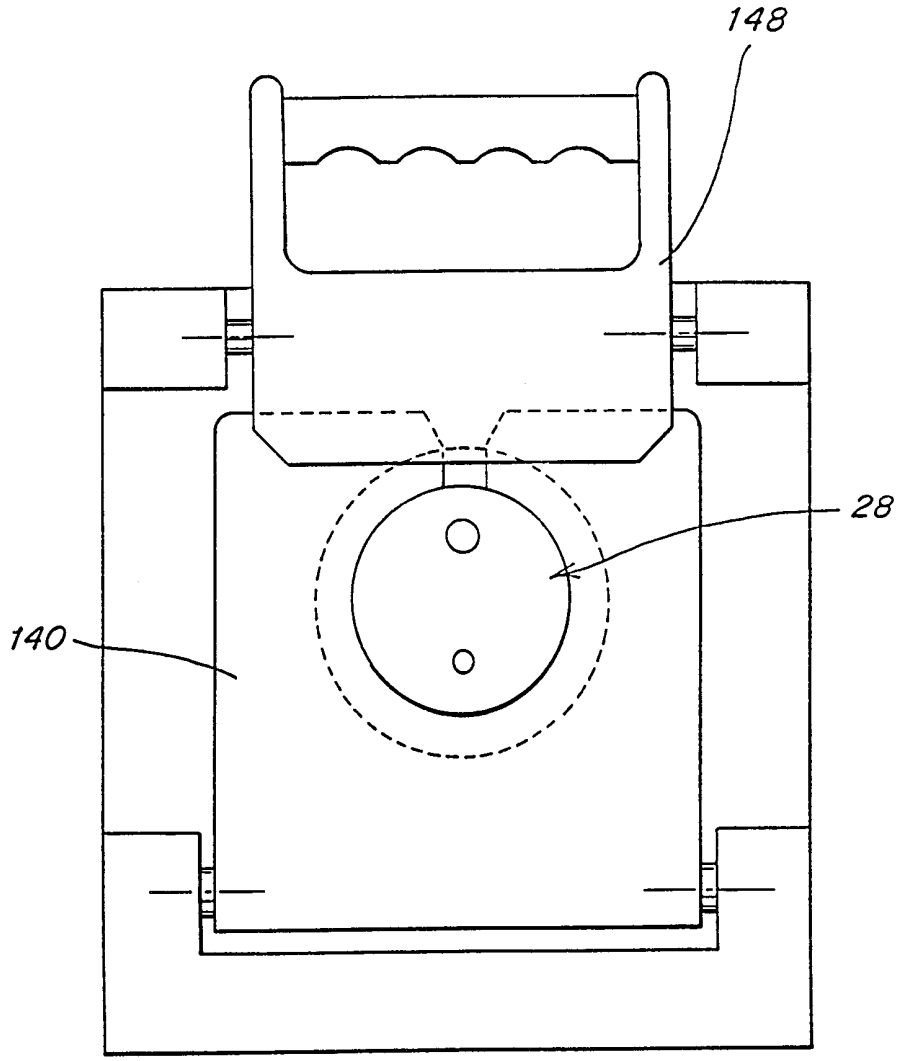

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/27824

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 31/00
US CL : 604/506
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/19, 22, 27, 49, 264, 500, 506, 507; 606/15-19, 167

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 practicable, search terms used)

APS, Derwent, Proquest-MEDLINE
Search Terms: water jet, fluid jet, transmyocardial revascularization (TMR)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, E	US 5,871,462 A (YODER et al.) 16 February 1999, col. 1 lines 25-28; cols. 1 and 2 lines 1-12 and 65-68; col. 3 lines 45-68; and col. 4 lines 5-7.	1-6, 9, 11, 14, 15, 18, 19, 21
Y	US 4,658,817 A (HARDY) 21 April 1987, col. 5 lines 27-45.	7, 8, 20
Y	US 5,389,096 A (AITA et al.) 14 February 1995, col. 2 lines 65-68; and col. 3 lines 1-9	17
Y	US 5,074,862 A (RAUSIS) 24 December 1991, col. 3 lines 38-43.	12, 13, 16
Y, P	US 5,792,453 A (HAMMOND et al.) 11 August 1998, Abstract.	1-21

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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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	Date of mailing of the international search report
13 MAY 1999	02 JUN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JENNIFER MAYNARD Telephone No. (703) 305-1356

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/27824

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,380,316 A (AITA et al.) 10 January 1995, Abstract.	1-21
A	US 4,913,698 A (ITO et al.) 03 April 1990, cols. 1 and 2 lines 1-9, and 39-68.	1-21
A	US 5,135,482 A (NERACHER) 04 August 1992, cols. 3 and 4.	1-21
A, P	US 5843996 A (WEGLICKI) 01 December 1998, Abstract.	1-21
A, P	GOMBOTZ, H. et al., British Journal of Anaesthesia, London, Methods for reduction of perioperative bleeding, December 1998. Volume 81, pages 1-7.	1-21