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- (71) Applicant: **MEDTRONIC VASCULAR, INC.** [US/US];
3576 Unocal Place, Santa Rosa, CA 95403 (US).
- (72) Inventors: **NASH, Stephen, G.**; 3576 Unocal Place, Santa Rosa, CA 95403 (US). **KELLY, Brian, J.**; 3576 Unocal Place, Santa Rosa, CA 95403 (US).
- (74) Agent: **HELDING, Gregory, T.**; Michael Best & Friedrich LLP, 790 N. Water Street, Suite 2500, Milwaukee, WI 53202-4108 (US).
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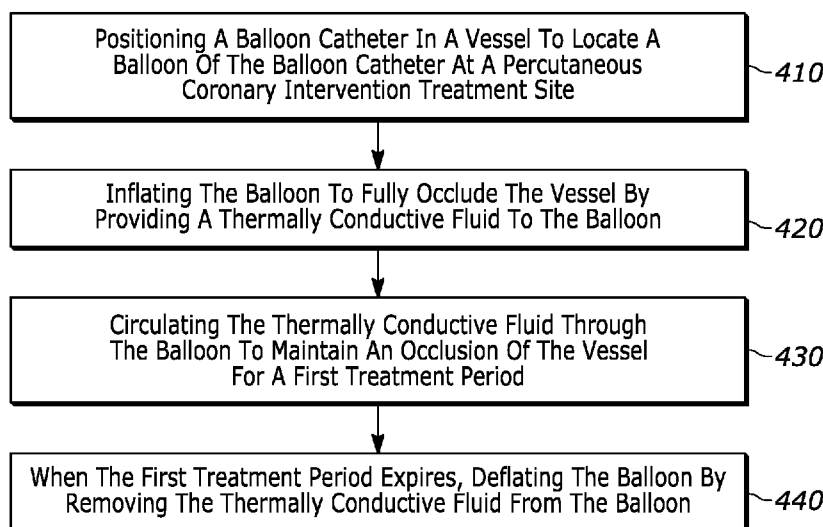


FIG. 4

(57) Abstract: A medical treatment system. One example system includes a balloon catheter and an electronic processor. The catheter includes: a balloon; an inflow lumen positioned within an interior of the balloon; and an outflow lumen positioned within the interior of the balloon. The electronic controller is coupled to the catheter and configured to, when the catheter is positioned in a vessel such that the balloon is located at a percutaneous coronary intervention treatment site, control a pump to inflate the balloon to fully occlude the vessel by providing a thermally conductive fluid to the balloon via the inflow lumen. The electronic controller is configured to circulate the fluid through the balloon to maintain an occlusion of the vessel for a first treatment period. The electronic controller is configured to, when the first treatment period expires, deflate the balloon by removing the fluid from the balloon via the outflow lumen.

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INTRAVASCULAR CRYOTHERAPY TO REDUCE REPERFUSION INJURY AND MICROVASCULAR OBSTRUCTION IN POST ST-ELEVATED MYOCARDIAL INFARCTION (STEMI) TREATMENT**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] The present application is related to and claims benefit from U.S. Provisional Patent Application Serial No. 63/508,614, filed June 16, 2023, entitled “Intravascular Cryotherapy to Reduce Reperfusion Injury and Microvascular Obstruction in Post ST-Elevated Myocardial Infarction (STEMI) Treatment,” the entire contents of which is incorporated herein by reference.

FIELD

[0002] The present technology is generally related to methods and systems for using cryotherapy to treat cardiac tissue after an ST-Elevated Myocardial Infarction (STEMI).

SUMMARY

[0003] Percutaneous coronary intervention (PCI) methods are used to treat ST-Elevated Myocardial Infarction (STEMI). Catheters are used to perform treatments, such as angioplasty, dilation, and the like. An operator (e.g., a physician) directs a catheter through a vein or artery into the interior region of the heart near the targeted cardiac tissue that is to be treated, such as a pulmonary vein ostium or atrial wall. In some treatments, a balloon is inflated to stretch open a narrow or blocked vessel, insert a stent, or both.

[0004] Some patients develop microvascular obstruction (MVO) despite successful treatment of a myocardial infarction with primary percutaneous coronary intervention. One factor leading to the development of MVO post STEMI is reperfusion related injury and distal embolization. MVO can lead to further damage can occur to the myocardium muscle. The presence of MVO is also linked to negative remodeling of the coronary artery and left ventricular dysfunction. These outcomes can lead to decreased long-term survival, increased morbidity, and reduced quality of life. Treatments beyond traditional percutaneous coronary intervention methods are needed.

[0005] Therapeutic hypothermia has been shown to reduce the incidence of MVO in patients experiencing STEMI. Current methods focus on reducing core body temperature. Some methods use external means (e.g., cooling blankets, gel pads, and ice packs), while other use internal methods, such as injecting cooled saline or through the use of central intravascular cooling

means. However, these methods are clinically inefficient and fail to target hypothermia to particular areas of tissue under treatment.

[0006] To address these problems, examples and aspects presented herein use an intravascular cryotherapy catheter positioned within an infarct related vessel to cool surrounding cardiac tissue to reduce inflammation and cellular metabolism of ischemic cells. In some aspects, the infarct vessel is opened, and an intravascular cryotherapy catheter is positioned in the infarct related vessel (either proximal or distal of the opened blockage). In some aspects, the cryocatheter allows for the normal flow of the artery to be preserved while lowering the temperature of the blood flowing distally and lowering the temperature of the surrounding muscle, which is in the area at risk.

[0007] In some aspects, the techniques described herein relate to a medical treatment system, the system including a balloon catheter and an electronic processor. The balloon catheter includes: a balloon; an inflow lumen positioned within an interior of the balloon; and an outflow lumen positioned within the interior of the balloon. The electronic controller is coupled to the balloon catheter and configured to, when the balloon catheter is positioned in a vessel such that the balloon is located at a percutaneous coronary intervention treatment site, control a pump to inflate the balloon to fully occlude the vessel by providing a thermally conductive fluid to the balloon via the inflow lumen. The electronic controller is configured to control the pump to circulate the thermally conductive fluid through the balloon via the inflow lumen and the outflow lumen to maintain an occlusion of the vessel for a first treatment period. The electronic controller is configured to, when the first treatment period expires, control the pump to deflate the balloon by removing the thermally conductive fluid from the balloon via the outflow lumen.

[0008] In some aspects, the techniques described herein relate to a method for operating a medical treatment device. The method includes positioning a balloon catheter in a vessel to locate a balloon of the balloon catheter at a percutaneous coronary intervention treatment site. The method includes inflating the balloon to fully occlude the vessel by providing a thermally conductive fluid to the balloon. The method includes circulating the thermally conductive fluid through the balloon to maintain an occlusion of the vessel for a first treatment period. The method includes, when the first treatment period expires, deflating the balloon by removing the thermally conductive fluid from the balloon.

[0009] The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the techniques described in this disclosure will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The accompanying figures, where like reference numerals refer to identical or functionally similar elements throughout the separate views, which together with the detailed description below are incorporated in and form part of the specification and serve to further illustrate various embodiments of concepts that include the claimed embodiments, and to explain various principles and advantages of aspects of those embodiments.

[0011] FIG. 1 is schematic illustration of an example vascular denervation system in accordance with some embodiments.

[0012] FIG. 2 is a block diagram that illustrates an electronic controller of the system of FIG. 1 in accordance with some embodiments.

[0013] FIG. 3 illustrates aspects of the operation of embodiments of the system of FIG. 1.

[0014] FIG. 4 is a flowchart illustrating a method for operating the system of FIG. 1 in accordance with some embodiments.

[0015] Skilled artisans will appreciate that elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.

[0016] The apparatus and method components have been represented where appropriate by conventional symbols in the drawings, showing only those specific details that are pertinent to understanding the embodiments of the present invention so as not to obscure the disclosure with details that will be readily apparent to those of ordinary skill in the art having the benefit of the description herein.

DETAILED DESCRIPTION

[0017] Specific embodiments of the present disclosure are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms “distal” and “proximal” are used in the following description with respect to a position or direction relative to the treating clinician. “Distal” or “distally” are a position distant from or in a direction away from the clinician. “Proximal” and “proximally” are a position near or in a direction toward the clinician.

[0018] Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways.

[0019] Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The terms “mounted,” “connected,” and “coupled” are used broadly and encompass both direct and indirect mounting, connecting, and coupling. The terms “connected” and “coupled” are not restricted to physical or mechanical connections or couplings, and can include electrical connections or couplings, whether direct or indirect. Electronic communications and notifications described herein may be performed using any known or future-developed means including wired connections, wireless connections, etc.

[0020] For ease of description, some or all of the example systems presented herein are illustrated with a single exemplar of each of its component parts. Some examples may not describe or illustrate all components of the systems. Other embodiments may include more or fewer of each of the illustrated components, may combine some components, or may include additional or alternative components.

[0021] FIG. 1 illustrates an example system 10 that is suitable for performing, among other things, vascular cryotherapy. The system 10 is for applying cryotherapy to an area of target tissue (e.g., an area of cardiac tissue within or adjacent to a cardiac artery, a pulmonary vein ostium, etc.) to induce therapeutic hypothermia. The system 10 may generally include a treatment device, such as a balloon catheter 12, and a console 14 for operating, monitoring, and regulating the operation of the balloon catheter 12 (e.g., with the electronic controller 33), and a

fluid supply reservoir 16 for delivering fluid to the balloon catheter 12. The fluid is a thermally conductive fluid. For example, the fluid may be liquid N₂O, sterile cooled saline, or another suitable liquid.

[0022] The balloon catheter 12 is a highly flexible medical treatment device that is suitable for passage through the vasculature. The balloon catheter 12 may be adapted for use with the fluid supply reservoir 16. In the example illustrated, the balloon catheter 12 has an elongate body 18 having a proximal portion 20 and a distal portion 22. The distal portion 22 includes a treatment element 23. The proximal portion 20 of the balloon catheter 12 is mated to a handle 24 that can include an element such as a lever or knob for manipulating the elongate body 18 and the treatment element 23. The distal portion 22 may also define a distal tip 29 defining an aperture (not shown) sized to allow for the passage of a guidewire 30 through the elongate body 18 and through the aperture.

[0023] The elongate body 18 is sized and configured to be passable through a patient's vasculature and/or positionable proximate to the area of target tissue, and may include one or more lumens (e.g., the inflow lumen 27 and the outflow lumen 28) disposed within the elongate body 18 that provide mechanical, electrical, and/or fluid communication between the proximal portion 20 of the elongate body 18 and the distal portion 22 of the elongate body 18. In some aspects, the elongate body 18 includes a guidewire lumen through which a sensing device, mapping device, the guidewire 30, or other system component may be located and extended from the distal portion 22 of the balloon catheter 12. The elongate body 18 may be rigid and/or flexible to facilitate the navigation of the balloon catheter 12 within a patient's body. In one aspect, the distal portion 22 of the elongate body 18 is flexible to allow for more desirable positioning proximate to an area of target tissue (e.g., positioning within the pulmonary artery, the aortic root, the carotid body, and the like). To access an area of target tissue, the balloon catheter 12 may be inserted through one or more blood vessels, such as, for example, one or more brachial arteries, one or more radial arteries, one or more femoral arteries, or other points of access including venous access.

[0024] The treatment element 23 includes a balloon 26 (for example, an occlusive balloon), to which fluid from the fluid supply reservoir 16 is provided. In some examples, fluid from the fluid supply reservoir 16 is circulated through the balloon 26. An inflow lumen 27 is in fluid

communication with the fluid supply reservoir 16 in the console 14 to supply fluid to the balloon 26 in response to console commands and other control input. In some aspects, a vacuum pump 34 (electronically coupled to and controlled by the electronic controller 33) in the console 14 creates a low pressure environment in an outflow lumen 28 so that the fluid is drawn into the outflow lumen 28, away from the balloon 26, towards the proximal portion 20 of the elongate body 18, and into the fluid recovery reservoir 40 within the console 14. In some aspects, the treatment element is configured to allow sterile fluid to controllably escape the balloon 26 (e.g., through the distal tip 29) into a vessel under treatment. In some aspects, the balloon 26 is constructed of a porous material, which is configured to allow sterile fluid to escape into a vessel under treatment through pores in the balloon 26 (e.g., when a fluid pressure is exceeded).

[0025] In some aspects, the balloon 26 is configured for performing angioplasty and/or cardiac stent placement.

[0026] Although not illustrated in FIG. 1, in some aspects, the treatment element 23 includes one or more temperature sensors positioned on or in the treatment element to continuously measure temperature values within, on, or proximate to the balloon 26. The one or more temperature sensors transmit temperature signals to the electronic controller 33 of the console 14.

[0027] In some aspects, the console 14 includes one or more pressure sensors 42 to continuously record the instantaneous pressure values within the balloon 26. The pressure sensors 42 may then generate and transmit a pressure signal to the electronic controller 33 of the console 14. Although not illustrated in FIG. 1, in some aspects, the balloon catheter 12 may also include a pressure sensor 42 within the balloon 26 (not shown) or a pressure monitoring tube (enclosed in the elongate body 18) in fluid communication with the pressure sensor 42 (housed in the console 14) and the balloon 26.

[0028] In some aspects, the system 10 may also include the use of one or more flow sensors (not shown) to monitor how much fluid is flowing into the balloon 26. The flow sensor may be positioned to sense flow in the inflow lumen 27 or the outflow lumen 28 and is configured to measure the rate or speed of fluid at a certain location and report the rate or speed to the electronic controller 33. In some aspects, each of the inflow lumen 27 or the outflow lumen 28 is monitored by a dedicated flow sensor.

[0029] In the illustrated example, the console 14 includes an electronic controller 33 (described more particularly with respect to FIG. 2) programmed or programmable to execute the automated or semi-automated operation and performance of the features, sequences, calculations, or procedures described herein. The electronic controller 33 is communicatively coupled to the temperature sensors, pressure sensors, flow sensors, and other components of the balloon catheter 12, including the vacuum pump 34. The console 14 may include one or more user input devices, controllers, speakers, and/or displays (each coupled to and controllable by the electronic controller 33) for collecting and conveying information from and to the user.

[0030] In some aspects, the treatment element 23 includes ultrasonic transducers (not shown) to record the reflected, refracted, scattered, and/or attenuated ultrasound signals from the target tissue. As the transducers record the ultrasound signals, they begin to vibrate and the mechanical vibrations are converted into electric current signals that are transmitted back to the console 14 or an external ultrasound control unit 37 which processes the signals to generate a sonogram or ultrasonogram showing the patient's tissue, organs, and/or a location of the balloon catheter 12 within the patient's body. The sonogram may then be relayed to a clinician via a display 35 of the console 14, or via a display 39 of the external ultrasound control unit 37, to assist the physician in positioning the balloon catheter 12 near or proximate to a desired treatment location.

[0031] FIG. 2 illustrates an example embodiment of the electronic controller 33, which includes an electronic processor 205 (e.g., a microprocessor, application specific integrated circuit, etc.), a memory 210, and an input/output interface 215. The electronic processor 205, the memory 210, and the input/output interface 215, as well as the other various modules are coupled directly, by one or more control or data buses (e.g., the bus 230), or a combination thereof. The memory 210 may be made up of one or more non-transitory computer-readable media and includes at least a program storage area and a data storage area. The program storage area and the data storage area can include combinations of several types of memory, such as read-only memory ("ROM"), random access memory ("RAM") (e.g., dynamic RAM ("DRAM"), synchronous DRAM ("SDRAM"), etc.), electrically erasable programmable read-only memory ("EEPROM"), flash memory, or other suitable memory devices. The electronic processor 205 is coupled to the memory 210 and the input/output interface 215. The electronic processor 205 sends and receives information (e.g., from the memory 210 and/or the input/output interface 215) and processes the information by executing one or more software instructions or

modules, capable of being stored in the memory 210, or another non-transitory computer readable medium. The software can include firmware, one or more applications, program data, filters, rules, one or more program modules, and other executable instructions. The electronic processor 205 is configured to retrieve from the memory 210 and execute, among other things, software for performing methods as described herein.

[0032] The input/output interface 215 transmits and receives information from devices external to the electronic controller 33 (e.g., over one or more wired and/or wireless connections), for example, components of the system 10. The input/output interface 215 receives input (e.g., from a human machine interface of the console 14), provides system output or a combination of both. The input/output interface 215 may also include other input and output mechanisms, which for brevity are not described herein and which may be implemented in hardware, software, or a combination of both.

[0033] It should be understood that although FIG. 2 illustrates only a single electronic processor 205, memory 210, and input/output interface 215, alternative embodiments of the electronic controller 33 may include multiple processors, memory modules, and/or input/output interfaces. It should also be noted that the system 10 may include other electronic controllers, each including similar components as, and configured similarly to, the electronic controller 33. In some embodiments, the electronic controller 33 is implemented partially or entirely on a semiconductor (e.g., a field-programmable gate array ["FPGA"] semiconductor) chip. Similarly, the various modules and controllers described herein may be implemented as individual controllers, as illustrated, or as components of a single controller. In some embodiments, a combination of approaches may be used.

[0034] In some aspects, the balloon catheter 12 may be used to perform angioplasty. For example, as illustrated in FIG. 3, a vessel 50 has a stenosis 55, caused by plaque buildup narrowing the vessel and reducing blood flow through the vessel. During angioplasty treatment, the balloon 26 is positioned in the vessel 50, such that the balloon 26 is located at a percutaneous coronary intervention treatment site (e.g., the site of the stenosis 55). An operator of the balloon catheter 12 operates it to inflate the balloon 26 to occlude the vessel 50. After the balloon 26 is deflated and removed from the vessel 50, the stenosis is resolved, and blood flow returns to the vessel.

[0035] However, as noted, microvascular obstruction may occur post treatment. To reduce the incidence of MVO, systems and methods for applying therapeutic hypothermia are presented herein. For example, FIG. 4 illustrates an example method 400 for operating the system of FIG. 1. Although the method 400 is described in conjunction with the system 10 as described herein, the method 400 could be used with other systems and devices. In addition, the method 400 may be modified or performed differently than the example provided.

[0036] At block 410, the method 400 includes positioning a balloon catheter 12 in a vessel to locate a balloon 26 of the balloon catheter 12 at a percutaneous coronary intervention treatment site. For example, a PCI treatment may have been performed on a stenosis, as described above with respect to FIG. 3. The balloon 26 is positioned (e.g., by an operator of the balloon catheter 12 manipulating the controls of the handle 24) at or near the site of the treated stenosis.

[0037] At block 420, the method 400 includes inflating the balloon 26 to occlude the vessel by providing a thermally conductive fluid to the balloon 26. For example, the electronic controller 33 may control the vacuum pump 34 to inflate the balloon 26 to occlude the vessel by providing a thermally conductive fluid (e.g., a sterile refrigerant) to the balloon 26 via the inflow lumen 27. In some aspects, the balloon 26 is inflated to a pressure such that it fully occludes the vessel. In some aspects, the balloon 26 is inflated to a pressure such that it partially occludes the vessel.

[0038] At block 430, the method 400 includes circulating or the thermally conductive fluid through the balloon 26 to maintain an occlusion of the vessel for a first treatment period. For example, the electronic controller 33 may control the vacuum pump 34 to circulate the thermally conductive fluid through the balloon 26 via the inflow lumen 27 and the outflow lumen 28. In some aspects, the fluid is maintained in the balloon 26 to hold a temperature and/or a pressure defined by a treatment protocol. In some aspects, the fluid is circulated at a rate, which maintains a pressure while increasing or decreasing a temperature of the fluid in the balloon 26. In some aspects, the electronic controller 33 receives temperature and pressure readings from sensors configured to monitor the temperature and pressure of the balloon 26 and controls the vacuum pump 34 based on those readings.

[0039] The treatment period (e.g., 30 seconds) may be defined by a treatment protocol or may be determined based on patient monitoring, which occurs during treatment.

[0040] At block 440, the method includes deflating the balloon 26 when the first treatment period expires. For example, the electronic controller 33, when the first treatment period expires, may control the vacuum pump 34 to deflate the balloon 26 by removing the thermally conductive fluid from the balloon 26 via the outflow lumen 28.

[0041] In some embodiments, the inflating and deflation of the balloon 26 may be repeated to apply multiple treatments to the same area. For example, the electronic controller 33 may control the pump to keep the balloon 26 deflated for a rest period, and then inflate and deflate the balloon 26 again, as described above. The rest period is a period of time defined by a treatment protocol.

[0042] In some embodiments, a long balloon is used. A long balloon is longer than, for example, those ordinarily used for cryoablation or angioplasty. For example, the balloon 26 may be configured to occupy a volume of the vessel between an ostium of the vessel and a location distal of the percutaneous coronary intervention treatment site. In this way, the balloon 26 may cool a larger area of cardiac tissue, a large volume of blood, or both.

[0043] In some embodiments, the balloon 26 is not a dedicated cryotherapy balloon, but is instead an angioplasty balloon. In such embodiments, an operator of the balloon catheter 12 may operate the catheter to perform a balloon angioplasty procedure, and then operate a cryo handle to inflate the balloon 26 to occlude the vessel by providing the thermally conductive fluid to the balloon 26. This would deliver the thermally conductive fluid into the balloon 26 in a controlled manner and regulate balloon pressure while applying cooling power. It could also be used to detect pressure leaks. In some aspects, the thermally conductive fluid may be used to inflate the balloon 26 during the angioplasty procedure in order to begin the therapeutic hypothermia sooner.

[0044] In some examples, an array of balloon catheters may be used. For example, the array could be distributed longitudinally from an ostium of the vessel to distal of the percutaneous coronary intervention treatment site to deliver the cold thermal energy to the wall of the vessel and cool the surrounding blood and tissue. In one example, a second balloon catheter may be positioned in the vessel such that a second balloon of the second balloon catheter is located at a first treatment site located distal to the ostium and proximal to the percutaneous coronary intervention treatment site. In another example, a third balloon catheter is positioned in the vessel

such that a third balloon of the third balloon catheter is located at a second treatment site located distal to the percutaneous coronary intervention treatment site. In this way, one, two, or three balloons may be used to apply therapeutic hypothermia.

[0045] In some aspects, one of the catheters described above may contain a lumen for delivering a thrombolytic liquid to the vessel as part of the Post STEMI treatment. In some aspects, the lumen may be used to deliver a cooled thrombolytic liquid to the vessel, enhancing the cooling process.

[0046] In some embodiments, a controlled amount of sterile thermally conductive fluid may be delivered into the vessel. For example, liquid N₂O would phase change to gas, cool, and be absorbed by the blood. The microbubbles of N₂O could also provide a therapeutic effect on distal thrombus. In one example, the electronic controller 33 may control the balloon catheter 12 to spray a controlled amount of the thermally conductive fluid into the vessel through a controllable opening at the distal tip 29. In another example, the electronic controller 33 may control the pump to circulate the thermally conductive fluid through the balloon 26 such that the controlled amount of thermally conductive fluid exits through a plurality of pores in the balloon 26.

[0047] In the foregoing specification, specific embodiments are described. However, one of ordinary skill in the art appreciates that various modifications and changes may be made without departing from the scope of the invention as set forth in the claims below. Accordingly, the specification and figures are to be regarded in an illustrative rather than a restrictive sense, and all such modifications are intended to be included within the scope of present teachings. For example, while some embodiments are illustrated and described as including a single ultrasonic energy source, such embodiments could be applied to any balloon-based system, including those with other types or quantities of heating element energy sources.

[0048] It should also be noted that a plurality of hardware and software-based devices, as well as a plurality of different structural components may be utilized to implement the embodiments provided herein. It should also be noted that a plurality of hardware and software-based devices, as well as a plurality of different structural components may be used to implement the invention. In addition, it should be understood that embodiments may include hardware, software, and electronic components or modules that, for purposes of discussion, may be illustrated and described as if the majority of the components were implemented solely in hardware. However,

one of ordinary skill in the art, and based on a reading of this detailed description, would recognize that, in at least one embodiment, the electronic based aspects of the invention may be implemented in software (e.g., stored on non-transitory computer-readable medium) executable by one or more processors. As such, it should be noted that a plurality of hardware and software-based devices, as well as a plurality of different structural components may be utilized to implement the invention. For example, “control units” and “controllers” described in the specification can include one or more processors, one or more application specific integrated circuits (ASICs), one or more memory modules including non-transitory computer-readable media, one or more input/output interfaces, and various connections (e.g., a system bus) connecting the components.

[0049] It will be appreciated that some embodiments may be comprised of one or more electronic processors such as microprocessors, digital signal processors, customized processors, and field programmable gate arrays (FPGAs) and unique stored program instructions (including both software and firmware) that control the one or more processors to implement, in conjunction with certain non-processor circuits, some, most, or all of the functions of the method and/or apparatus described herein. Alternatively, some or all functions could be implemented by a state machine that has no stored program instructions, or in one or more application specific integrated circuits (ASICs), in which each function or some combinations of certain of the functions are implemented as custom logic. Of course, a combination of the two approaches could be used.

[0050] Moreover, some embodiments may be implemented as a computer-readable storage medium having computer readable code stored thereon for programming a computer (e.g., comprising an electronic processor) to perform a method as described and claimed herein. Examples of such computer-readable storage media include, but are not limited to, a hard disk, a CD-ROM, an optical storage device, a magnetic storage device, a ROM (Read Only Memory), a PROM (Programmable Read Only Memory), an EPROM (Erasable Programmable Read Only Memory), an EEPROM (Electrically Erasable Programmable Read Only Memory) and a Flash memory. Further, it is expected that one of ordinary skill, notwithstanding possibly significant effort and many design choices motivated by, for example, available time, current technology, and economic considerations, when guided by the concepts and principles disclosed herein will

be readily capable of generating such software instructions and programs and ICs with minimal experimentation.

[0051] It should be understood that although certain drawings illustrate hardware and software located within particular devices, these depictions are for illustrative purposes only. In some examples, the illustrated components may be combined or divided into separate software, firmware and/or hardware. For example, instead of being located within and performed by a single electronic processor, logic and processing may be distributed among multiple electronic processors. Regardless of how they are combined or divided, hardware and software components may be located on the same computing device or may be distributed among multiple different devices.

[0052] In this specification, relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. The terms “comprises,” “comprising,” “has,” “having,” “includes,” “including,” “contains,” “containing,” or any other variation thereof, are intended to cover a non-exclusive inclusion, such that a process, method, article, or apparatus that comprises, has, includes, contains a list of elements does not include only those elements but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. An element preceded by “comprises ...a,” “has ...a,” “includes ...a,” or “contains ...a” does not, without more constraints, preclude the existence of additional identical elements in the process, method, article, or apparatus that comprises, has, includes, contains the element. The terms “a” and “an” are defined as one or more unless explicitly stated otherwise herein. The terms “substantially,” “essentially,” “approximately,” “about,” or any other version thereof, are defined as being close to as understood by one of ordinary skill in the art, and in one non-limiting embodiment the term is defined to be within 10%, in another embodiment within 5%, in another embodiment within 1% and in another embodiment within 0.5%. A device or structure that is “configured” in a certain way is configured in at least that way but may also be configured in ways that are not listed.

[0053] The following paragraphs provide various examples of the embodiments disclosed herein.

[0054] Example 1 is a medical treatment system, the system comprising: a balloon catheter including: a balloon, an inflow lumen positioned within an interior of the balloon, and an outflow lumen positioned within the interior of the balloon; and an electronic controller coupled to the balloon catheter and configured to: when the balloon catheter is positioned in a vessel such that the balloon is located at a percutaneous coronary intervention treatment site, control a pump to inflate the balloon to fully occlude the vessel by providing a thermally conductive fluid to the balloon via the inflow lumen; control the pump to circulate the thermally conductive fluid through the balloon via the inflow lumen and the outflow lumen to maintain an occlusion of the vessel for a first treatment period; and when the first treatment period expires, control the pump to deflate the balloon by removing the thermally conductive fluid from the balloon via the outflow lumen.

[0055] Example 2 includes the subject matter of Example 1, and may further specify that the electronic controller is further configured to: control the pump to maintain the balloon in a deflated state until a rest period expires; when the rest period expires, control the pump to circulate the thermally conductive fluid through the balloon via the inflow lumen and the outflow lumen to inflate the balloon to fully occlude the vessel; control the pump to circulate the thermally conductive fluid through the balloon via the inflow lumen and the outflow lumen to maintain occlusion of the vessel for a second treatment period; and when the second treatment period expires, control the pump to deflate the balloon by removing the thermally conductive fluid from the balloon via the outflow lumen.

[0056] Example 3 includes the subject matter of any of Examples 1, 2, and 5–11, and may further specify that the balloon is configured to occupy a volume of the vessel between an ostium of the vessel and a location distal of the percutaneous coronary intervention treatment site.

[0057] Example 4 includes the subject matter of any of Examples 1, 2, and 5–11, and may further specify that the balloon is an angioplasty balloon; and inflating the balloon to fully occlude the vessel by providing the thermally conductive fluid to the balloon includes operating a cryo handle of the medical device.

[0058] Example 5 includes the subject matter of any of Examples 1–4, and may further specify that the electronic controller is further configured to: when a second balloon catheter is positioned in the vessel such that a second balloon of the second balloon catheter is located at a

first treatment site located distal to an ostium of the vessel and proximal to the percutaneous coronary intervention treatment site, control the pump to inflate the second balloon to fully occlude the vessel by providing a thermally conductive fluid to the second balloon; control the pump to circulate the thermally conductive fluid through the second balloon to inflate the second balloon for the first treatment period; and when the first treatment period expires, control the pump to deflate the second balloon by removing the thermally conductive fluid from the second balloon.

[0059] Example 6 includes the subject matter of Example 5, and may further specify that the electronic controller is further configured to: when a third balloon catheter is positioned in the vessel such that a third balloon of the third balloon catheter is located at a second treatment site located distal to the percutaneous coronary intervention treatment site, control the pump to inflate the third balloon to fully occlude the vessel by providing a thermally conductive fluid to the third balloon; control the pump to circulate the thermally conductive fluid through the third balloon to inflate the third balloon for the first treatment period; and when the first treatment period expires, control the pump to deflate the third balloon by removing the thermally conductive fluid from the third balloon.

[0060] Example 7 includes the subject matter of Example 6 and may further specify that the electronic controller is further configured to: control one selected from a group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver a thrombolytic liquid to the vessel.

[0061] Example 8 includes the subject matter of Example 7, and may further specify that the electronic controller is further configured to control one selected from the group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver the thrombolytic liquid to the vessel by controlling one selected from the group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver a cooled thrombolytic liquid to the vessel.

[0062] Example 9 includes the subject matter of any of Examples 1–8, and may further specify that the electronic controller is further configured to: control the pump to inflate the balloon to partially occlude the vessel by providing the thermally conductive fluid to the balloon;

and control the pump to circulate the thermally conductive fluid through the balloon to maintain a partial occlusion of the vessel for the first treatment period.

[0063] Example 10 includes the subject matter of any of Examples 1–9 and may further specify that the electronic controller is further configured to: control the balloon catheter to spray a controlled amount of the thermally conductive fluid into the vessel.

[0064] Example 11 includes the subject matter of Example 10, and may further specify that the electronic controller is further configured to: controlling the balloon catheter to spray the controlled amount of the thermally conductive fluid into the vessel includes controlling the pump to circulate the thermally conductive fluid through the balloon such that the controlled amount of thermally conductive fluid exits through a plurality of pores in the balloon.

[0065] Example 12 is a method for operating a medical treatment device, the method comprising: positioning a balloon catheter in a vessel to locate a balloon of the balloon catheter at a percutaneous coronary intervention treatment site; inflating the balloon to fully occlude the vessel by providing a thermally conductive fluid to the balloon; circulating the thermally conductive fluid through the balloon to maintain an occlusion of the vessel for a first treatment period; and when the first treatment period expires, deflating the balloon by removing the thermally conductive fluid from the balloon.

[0066] Example 13 includes the subject matter of Example 12, and may further specify maintaining the balloon in a deflated state until a rest period expires; when the rest period expires, circulating the thermally conductive fluid through the balloon to inflating the balloon to fully occlude the vessel; circulating the thermally conductive fluid through the balloon to maintain occlusion of the vessel for a second treatment period; and when the second treatment period expires, deflating the balloon by removing the thermally conductive fluid from the balloon.

[0067] Example 14 includes the subject matter of any of Examples 12 and 13 and may further specify that positioning the balloon catheter in a vessel at a percutaneous coronary intervention treatment site includes positioning a balloon configured to occupy a volume of the vessel between an ostium of the vessel and a location distal of the percutaneous coronary intervention treatment site.

[0068] Example 15 includes the subject matter of Example 12 and may further specify that the balloon is an angioplasty balloon; and may further include inflating the balloon to fully occlude the vessel by providing the thermally conductive fluid to the balloon includes operating a cryo handle of the medical device.

[0069] Example 16 includes the subject matter of any of Examples 12, 13, and 15, and may further specify positioning a second balloon catheter in the vessel to locate a second balloon of the second balloon catheter at a first treatment site located distal to an ostium of the vessel and proximal to the percutaneous coronary intervention treatment site; circulating the thermally conductive fluid through the second balloon to inflate the second balloon for the first treatment period; and when the first treatment period expires, deflating the second balloon by removing the thermally conductive fluid from the second balloon.

[0070] Example 17 includes the subject matter of Example 16, and may further specify positioning a third balloon catheter in the vessel to locate a third balloon of the third balloon catheter at a second treatment site located distal to the percutaneous coronary intervention treatment site; circulating the thermally conductive fluid through the third balloon to inflate the third balloon for the first treatment period; and when the first treatment period expires, deflating the third balloon by removing the thermally conductive fluid from the third balloon.

[0071] Example 18 includes the subject matter of Example 17 and may further specify controlling one selected from a group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver a thrombolytic liquid to the vessel.

[0072] Example 19 includes the subject matter of Example 18, and may further specify that controlling one selected from the group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver the thrombolytic liquid to the vessel includes controlling one selected from the group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver a cooled thrombolytic liquid to the vessel.

[0073] Example 20 includes the subject matter of any of Examples 12–19 and may further specify inflating the balloon to partially occlude the vessel by providing the thermally conductive fluid to the balloon; and circulating the thermally conductive fluid through the balloon to maintain a partial occlusion of the vessel for the first treatment period.

[0074] Example 21 includes the subject matter of any of Examples 12–20 and may further specify controlling the balloon catheter to spray a controlled amount of the thermally conductive fluid into the vessel.

[0075] Example 22 includes the subject matter of Example 21 and may further specify that controlling the balloon catheter to spray a controlled amount of the thermally conductive fluid into the vessel includes circulating the thermally conductive fluid through the balloon such that the controlled amount of thermally conductive fluid exits through a plurality of pores in the balloon.

[0076] Various features and advantages of the embodiments presented herein are set forth in the following claims.

CLAIMS

What is claimed is:

1. A medical treatment system (10), the system comprising:
 - a balloon catheter (12) including:
 - a balloon (26);
 - an inflow lumen (27) positioned within an interior of the balloon (26); and
 - an outflow lumen (28) positioned within the interior of the balloon (26); and
 - an electronic controller (33) coupled to the balloon catheter (12) and configured to:
 - when the balloon catheter (12) is positioned in a vessel such that the balloon (26) is located at a percutaneous coronary intervention treatment site, control a pump (34) to inflate the balloon to occlude the vessel by providing a thermally conductive fluid to the balloon (26) via the inflow lumen (27);
 - control the pump (34) to circulate the thermally conductive fluid through the balloon (26) via the inflow lumen (27) and the outflow lumen (28) to maintain an occlusion of the vessel for a first treatment period; and
 - when the first treatment period expires, control the pump (34) to deflate the balloon (26) by removing the thermally conductive fluid from the balloon (26) via the outflow lumen (28).
2. The system of claim 1, wherein the electronic controller (33) is further configured to:
 - control the pump (34) to maintain the balloon (26) in a deflated state until a rest period expires;
 - when the rest period expires, control the pump (34) to circulate the thermally conductive fluid through the balloon (26) via the inflow lumen (27) and the outflow lumen (28) to inflate the balloon (26) to occlude the vessel;
 - control the pump (34) to circulate the thermally conductive fluid through the balloon (26) via the inflow lumen (27) and the outflow lumen (28) to maintain occlusion of the vessel for a second treatment period; and
 - when the second treatment period expires, control the pump (34) to deflate the balloon (26) by removing the thermally conductive fluid from the balloon (26) via the outflow lumen (28).

3. The system of any of claims 1 and 2, wherein the balloon (26) is configured to occupy a volume of the vessel between an ostium of the vessel and a location distal of the percutaneous coronary intervention treatment site.

4. The system of any of claims 1–3, wherein:
the balloon (26) is an angioplasty balloon; and
inflating the balloon (26) to occlude the vessel by providing the thermally conductive fluid to the balloon (26) includes operating a cryo handle.

5. The system of any of claims 1–4, wherein the electronic controller (33) is further configured to:

when a second balloon catheter is positioned in the vessel such that a second balloon of the second balloon catheter is located at a first treatment site located distal to an ostium of the vessel and proximal to the percutaneous coronary intervention treatment site, control the pump to inflate the second balloon to occlude the vessel by providing a thermally conductive fluid to the second balloon;

when a third balloon catheter is positioned in the vessel such that a third balloon of the third balloon catheter is located at a second treatment site located distal to the percutaneous coronary intervention treatment site, control the pump to inflate the third balloon to occlude the vessel by providing a thermally conductive fluid to the third balloon;

control the pump to circulate the thermally conductive fluid through the second balloon to inflate the second balloon for the first treatment period; and

control the pump to circulate the thermally conductive fluid through the third balloon to inflate the third balloon for the first treatment period; and

when the first treatment period expires, control the pump to deflate the second balloon by removing the thermally conductive fluid from the second balloon and control the pump to deflate the third balloon by removing the thermally conductive fluid from the third balloon.

6. The system of claim 5, wherein the electronic controller is further configured to:
control one selected from a group consisting of the balloon catheter, the second balloon catheter, and the third balloon catheter to deliver one of a thrombolytic liquid and a cooled thrombolytic liquid to the vessel.
7. The system of any of claims 1–6, wherein the electronic controller is further configured to:
control the pump to inflate the balloon to occlude the vessel by performing one of
controlling the pump to inflate the balloon to fully occlude the vessel
controlling the pump to inflate the balloon to partially occlude the vessel.
8. The system of any of claims 1–7, wherein the electronic controller is further configured to:
control the balloon catheter to spray a controlled amount of the thermally conductive fluid into the vessel.
9. The system of any of claims 1–8, wherein the electronic controller is further configured to:
controlling the balloon catheter to spray the controlled amount of the thermally conductive fluid into the vessel includes controlling the pump to circulate the thermally conductive fluid through the balloon such that the controlled amount of thermally conductive fluid exits through a plurality of pores in the balloon.

10. A method (400) for operating a medical treatment device, the method (400) comprising:
 - positioning a balloon catheter (12) in a vessel to locate a balloon (26) of the balloon catheter (12) at a percutaneous coronary intervention treatment site;
 - inflating the balloon (26) to occlude the vessel by providing a thermally conductive fluid to the balloon;
 - circulating the thermally conductive fluid through the balloon (26) to maintain an occlusion of the vessel for a first treatment period; and
 - when the first treatment period expires, deflating the balloon (26) by removing the thermally conductive fluid from the balloon (26).
11. The method (400) of claim 10, further comprising:
 - maintaining the balloon in a deflated state until a rest period expires;
 - when the rest period expires, circulating the thermally conductive fluid through the balloon to inflating the balloon to occlude the vessel;
 - circulating the thermally conductive fluid through the balloon to maintain occlusion of the vessel for a second treatment period; and
 - when the second treatment period expires, deflating the balloon by removing the thermally conductive fluid from the balloon.
12. The method (400) of any of claims 10 and 11, wherein positioning the balloon catheter in a vessel at a percutaneous coronary intervention treatment site includes positioning a balloon configured to occupy a volume of the vessel between an ostium of the vessel and a location distal of the percutaneous coronary intervention treatment site.
13. The method (400) of any of claims 10–12, further comprising:
 - positioning a second balloon catheter in the vessel to locate a second balloon of the second balloon catheter at a first treatment site located distal to an ostium of the vessel and proximal to the percutaneous coronary intervention treatment site;
 - circulating the thermally conductive fluid through the second balloon to inflate the second balloon for the first treatment period; and
 - when the first treatment period expires, deflating the second balloon by removing the thermally conductive fluid from the second balloon.

14. The method (400) of any of claims 10–13, further comprising:
- positioning a third balloon catheter in the vessel to locate a third balloon of the third balloon catheter at a second treatment site located distal to the percutaneous coronary intervention treatment site;
 - circulating the thermally conductive fluid through the third balloon to inflate the third balloon for the first treatment period; and
 - when the first treatment period expires, deflating the third balloon by removing the thermally conductive fluid from the third balloon.
15. The method (400) of any of claims 10–14, wherein inflating the balloon to occlude the vessel includes performing one of inflating the balloon to fully occlude the vessel or inflating the balloon to partially occlude the vessel.

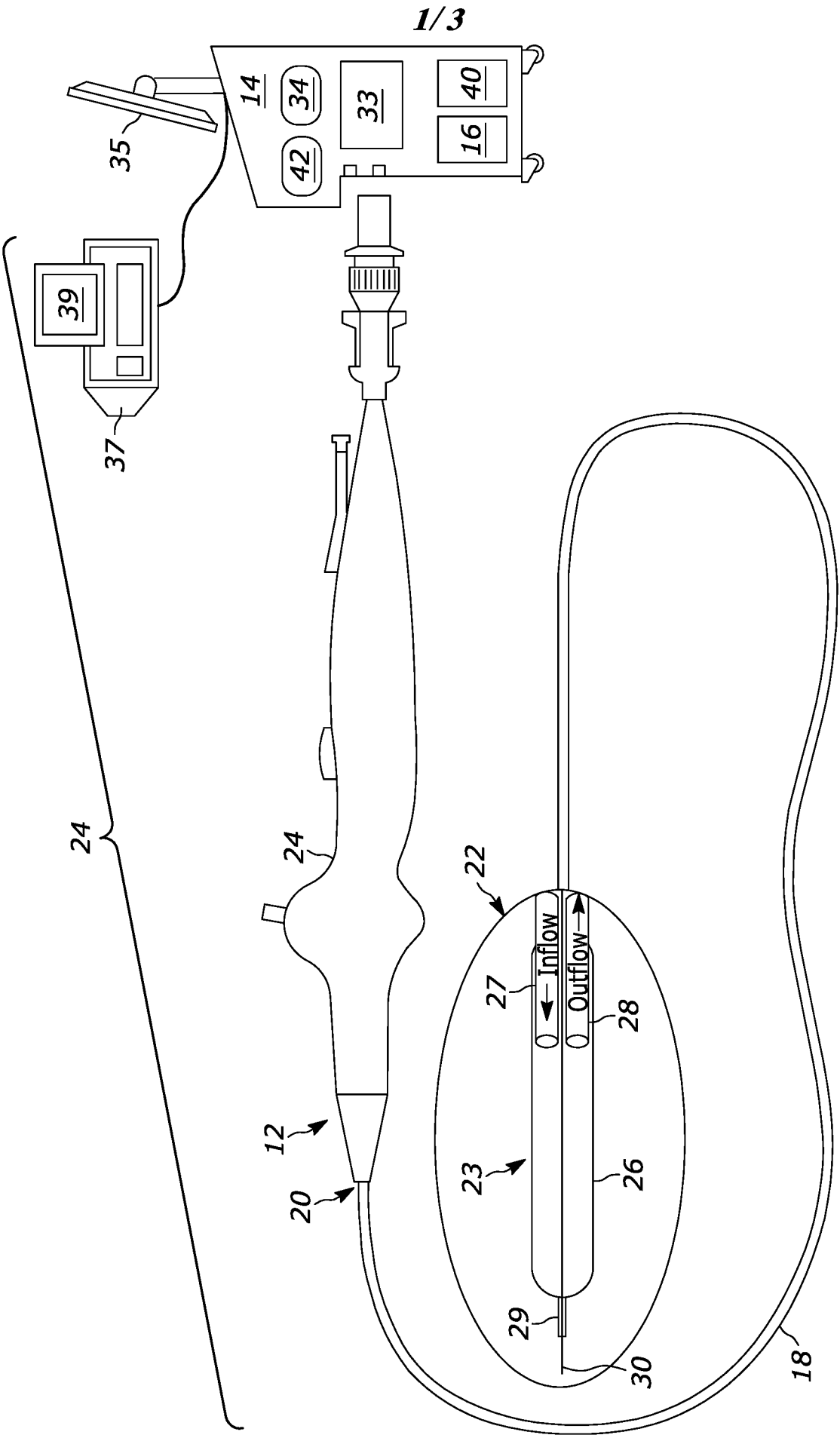


FIG. 1

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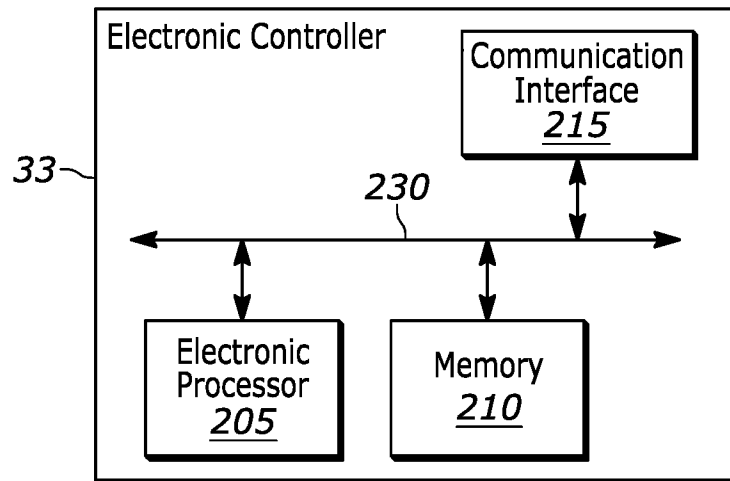


FIG. 2

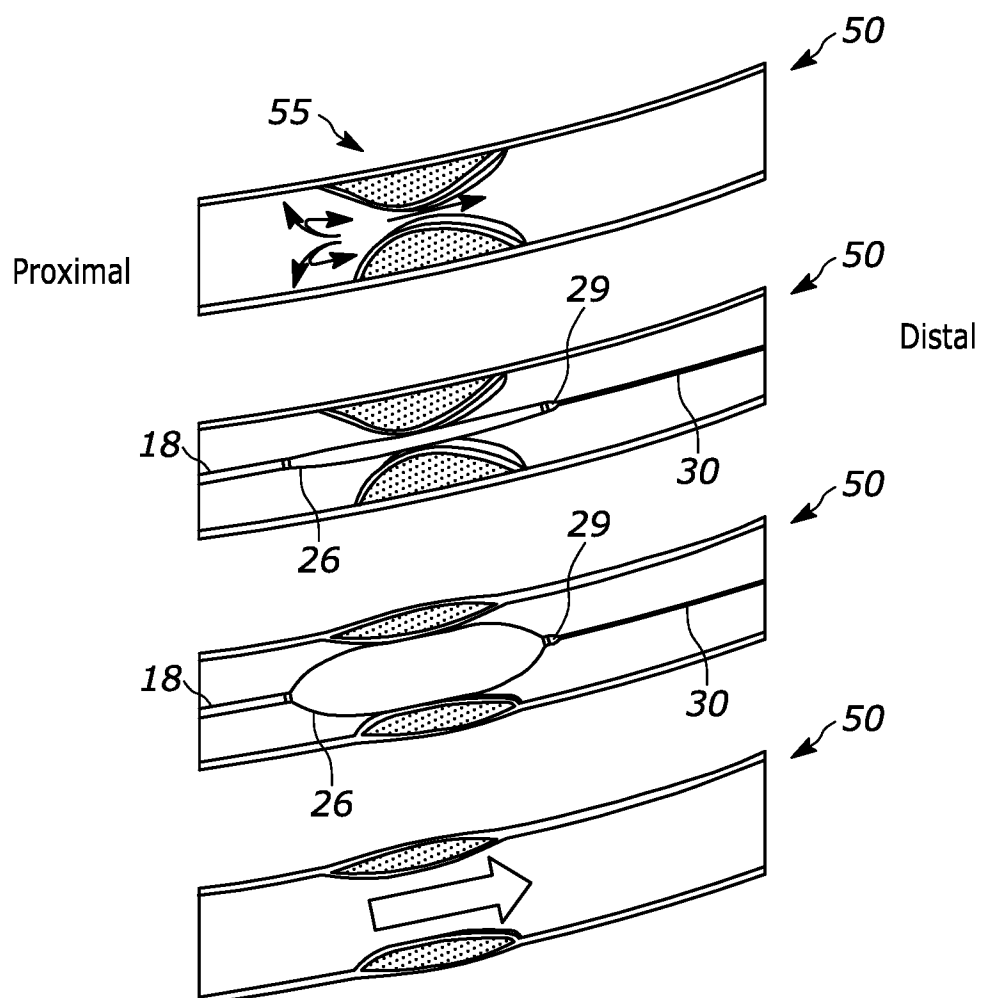
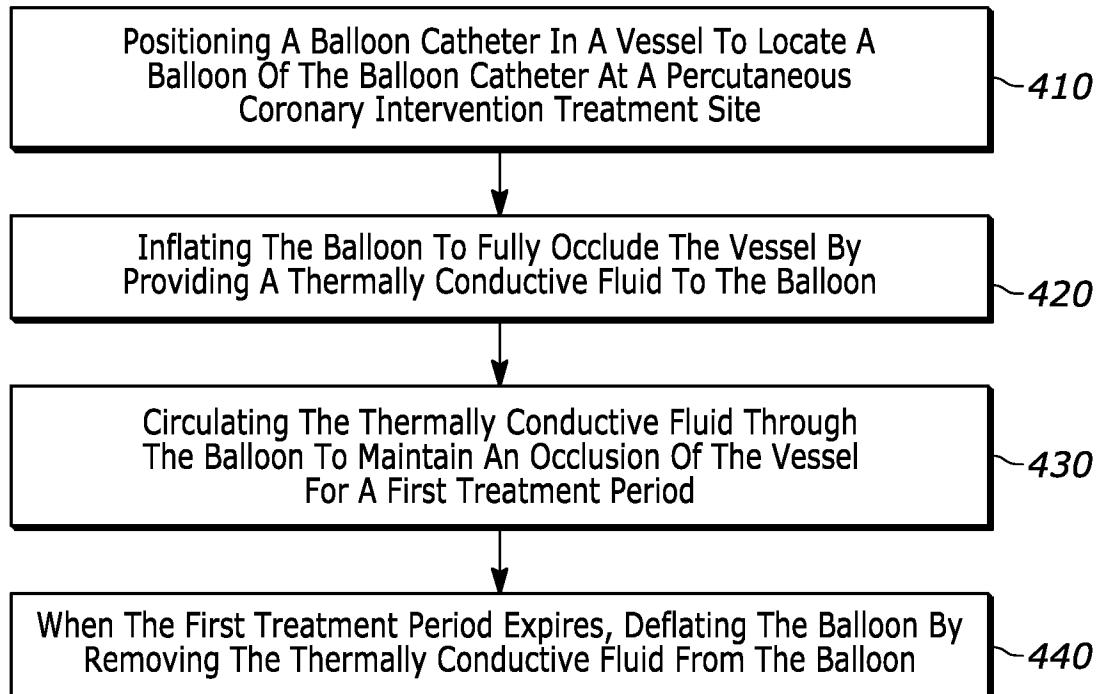


FIG. 3

3/3**FIG. 4**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/033026

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 practicable, search terms used) EPO-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 2008/300571 A1 (LEPIVERT PATRICK [US]) 4 December 2008 (2008-12-04) paragraphs [0075], [0076], [0103], [0119]; figure 1A -----	1 - 9
X	US 2007/160645 A1 (VINTEN-JOHANSEN JAKOB [US]) 12 July 2007 (2007-07-12) paragraphs [0058] - [0062], [0072] -----	1 - 5, 7
X	US 2012/289982 A1 (GUNDAY ERHAN H [US] ET AL) 15 November 2012 (2012-11-15) paragraph [0081]; figures 12A-F -----	1 - 7
X	US 2014/371736 A1 (LEVIN PHILLIP S [US] ET AL) 18 December 2014 (2014-12-18) paragraphs [0114] - [0116], [0122], [0125], [0128], [0130], [0133], [0134]; figure 2 ----- - / - -	1 - 7
☒ 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 "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "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 13 September 2024		Date of mailing of the international search report 30/09/2024
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Seon, Jean-Antoine

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/033026

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.: 10 - 15
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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:

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.:

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/US2024/033026

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/142666 A1 (PHELAN JIM [IE] ET AL) 22 May 2014 (2014-05-22) paragraph [0030]; figure 4H -----	1 - 7
X	US 2005/038421 A1 (JOYE JAMES [US] ET AL) 17 February 2005 (2005-02-17) paragraph [0049]; figures 11A-D -----	1 - 5, 7

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 10-15

1.1 The subject matter of claims 10-15 relates to a surgical method. According to Rule 39.1 (iv) PCT the international search authority is not required to search subject matter falling under this category. The reasons are the following: 1.2 The method relates to the insertion and control of the surgical instrument within the body, and therefore the whole method is considered surgical.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2024/033026

Patent document cited in search report			Publication date		Patent family member(s)			Publication date	
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			US	2008300571	A1	04-12-2008			
			WO	2008150871	A1	11-12-2008			

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			WO	2008115603	A1	25-09-2008			

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			AU	2018200371	A1	08-02-2018			
			AU	2020202563	A1	07-05-2020			
			CA	2865567	A1	06-09-2013			
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