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(54) HEAT TRANSFER CATHETER WITH ELASTIC FLUID LUMENS

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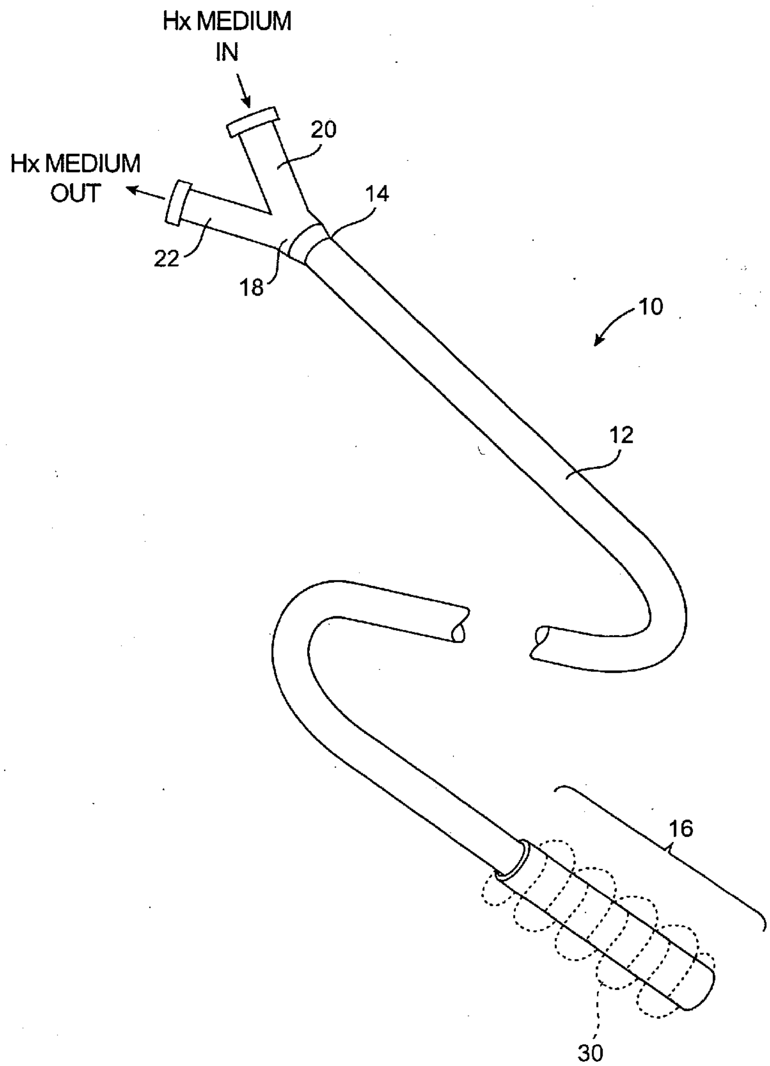
(57) ABSTRACT

The heat exchange catheters comprise a catheter body having a heat exchange structure formed over a distal region thereof. Heat exchange structure comprises an elastic chamber or balloon which conforms closely to the catheter body when uninflated and which expands to enhance the available heat transfer surface when heat exchange medium is introduced. The elastic structures may consist of elastomeric sheets or membranes or may comprise non-distensible sheets or membranes having elastic elements in order to control expansion and contraction. Methods for fabrication and use are also disclosed.



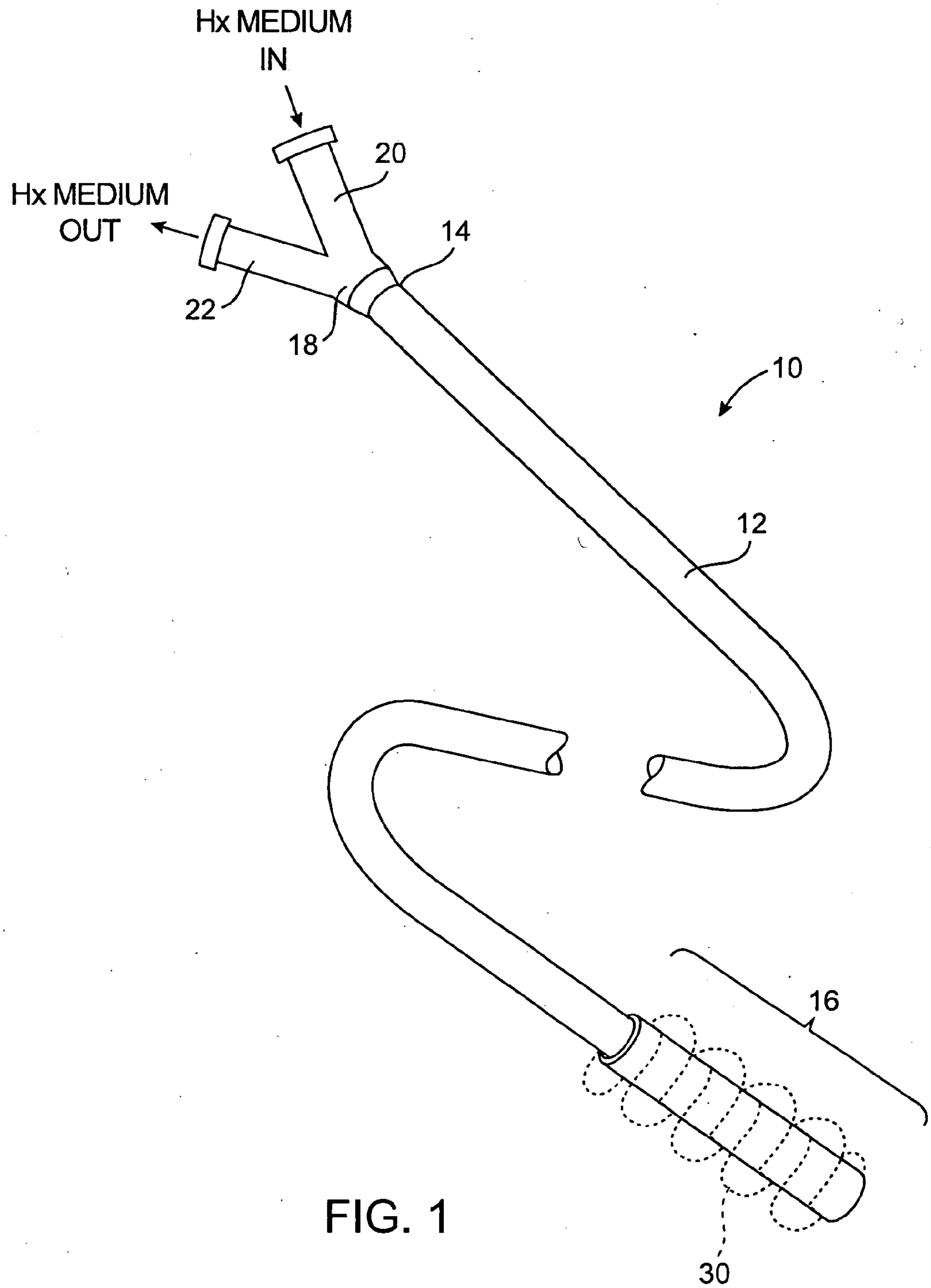


FIG. 1

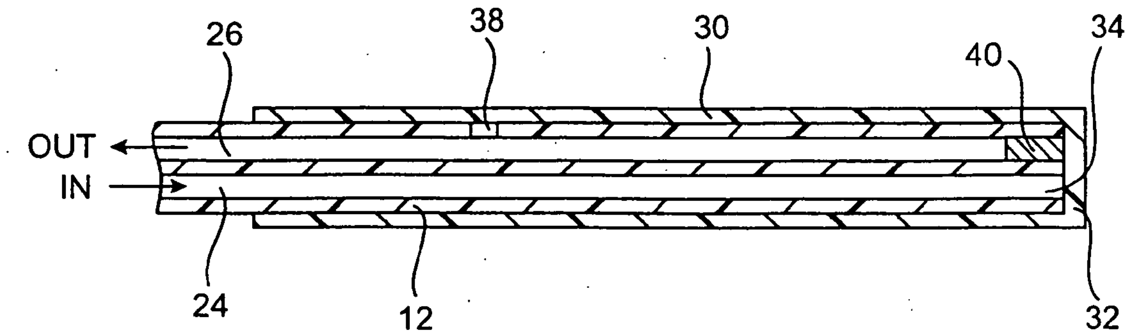


FIG. 2A

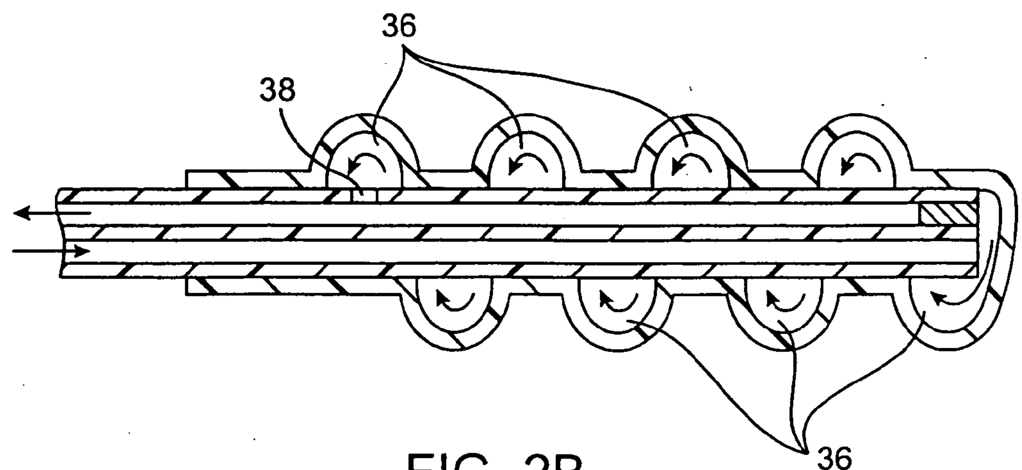


FIG. 2B

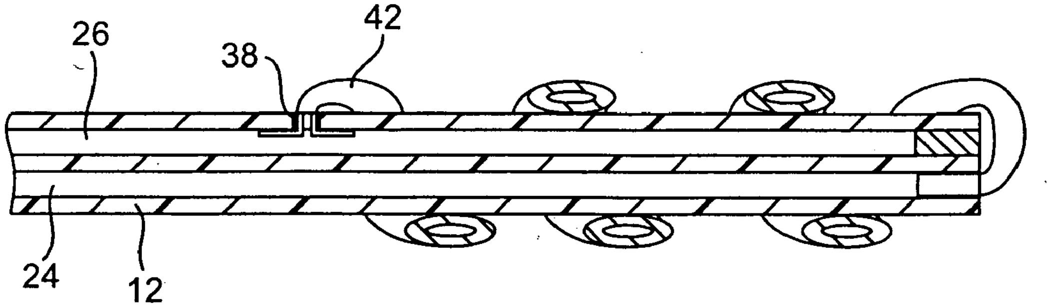


FIG. 3A

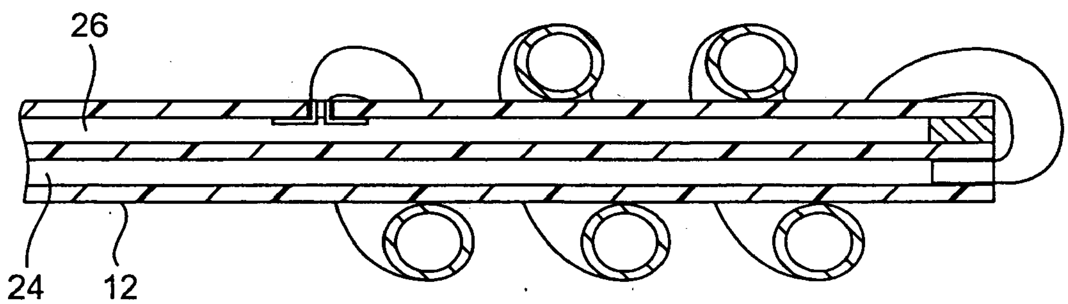


FIG. 3B

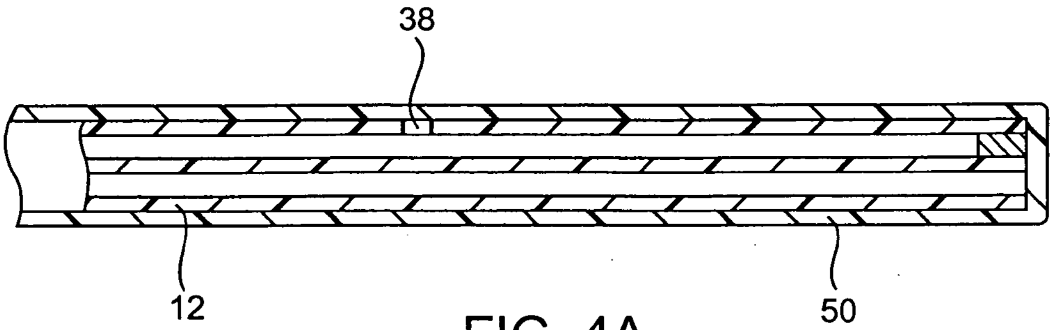


FIG. 4A

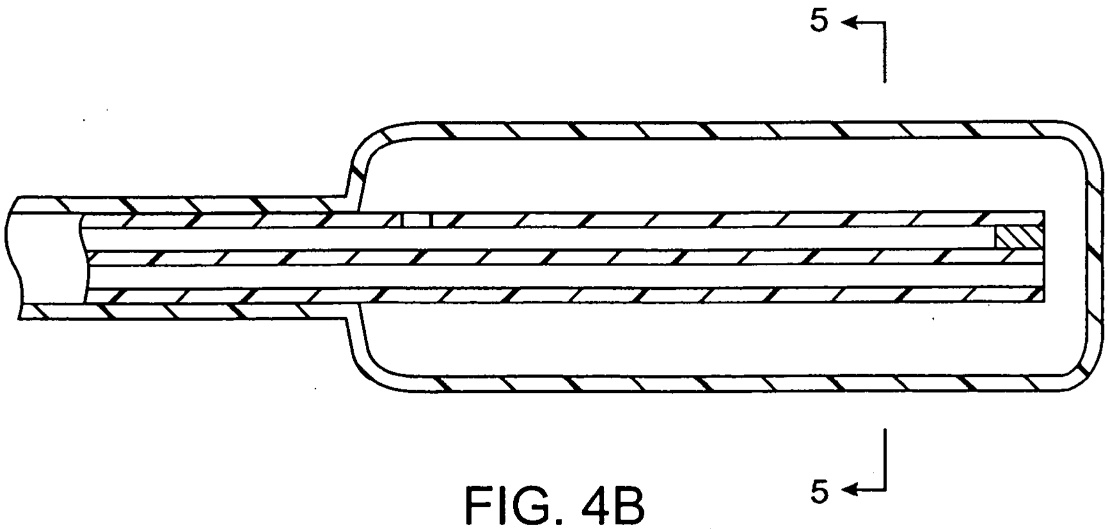


FIG. 4B

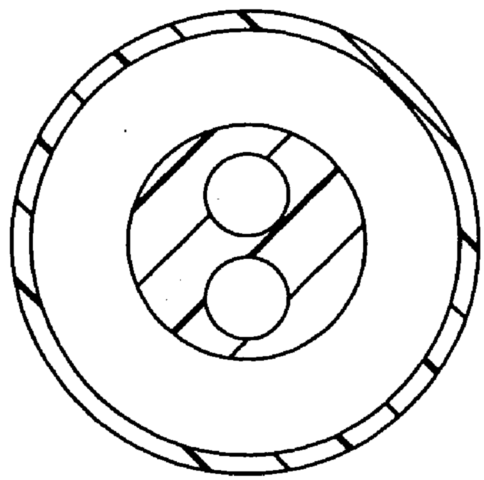


FIG. 5A

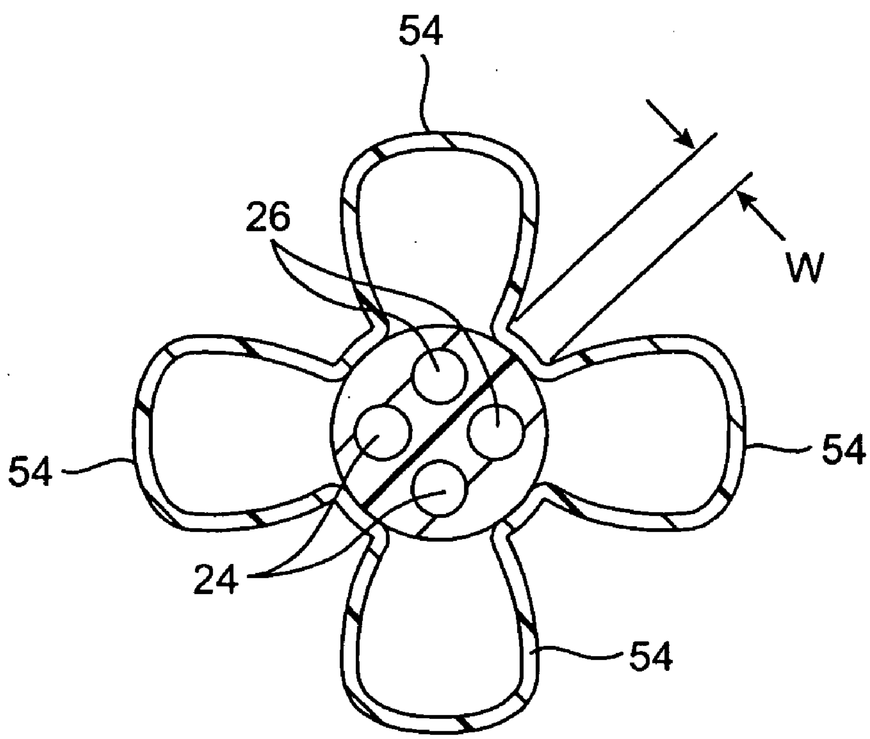


FIG. 5B

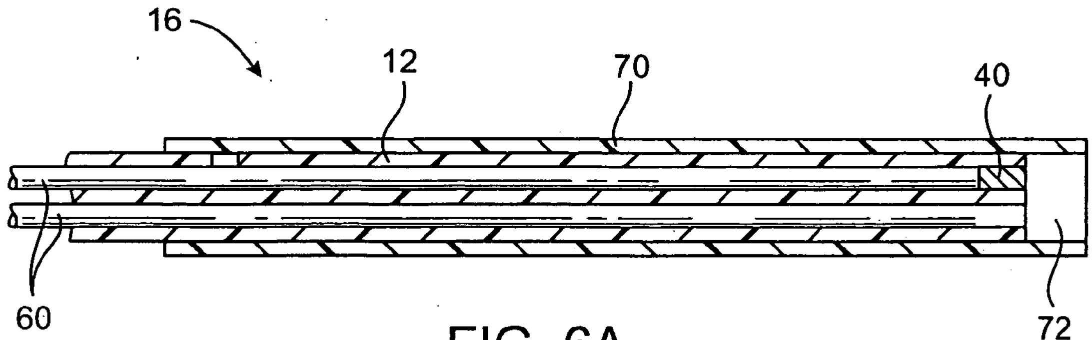


FIG. 6A

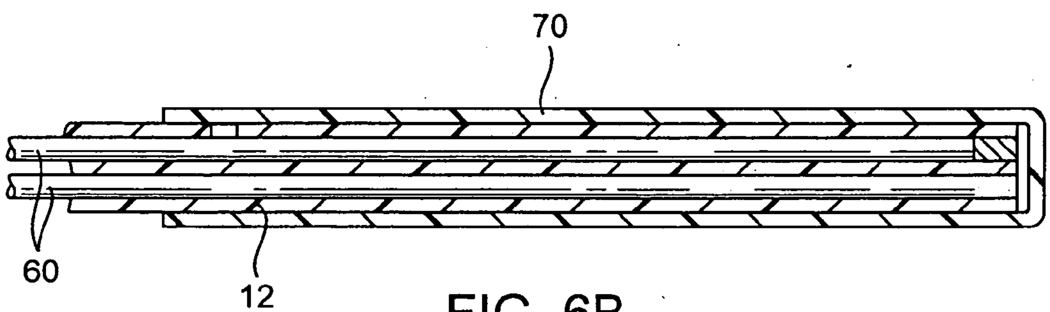


FIG. 6B

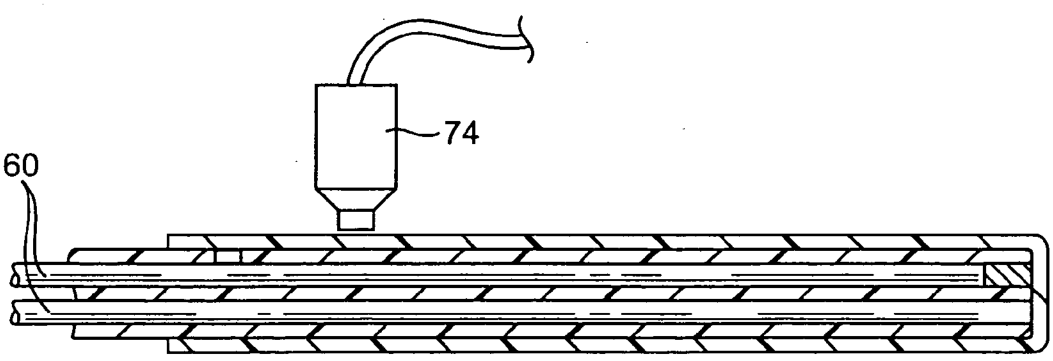


FIG. 6C

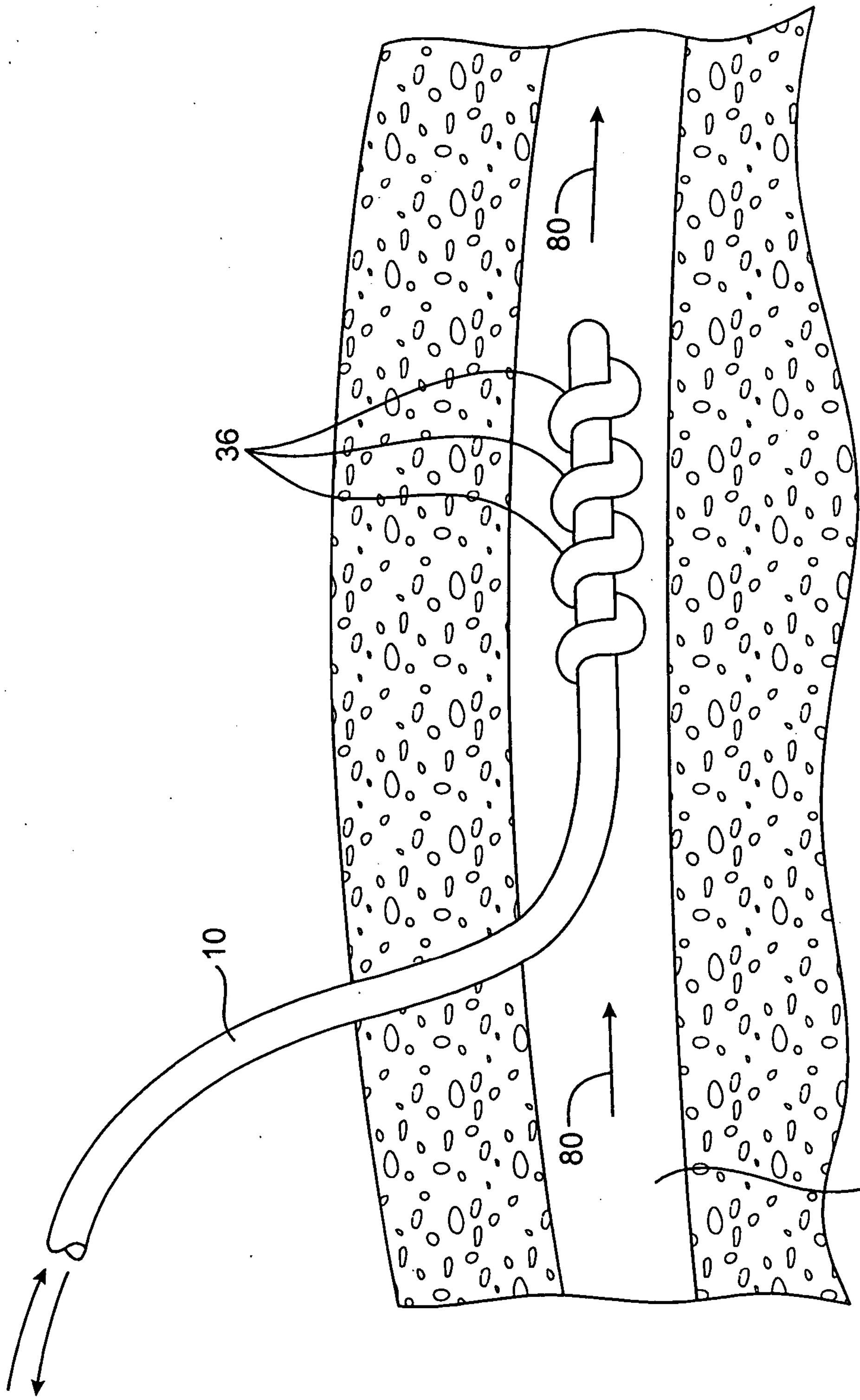


FIG. 7

HEAT TRANSFER CATHETER WITH ELASTIC FLUID LUMENS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of application Ser. No. 09/872,818 (Attorney Docket No. 020878-000200), filed on May 31, 2001, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to the construction and use of heat exchange catheters having elastically inflatable heat exchange surfaces.

[0004] Under ordinary circumstances, the thermoregulatory system of the human body maintains a near constant temperature of about 37° C. (98.6° F.), a temperature referred to as normothermia. For various reasons, however, a person may develop a body temperature that is below normal temperature, a condition know as hypothermia, or a temperature that is above normal temperature, a condition known as hyperthermia. Hypothermia and hyperthermia are generally harmful, and if severe, the patient is generally treated to reverse the condition and return the patient to normothermia. Accidental hypothermia significant enough to require treatment may occur in patients exposed to overwhelming cold stress in the environment or whose thermoregulatory ability has been lessened due to injury, illness or anesthesia. For example, this type of hypothermia sometimes occurs in patients suffering from trauma or as a complication in patients undergoing surgery. Likewise, examples of hyperthemnia include exposure to overwhelming exposure to hot environmental stimulation, injury or illness, or complications of anesthesia.

[0005] In certain situations, however, hyperthermia and especially hypothermia may be desirable and may even be intentionally induced. For instance, hypothermia is generally recognized as being neuroprotective, and may, therefore, be induced in conjunction with treatments for ischemic or hemorrhagic stroke, blood deprivation such as caused by cardiac arrest, intracerebral or intracranial hemorrhage, and head and spinal trauma. In each of these instances, damage to neural tissue may occur because of ischemia, increased intracranial pressure, edema or other processes, often resulting in a loss of cerebral function and permanent neurological deficits. Intentionally induced hypothermia may reduce or avoid the damage that would otherwise occur if the patient temperature was normothennic or hyperthermic.

[0006] Other examples where hypothermia may be neuroprotective include periods of cardiac arrest in myocardial infarction and heart surgery, neurosurgical procedures such as aneurysm repair surgeries, endovascular aneurysm repair procedures, spinal surgeries, procedures where the patient is at risk for brain, cardiac or spinal ischemia such as beating heart by-pass surgery or any surgery where the blood supply to the heart, brain or spinal cord may be temporarily interrupted. Hypothermia has also been found to be advantageous as a treatment to protect both neural tissue and cardiac muscle tissue during or after a myocardial infract (MI).

[0007] Body heating and cooling can be achieved in a variety of ways. Body heating is most simply achieved by wrapping a patient in blankets and/or heated jackets in order to raise body temperature over time. Body cooling can be similarly achieved using cooling jackets. The ability to cool patients using external cooling, however, is problematic. Induced cooling will trigger a patient's thermoregulatory responses, causing patient's body to generate more heat in order to maintain body temperature. It has also been found that external cooling can cause the patient to "shiver," and that shivering not only causes discomfort but also induces the patient's body to generate still more heat in response.

[0008] In order to overcome the deficiencies of external body heating and cooling, it has been proposed to heat or cool blood in a patient's circulation, thus effecting an internal modification of body temperature. For example, it has been proposed to remove blood in a patient, e.g., from the inferior vena cava, externally heat or cool the blood, and then return the blood to patient circulation. Such external cooling of patient blood is performed, for example, during cardiopulmonary bypass surgery where the heart is stopped and the blood is also oxygenated. Such external blood cooling, however, suffers from a number of deficiencies. It is quite invasive to the patient, is damaging to the blood (causing significant hemolysis over time), generally must be performed in a sophisticated operating room and by highly trained and expensive medical specialists, and can only be performed for up to several hours before it must be discontinued. Thus, external blood heating or cooling is not appropriate for many circumstances.

[0009] Of particular interest to the present invention, an improved method for adding or removing heat from patient circulation uses a heat exchange catheter placed in the bloodstream of a patient, as described in U.S. Pat. No. 5,486,208 to Ginsburg, the complete disclosure of which is incorporated herein by reference. The Ginsburg patent discloses a method of controlling the temperature of a body by adding or removing heat to the blood by inserting a heat exchange catheter having a heat exchange region into the vascular system and exchanging heat between the heat exchange region and the blood to affect the temperature of a patient. One method disclosed for doing so includes inserting a catheter having a heat exchange region comprising a balloon into the vasculature of a patient and circulating warm or cold heat exchange fluid through the balloon while the balloon is in contact with the blood. Other patents and applications describing heat exchange catheters are listed below.

[0010] Heretofore, the balloons of heat exchange catheters have generally been formed from polyethylene terephthalate (PET) and other substantially non-distensable materials, i.e., materials which are essentially non-elastic and do not stretch when the balloon is filled with heat exchange medium. Distensible or elastomeric heat exchange structures, however, may have certain advantages over non-distensible heat exchange structures in many situations. For example, when the balloon is non-elastic, it needs to be folded or otherwise constrained on the distal end of the heat exchange catheter in order to facilitate introduction. After use and deflection prior to withdrawal, the heat exchange balloon becomes loose and floppy, rendering withdrawal of the catheter more difficult. In its loose and floppy condition, it may be more prone to damage upon withdrawal from the patient. Further, responsiveness to various ranges of pressures is sometimes an advantage, for example when pulsing or fluctuating motion desirable to induce mixing for enhanced heat exchange in flowing fluid such as blood. The control of size by control of pressure in the elastomeric heat exchange structure may be an advantage, for example, when a range of heat exchange surface sized can be obtained for different sized patients using the same type of device by controlling the pressure of the heat exchange fluid. Moreover, manufacturing of heat exchange catheters with PET and other non-distensible balloon materials may be more difficult and expensive than manufacturing the device with elastomeric material.

[0011] For these reasons, it would be desirable to provide improved heat exchange catheters, and in particular improved balloon structures on such heat exchange catheters. Such balloon structures will preferably conform closely to the exterior surface of the heat exchange catheter when introduced and will return to such a closely conforming configuration when withdrawn after use. Such balloon structures should provide adequate or improved heat transfer characteristics when compared with the PET and other non-distensible balloon materials of prior art. Moreover, such balloon structures should be fabricated from materials which are bio-compatible and which induce little or no clot formation (are non-thrombogenic). At least some of these objectives will be met by the inventions described hereinafter.

[0012] 2. Description of the Background Art

[0013] Patents and published applications assigned to the assignee of the present invention include U.S. Pat. Nos. 6,306,161; 6,264,679; 6,231,594; 6,149,676; 6,149,673; 6,110,168; 5,989,238; 5,879,329; and 5,837,003; U.S. Patent Publication US 2001/005791; and Published PCT Applications WO 01/64164; WO 01/58397; WO 01/152781; WO 01/43661; WO 01/13809; WO 01/10323; WO 00/10494; WO 98/31312; and WO 98/26831. Other patents relating to body cooling include U.S. Pat. Nos. 6,325,818; 6,312,452; 6,261,312; 6,254,626; 6,251,130; 6,251,129; 6,245,095; 6,238,428; 6,235,048; 6,231,595; 6,224,624; 6,149,677; 6,096,068; 6,042,559; 6,299,599; 6,290,717; 6,287,326; 6,165,207; 6,149,670; 6,146,411; 6,126,684; 6,019,703; and 5,269,758. The full disclosures of each of these patents and published applications are incorporated herein.

BRIEF SUMMARY OF THE INVENTION

[0014] This section describes what may be typical features and characteristics of a medical device of the invention, but unless the feature is specifically stated to be necessary, the references are not limiting of the invention despite their inclusion in this section.

[0015] The present invention provides improved heat exchange catheters having elastic heat exchange structures, referred to hereinafter as "balloons" or "chambers." The heat exchange structures are elastically expansible so that they inflate or enlarge when a suitable heat exchange medium, such as heated or cooled saline, is introduced to the heat exchange structure under pressure. The heat exchange medium will usually, although not necessarily be non-compressible. The pressure-induced expansion enlarges the heat exchange structure, thus increasing the surface area of the heat exchange structure which is available for transferring heat to or from the circulating blood in a patient's vasculature.

[0016] Many aspects of the construction of the heat exchange catheters may be conventional and may, for example, incorporate many elements of the heat exchange catheters described in the patents and applications, which have been incorporated by reference above. For example, the heat exchange structures of the present invention will be incorporated on a catheter body having a proximal end, a distal region, and usually at least two fluid flow lumens therethrough. The catheter body will be suitable for percutaneous introduction to the patient's vasculature through a variety of access sites, such as introduction into the femoral vein and advancement into the inferior vena cave (IVC) or introduction into one of the carotid veins or the subclavian vein and advancement into the superior vena cava (SVC). Any other appropriate site may be used; for example placement in the arterial vasculature may be made by introduction into the femoral artery and advancement into the aorta. Other placement as may be appropriate for the particular purpose is within the contemplation of this patent, for example into the renal arteries to cool the kidneys, into the hepatic arteries to cool the liver or into the carotid arteries to cool the bead or brain.

[0017] The catheter bodies will typically have a length in the range from 15 cm to 100 cm, typically from 25 cm to 75 cm, and a diameter from 1 mm to 4 mm, usually from 2 mm to 4 mm. The catheter bodies will typically be formed from a relatively hard, non-elastic polymer, typically having a hardness in the range from 75 A to 82 D, usually from 85 A to **72** D. Suitable polymeric materials include polyurethanes, C-Flex®, and the like. Specific catheter body designs are disclosed, for example, in U.S. Pat. No. 6,264,679, assigned to the assignee in the present application, and WO 00/10494, the full disclosures which are incorporated herein by reference, as well as PCT application PCT/US01/03828, assigned to the assignee in the present application, and WO 00/10494, the full disclosures of which are incorporated herein by reference.

[0018] As used herein, the term "elastic" includes heat exchange structures which are formed from a suitable elastomer, as well as structures which are formed from non-elastomeric sheets or membranes and which incorporate elastic reinforcement or constraining materials so that the structures may elastically expand and deflate as the heat exchange medium is introduced and removed. Suitable elastomers will usually be softer and often thinner than the material from which the catheter body has been formed, but may be composed of the same polymeric resin. Suitable elastomeric balloon or chamber materials will have hardness in the range from 65 A to 45 D, usually from 75 A to 100 A. Suitable elastomers include polyurethanes, silicone ruber, natural and synthetic latex (although generally not preferred), polyvinyls, plastisized PVC and the like. An exemplary and presently preferred material is styrene-ethylene-butylene-modified block copolymer with silicone oil, available under the C-Flex® tradename. The use of a heat exchange structure material which is the same as (although softer and more elastic than) the catheter body material is advantageous since it facilitates heat sealing of the materials together, as will be described in more detail below.

[0019] The catheter bodies of the heat exchange catheters of the present invention will usually have at least two lumens to provide for inflow and outflow of the heat exchange medium, respectively. Optionally, additional lumens may be provided for supply of heat exchange medium to different compartments within the heat exchange structure or for other purposes.

[0020] In a first aspect of the present invention, heat exchange catheters comprise a catheter body having a proximal end and a distal end. A heat exchange balloon structure is disposed over the distal region, and the balloon structure is constructed or composed of the elastic material selected so that the structure initially conforms to the distal region of the catheter body (preferably without folding as is characteristic of non-distensible balloons such as angioplasty balloons) and expands elastically in response to the introduction of the heat exchange medium under pressure. When the treatment is done, and the supply of the heat exchange medium terminated, the heat exchange balloon structure will deflate elastically so that it again conforms to the catheter body to facilitate removal of the catheter. While the heat exchange structures will be highly elastic, it will be appreciated that some hysteresis, i.e., loss of the elasticity, is acceptable. It is preferred, however, that the elongation of the balloon structure in any one direction be less than 10% after use, preferably being less than 0.5%.

[0021] Preferred balloons and other heat exchange structures will be relatively small when deflated, having a diameter or width which does not significantly exceed that of round catheter body. The functional deflated cross-sectional size is sometimes called profile. If the catheter is not round, this still gives a functional measure of the size since this is the size of puncture introducer hole that is necessary in order to insert the catheter. Profile is generally measured in French size (Fr) with one Fr equal to 0.33 mm. The Fr size of the preferred catheters including balloons will generally be between 4 Fr and 14 Fr with a size between about 6 Fr and 10 Fr being preferable. Generally, a smaller French size for insertion is preferable to a larger size, and one advantage of the elastomeric heat exchange region is the potential of having a very large heat exchange surface when inflated despite a small French size when deflated for insertion. When inflated at a typical heat exchange medium pressure in the range from 0.5 psig to 50 psig, however, the heat exchange balloons or other structures will have a surface area which is significantly greater, typically increasing by at least 10% more typically by at least 25%.

[0022] In a second aspect of the present invention, the heat exchange catheter comprises a catheter body having a proximal end, a distal region, an inflow lumen, and an outflow lumen. The heat exchange balloon or other structure comprises a plurality of elastic polymer chambers disposed over the distal region and fluidly connected at an inlet end to the inflow lumen and at an outlet end to the outflow lumen. By dividing the inflow of heat exchange medium among a plurality of heat exchange chambers, the heat transfer rate can be improved. Polymeric chambers may be arranged axially, helically, or in other patterns over the distal region of the catheter body. The number of chambers may vary, typically be in the range from two to twelve, usually from two to eight, and preferably from four to eight. In order to further enhance heat transfer, it is sometimes desirable to circumferentially space-apart the axial or spiral chambers which are formed over the distal region. The surface areas when inflated and deflated, material properties, and other characteristics of these catheters will generally be the same as described with respect to the first embodiment of the catheter set forth above.

[0023] In a third embodiment, a heat exchange catheter constructed in accordance with the principles of the present invention comprises a catheter body having a proximal end, a distal region, an inflow lumen, and an outflow lumen. An elastomer tube (either consisting of an elastomeric material or reinforced or constrained by elastomeric components) is coaxially positioned over the distal region, and the tube is sealed to the catheter body along a multiplicity of lines to define at least one, and usually a plurality of separate inflatable chambers, each of which is fluidly connected at an inlet end to the inflow lumen and at an outlet end to the outflow lumen. The surface areas of the chambers, materials of the balloon and catheter body, catheter dimensions, and the like, may all be the same as described with the first and second embodiments of the present invention as set forth above.

[0024] In a fourth aspect, the present invention comprises a method for fabricating a catheter. A tubular catheter body is first positioned over a mandrel where the catheter body has at least an inflow lumen and an outflow lumen. An elastomer tube (as defined above) is placed over the distal region of the catheter body, and the elastomer tube is then attached to the catheter body in order to define a plurality of separate, elastically expandable chambers between the outside of the catheter body and the inside of the elastomer tube. The chambers are arranged so that an inlet end of each chamber is fluidly connected to the inflow lumen and an outlet end of each chamber is fluidly connected to the outflow lumen. The dimensions, materials, and other characteristics of the catheter body and elastomer tube may generally be the same as set forth above for the catheter body and elastic heat exchange region.

[0025] In the preferred embodiments, the elastomer tube is attached to the catheter body using heat staking in which case it further preferred that the elastomer tube be "heat sealable" with the material of the catheter body, typically being the same material but having a different hardness. By "heat sealable" it is meant that the materials of the catheter body and the elastomer tube will, when exposed to heat, at least partially melt and meld together along lines formed by a suitable heating tool. Such heat staking or other sealing will preferably be performed over a multiplicity of lines to define the plurality of chambers therebetween. Chambers may be formed axially, helically, or in other patterns as desired. In a preferred aspect of the fabrication method, the heat stake or other attachment lines will be formed to have a width in the circumferential direction in the range from 0.01 mm to 2 mm, preferably from 0.1 mm to 0.5, in order to circumferentially separate adjacent heat exchange chambers.

[0026] In a fifth aspect of the present invention, a method for exchanging heat with vascular circulation of a patient comprises percutaneously introducing a catheter to a blood vessel of the patient. The catheter includes at least one elastic chamber conformed over a surface thereof while it is introduced. After introduction, the chamber is elastically inflated with a heat exchange medium, typically heated or cooled saline, whereby heat is exchanged between the heat exchange medium and the vascular circulation. Typically, the catheter may be introduced into a blood vessel, such as the femoral vein, an advanced so that the heat exchange region is at a desired location in the vasculature such as the IVC. The heat exchange chamber is inflated with heat exchange medium at a pressure in the range from 0.5 psi to 50 psi, preferably from 1 psi to 30 psi, and a flow rate in the range from 5 ml/min to 1000 m/min, preferably from 100 ml/min to 500 ml/min. For heating, the temperature of the medium will typically be in the range from 33° C. to 48° C., usually from 38° C. to 42° C. For cooling, the temperature of the medium will typically be from −10° C. to 34° C., usually from 0° C. to 10° C. In a particular aspect of the present invention, the heat exchange medium may be pulsed within the elastic heat exchange structure in order to cause the heat exchange surface to move or pulse, as generally described in commonly assigned patent application Ser. No. 09/872,818, the full disclosure which has previously been incorporated herein by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] **FIG. 1** is a perspective illustration of a heat exchange catheter constructed in accordance with the principles of the present invention.

[0028] **FIGS. 2A and 2B** illustrate a first embodiment of a heat exchange structure according to the present invention.

[0029] **FIGS. 3A and 3B** illustrate a second embodiment of the heat exchange structure of the present invention.

[0030] **FIGS. 4A and 4B** illustrate a third embodiment of the heat exchange structure of the present invention.

[0031] **FIGS. 5A and 5B** illustrate alternate cross-sectional views taken along line **5-5** of **FIG. 4B**.

[0032] FIGS. **6A-6C** illustrate a method of fabricating the heat exchange catheters of the present invention.

[0033] **FIG. 7** illustrates the heat exchange catheter of **FIG. 1** being used to treat a patient.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

[0034] Referring to **FIG. 1, a** heat exchange catheter **10** comprises a catheter body **12** having a proximal end **14** and a distal region **16**. The catheter body **12** is a multi-lumen tube having the dimensions and characteristics set forth above. A hub **18** is attached at the proximal end **14** of the catheter body and includes an inlet port **20** and an outlet port **22**. The inlet port is fluidly connected to an inflow lumen **24** **(FIG. 2A)** in the catheter body while the outlet port **22** is connected to an outflow lumen **26**. The inlet port **20** and outlet port **22** will typically comprise luer fittings or rather conventional attachments suitable for connecting to a source of recirculating heat exchange medium, such as heated or cooled saline. Other suitable heat exchange medium may include saline in other concentration, superoxygenated fluid, carbon dioxide, helium, water, or any other similar fluid that is non-toxic in case of rupture in the heat exchange region. Suitable external heat exchange sources such as pumps and mechanical heat exchangers are described in the patent and medical literature. See, for example, WO 01/64146, a PCT publication whose applicant is the assignee of the present application.

[0035] A heat exchange structure, such as a helical elastic chamber **30** is formed over the distal region **16** and fluidly connected to the inflow lumen **24** and outflow lumen **26**, as best illustrated in **FIGS. 2A and 2B**. In its deflated state **(FIG. 2A)** the heat exchange structure **20** comprises an elastomer tube having a closed distal end **32** which is tightly conformed over the catheter body **12**. The structure **30** will be sealed or staked to the catheter body **12** along a line or multiplicity of lines which define the geometry of the structure when inflated, e.g., as a helical structure as shown in **FIGS. 1 and 2B**. Other geometries will described below.

[0036] Heat exchange medium will flow in through port **20** and lumen **24** until reaching an open distal port **34** of the lumen. At this point, the medium inflates the heat exchange structure to create an expanded helical chamber **36**. The heat exchange medium then flows back in the direction as shown by the arrows in **FIG. 2B** until reaching an outlet port **38** which permits the medium to flow into the outlet lumen **26** and eventually out through outlet port **22**. A plug **40** is provided at the distal end of the outlet lumen **26** in order to prevent flow of the heat exchange medium in the wrong direction.

[0037] Although illustrated as a single spiral structure in **FIGS. 1, 2A**, **2B**, it will appreciated that the helical heat exchange structure may preferably be formed as two or more parallel helical lumens. The use of a plurality of lumens is generally preferred since it increases the total heat exchange area between the heat exchange medium and the blood flowing through the vasculature.

[0038] While the heat exchange structures will preferably be formed from a tubular member attached over the outer surface of the distal region of the catheter body (to form the heat exchange volume between the other surface of the catheter body and an inner surface of the tubular member), in some instances it could be formed from a separate tube which is wound or otherwise arranged over the catheter body **12**, e.g., as shown in **FIGS. 3A and 3B**. An elastomer tube **42** can be inserted through a port **38** and attached to the inner surface of lumen **26**, as illustrated in **FIG. 3A**. An opposite end of the tube **42** can then be inserted into the distal end of lumen **24** and attached, as also shown in **FIG. 3A**. Introduction of heat exchange medium through lumen **24** will then expand the tube, as shown in **FIG. 3B**. Removal of the heat exchange medium, will, of course, result in the elastic tubes collapsing into their low profile configuration, again as shown in **FIG. 3A**.

[0039] A variety other configurations could also be employed. A simple balloon structure without helical or other chambers formed therein is illustrated in **FIGS. 4A and 4B**. The structure of the catheter body **12** remains the same, but an elastomer tube **50** is formed over the entire length of the catheter body, as shown in **FIG. 4A**. By heat staking or otherwise sealing the tube over only a proximal portion of the catheter body, a balloon may be fully inflated, as shown in **FIG. 4B**. Such full inflation is shown in the cross-sectional view of **FIG. 5A**. Alternatively, the tube **50** could be axially heat staked or otherwise sealed to the catheter body, resulting in a multiple axial lobe embodiment as illustrated in the cross-sectional view of **FIG. 5B**. As with the helical embodiments, it will be desirable to heat stake or otherwise attach the elastomeric sheath along a line having a width W in the ranges set forth above. In this way, the distances between each of the lobes **54** are circumferentially spaced apart to enhance heat transfer. In the embodiment of **FIG. 5**, pairs of inflow and outflow lumens **24** and **26** are provided for each of the pairs of lobes. Other manifold means could be provided in order to interconnect the lobes in the desired manner.

[**0040**] The preferred catheters of the present invention may be fabricated according to the method illustrated in FIGS. **6**A-**6**C. The catheter body **12** is placed over a plurality of mandrels **60**, with one mandrel being provided for each internal lumen. At least one of the mandrels **60** will be spaced in a proximal direction to permit introduction of plug **40**. An elastomer tube is then expanded and placed over the distal region **16** of the catheter body **12**, as illustrated in **FIG. 6A**. Distal end **72** of the elastomer tube **70** is then closed and sealed, as shown in **FIG. 6B**. A heating unit **74** is then used to heat stake the elastomer tube **70** to the exterior surface of the catheter body **12** allowing axial, spiral, or other desired lines in order to define the number and geometry of heat transfer chambers that is desired. Then the mandrels are removed and the catheter is ready for final fabrication and use.

[**0041**] Use of the catheter **10** for exchanging heat with patient circulation and a blood vessel BV, as illustrated in **FIG. 7**. The catheter is percutaneously introduced to the target blood vessel, such as the IVC, and proximal hub **18** **(FIG. 1)** attached to a suitable source of heat exchange medium, such as the heat exchange device illustrated in WO 01/64146, incorporated herein by reference previously. The heat exchange medium is introduced at a pressure and a flow rate in the ranges generally described above so that the spiral heat exchange chamber **36** inflates. The inflation increases the available heat exchange area, but does not cause the catheter to engage the blood vessel walls and inhibit blood flow. Thus, blood flowing in the direction of arrows **80** passes by the exterior of the spiral heat exchange structure **36**, with heat transfer taking place between the structure and the blood. The availability of an elastic heat exchange structure permits some control over the rate of heat transfer based on the pressure the flow rate of the heat exchange medium being introduced, and if the inflation is pulsitile, the rate of pulsation. For example, the amount of inflation may be adjusted to optimize the heat exchange surface. If a large surface with a high flow rate of the heat exchange fluid is desired to maximize heat exchange, the pressure of the heat exchange fluid may be increased. If the patient is small and a smaller heat exchange surface is desired because, for example, the vessel in which the heat exchange region is located is small, then lower pressure may be used to circulate heat exchange fluid. If a very small rate of heat exchange is desired, for example, if the patient is being maintained at a target temperature, then a very low inflation/circulation pressure may be used. It is also true that heat exchange may be increased by pulsation of the heat exchange region. The rate of pulsation may be controlled to control the rate of heat exchange.

[**0042**] The pressure and the rate of pulsation may be controlled by feedback from either the patient or from the heat exchange fluid. For example, pressure feedback from the heart exchange fluid may be used to control the pressure for the expansion of the heat exchange region. Alternatively, the expansion of the balloon may be controlled based on feedback of the flow rate of the heat exchange fluid, patient temperature, rate of change of patient temperature. Similarly the pulse rate if any applied to the balloon may be controlled based on pressure feedback, flow rate of heat exchange fluid, patient temperature, rate of change of patient temperature, and the like.

[**0043**] Another advantage to the ability of this catheter to expand under pressure might be to seal off a vessel where the balloon is located or a side branch over which the balloon is located. For example, it might be advantageous to expand the heat exchange balloon sufficiently to block flow through the vessel or into a side branch vessel in coordination with an intraaortic balloon pump. Similarly it might be advantageous to temporarily seal off a section of a patient's vasculature to help localize the application of certain drugs within the vasculature while at the same time providing a heating or cooling balloon structure.

[**0044**] The embodiments set forth herein are merely exemplary of the systems and methods of the present invention. Such exemplary methods are not meant to be limiting, and it will be appreciated that a number of modifications and variations of the specific methods and structures described herein may be practiced within the scope of the invention as set forth in the claims below.

What is claimed is:

1. A heat exchange catheter comprising:

a catheter body having a proximal end and a distal region; and

a heat exchange balloon structure disposed over the distal region;

wherein the heat exchange balloon structure expands and deflates elastically when uninflated.

2. A heat exchange catheter as in claim 1, wherein the heat exchange balloon structure conforms without folding to the distal region of the catheter body when uninflated.

3. A heat exchange catheter as in claim 1, wherein the heat exchange balloon structure has a diameter when uninflated which does not exceed that of the catheter body.

4. A heat exchange catheter as in claim 1, wherein the surface area of the heat exchange balloon structure increases by at least 10% when inflated by heat exchange medium at a pressure in the range from 0.5 psig to 50 psig.

5. A heat exchange catheter as in claim 1, wherein the catheter body comprises a polymeric material having a hardness in the range from 75 A to 80 D.

6. A heat exchange catheter as in claim 4, wherein the catheter body has a length in the range from 15 cm to 100 cm and a diameter in the range from 1 mrn to 4 mm.

7. A heat exchange catheter as in any of claim 1 to **6**, wherein the heat exchange balloon structure comprises a polymeric material having a hardness in the range from 65 A to 45 D.

8. A heat exchange catheter as in claim 6, wherein the polymeric material is selected from the group consisting of polyurethanes, silicone rubber, latex, polyvinyls, plasticized PVC, and styrene-ethylene-butylene modified block copolymer with silicone oil.

9. A heat exchange catheter as in claim 7, wherein the catheter body and the balloon comprise the same material having different hardnesses.

10. A heat exchange catheter as in claim 9, wherein the same material is selected from the group consisting of polyurethanes, silicone rubber, latex, polyvinyls, plasticized PVC, and styrene-ethylene-butylene modified block copolymer with silicone oil.

11. A heat exchange catheter comprising:

a catheter body having a proximal end, a distal region, an inflow lumen, and an outflow lumen; and

a heat exchange balloon structure comprising a plurality of elastic polymeric chambers disposed over the distal region and fluidly connected at an inlet end to the inflow lumen and at an outlet end to the outflow lumen.

12. A heat exchange catheter as in claim 11, wherein the elastic polymeric chambers are arranged axially over the distal region.

13. A heat exchange catheter as in claim 11, wherein the elastic polymeric chambers are arranged spirally over the distal region.

14. A heat exchange catheter as in any of claims **11**-**13**, wherein the heat exchange balloon structure comprises from two to twelve elongated chambers.

15. A heat exchange catheter as in claim 14, wherein the elongated chambers are circumferentially spaced apart.

16. A heat exchange catheter as in claim 11, wherein the heat exchange balloon structure conforms without folding to the distal region of the catheter body when uninflated.

17. A heat exchange catheter as in claim 11, wherein the heat exchange balloon structure has a diameter when uninflated which does not exceed that of the catheter body.

18. A heat exchange catheter as in claim 11, wherein the surface area of the heat exchange balloon structure increases by at least 10% when inflated by heat exchange medium at a pressure in the range from 0.5 psig to 50 psig.

19. A heat exchange catheter as in claim 11, wherein the catheter body comprises a polymeric material having a hardness in the range from 75 A to 80 D.

20. A heat exchange catheter as in claim 19, wherein the catheter body has a length in the range from 15 cm to 100 cm and a diameter in the range from 1 mm to 4 mm.

21. A heat exchange catheter as in any of claim 11 to **20**, wherein the heat exchange balloon structure comprises a polymeric material having a hardness in the range from 65 A to 45 D.

22. A heat exchange catheter as in claim 21, wherein the catheter body and the balloon comprise the same material having different hardnesses.

23. A heat exchange catheter as in any of claim 11 to **12**, wherein the heat exchange balloon structure comprises a polymeric material having a hardness in the range from 65 A to 45 D.

24. A heat exchange catheter comprising:

a catheter body having a proximal end, a distal region, an inflow lumen, and an outflow lumen; and

an elastomer tube coaxially positioned over the distal region;

wherein the elastomer tube is sealed to the catheter body along a multiplicity of lines to define a plurality of separate inflatable chambers, each at which is fluidly connected at an inlet end to the inflow lumen and at an outlet end to the outflow lumen.

25. A heat exchange catheter as in claim 24, wherein the inflatable chambers are arranged axially over the distal region.

26. A heat exchange catheter as in claim 24, wherein the inflatable chambers are arranged spirally over the distal region.

27. A heat exchange catheter as in claim 24, wherein the catheter comprises from two to twelve inflatable chambers.

28. A heat exchange catheter as in claim 27, wherein the inflatable chambers are circumferentially spaced apart.

29. A heat exchange catheter as in claim 24, wherein the heat exchange balloon structure conforms without folding to the distal region of the catheter body when uninflated.

30. A heat exchange catheter as in claim 24, wherein the heat exchange balloon structure has a diameter when uninflated which does not exceed that of the catheter body.

31. A heat exchange catheter as in claim 24, wherein the surface area of the heat exchange balloon structure increases by at least 10% when inflated by heat exchange medium at a pressure in the range from 0.5 psig to 50 psig.

32. A heat exchange catheter as in claim 24, wherein the catheter body comprises a polymeric material having a hardness in the range from 75 A to 80 D.

33. A heat exchange catheter as in claim 32, wherein the catheter body has a length in the range from 15 cm to 100 cm and a diameter in the range from 1 mm to 4 mm.

34. A heat exchange catheter as in any of claim 24 to **33**, wherein the heat exchange balloon structure comprises a polymeric material having a hardness in the range from 65 A to 45 D.

35. A heat exchange catheter as in claim 34 wherein the catheter body and the elastomer tube comprise the same material having different hardnesses.

36. A heat exchange catheter as in any of claim 24 to **33**, wherein the heat exchange balloon structure comprises a polymeric material having a hardness in the range from 65 A to 45 D.

37. A method for fabricating a catheter, said method comprising:

positioning a tubular catheter body over a mandrel, wherein said catheter body has at least an inflow lumen and an outflow lumen;

placing an elastomer tube over a distal region of the catheter body;

attaching the elastomer tube to the tubular catheter body to define a plurality of separate elastically expandable chambers between the outside of the catheter body and the inside of the elastomer tube, wherein an inlet end of the chamber is fluidly connected to the inflow lumen and an outlet end of the chamber is fluidly connected to the outflow lumen.

38. A method as in claim 37, wherein tubular catheter body comprises a polymer having a hardness in the range from 75 A to 82 D and the elastomer tube comprises an elastomer having a hardness in the range from 65 A to 45 D.

39. A method as claim 38, wherein the polymer is selected from the group consisting of polyurethanes, silicone rubber, latex, polyvinyls, plasticized PVC, and styrene-ethylene-butylene modified block copolymer with silicone oil and the elastomer is selected from the group consisting of polyurethanes, silicone rubber, latex, polyvinyls, plasticized PVC, and styrene-ethylene-butylene modified block copolymer with silicone oil (C-Flex®), polyurethanes.

40. A method as in claim 39, wherein the polymer and the elastomer are the same material but have different hardnesses.

41. A method as in claim 37, wherein attaching comprises heat staking.

42. A method as in claim 37 or **41**, wherein attaching comprises sealing along a multiplicity of lines to define the chambers therebetween.

43. A method as in claim 42, wherein the lines are arranged axially.

44. A method as in claim 42, wherein the lines are arranged spirally.

45. A method as in claim 42, wherein the lines have a width in the range from 0.01 mm to 2 mm to circumferentially separate adjacent chambers.

46. A method for exchanging heat with vascular circulation of a patient, said method comprising;

percutaneously introducing a catheter to a blood vessel of the patient, wherein the catheter includes at least one elastic chamber conformed over a surface thereof;

elastically inflating the chamber with a heat exchange medium, whereby heat is exchanged between the heat exchange medium and the vascular circulation.

47. A method as in claim 46, wherein the catheter is introduced to a blood vessel selected from the group consisting of

a. the inferior vena cava;

b. the superior vena cave;

c. a jugular vein;

d. a carotid artery;

e. the aorta; and

f. a renal artery.

48. A method as in claim 46, wherein the at least one chamber is inflated with the heat exchange medium at a pressure in the range from 0.5 psig to 50 psig and a flow rate in the range from 5 ml/min to 1000 ml/min.

49. A method as in claim 46, wherein elastically inflating comprises pulsing the pressure of the heat exchange medium, whereby the surface of the elastic chamber moves in order to enhance heat transfer.

50. A method as in claim 46, wherein pressure feedback from the pressure of the heat exchange fluid is used to control the expansion of the heat exchange balloon.

51. A method as in claim 46, wherein the flow rate feedback from the heat exchange fluid is used to control the expansion of the balloon.

52. A method as in claim 46, wherein the balloon is expanded to a sized based on the size of the vessel in which the heat exchange region is located.

53. A method as in claim 46, wherein the pulse rate of the expansion/deflation cycle is controlled to optimize heat exchange

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