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(54) **INDWELLING HEAT EXCHANGE CATHETER AND METHOD OF USING SAME**

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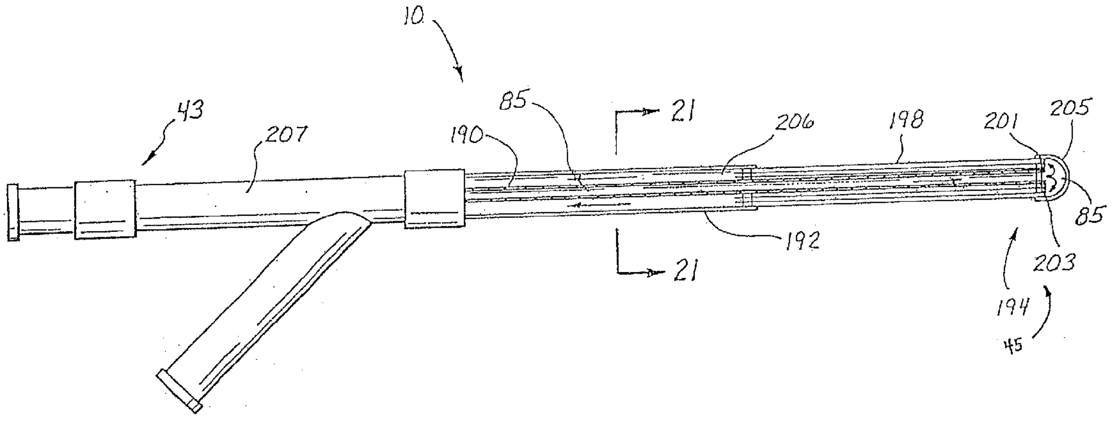
(57) **ABSTRACT**

A catheter is adapted to exchange heat with a body fluid, such as blood, flowing in a body conduit, such as a blood vessel. The catheter includes a shaft with a heat exchange region disposed at its distal end. This region may include hollow fibers which are adapted to receive a remotely cooled heat exchange fluid preferably flowing in a direction counter to that of the body fluid. The hollow fibers enhance the surface area of contact, as well as the mixing of both the heat exchange fluid and the body fluid. The catheter can be positioned to produce hypothermia in a selective area of the body or alternatively positioned to systemically cool the entire body system.



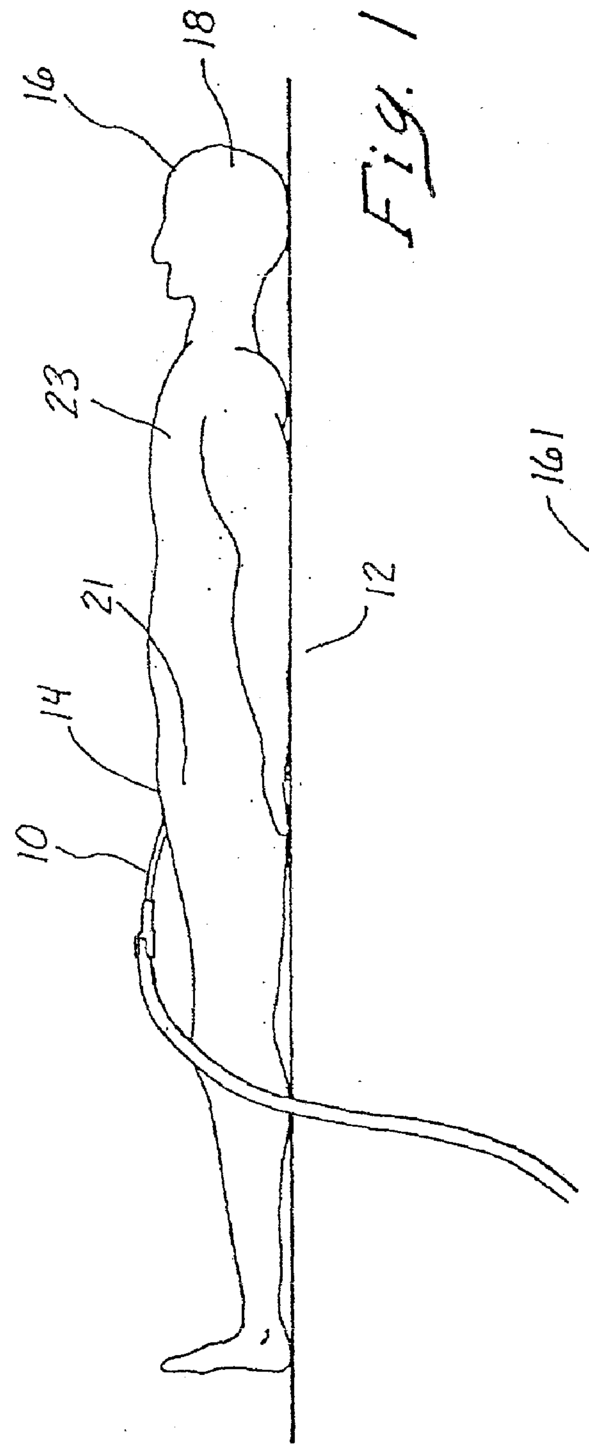


Fig. 1

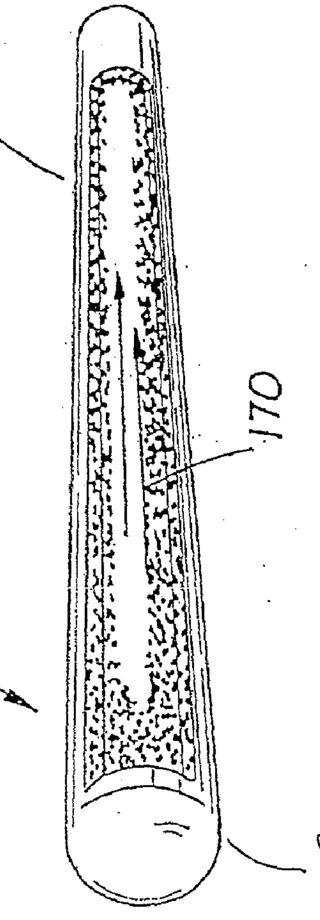


Fig. 12

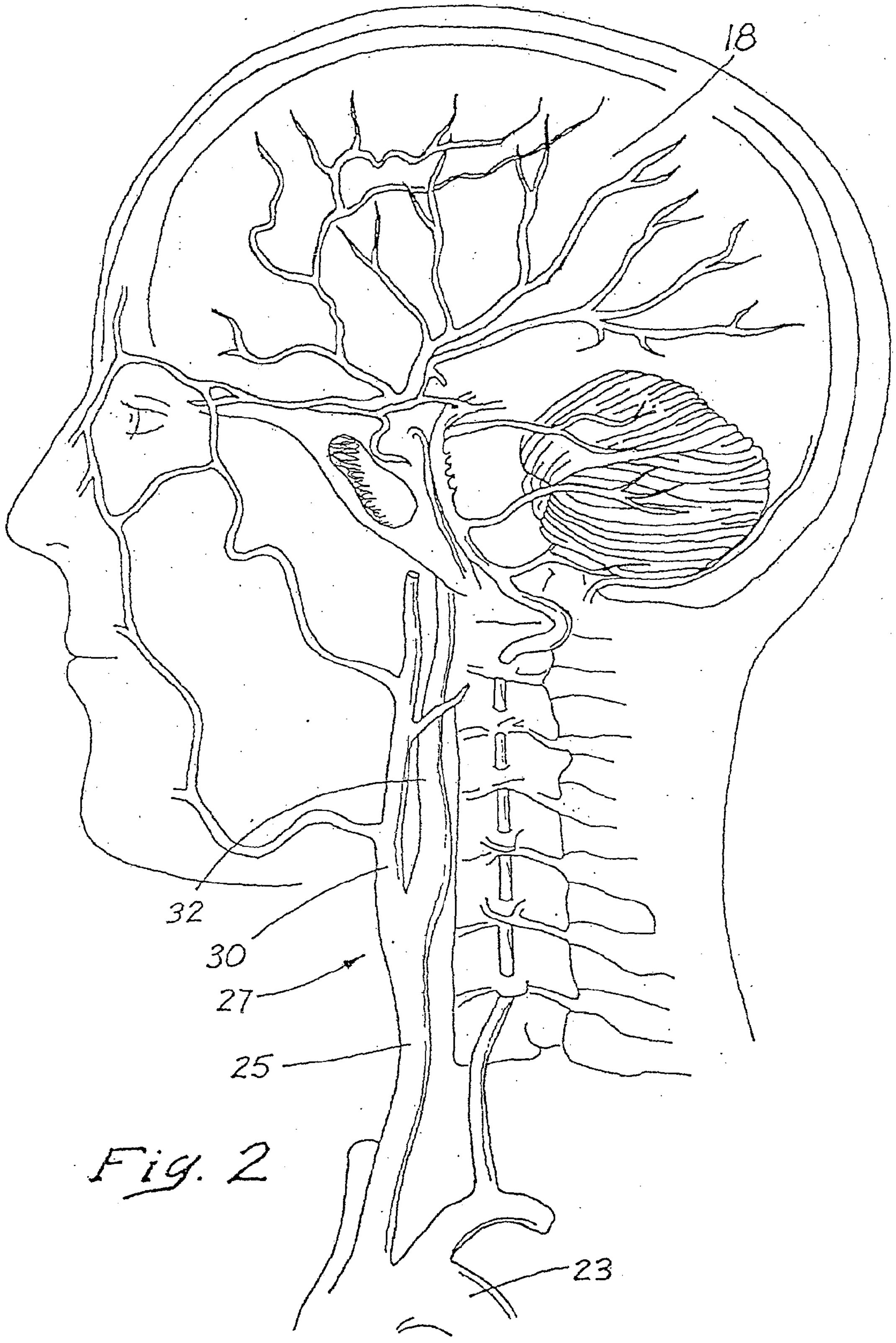
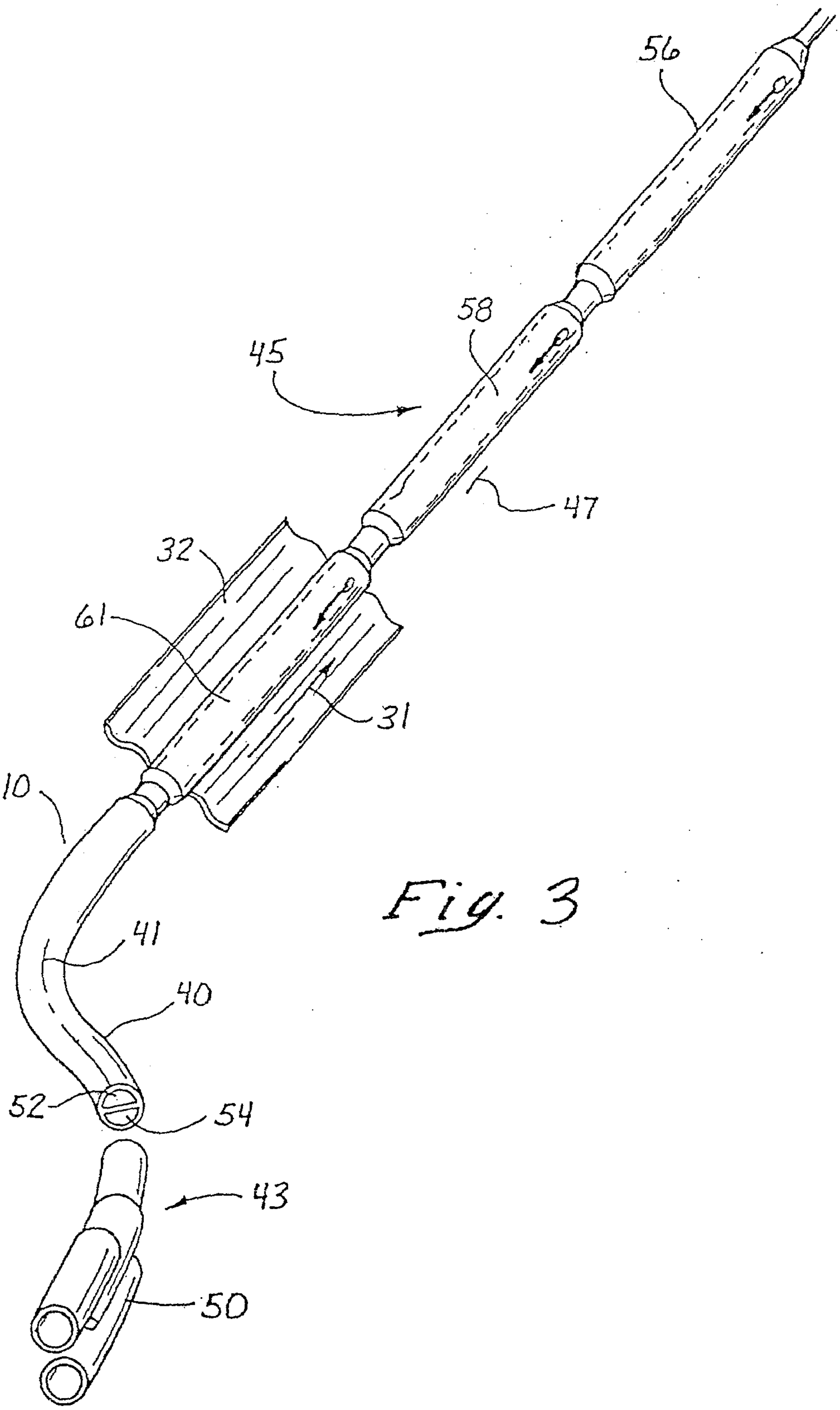


Fig. 2



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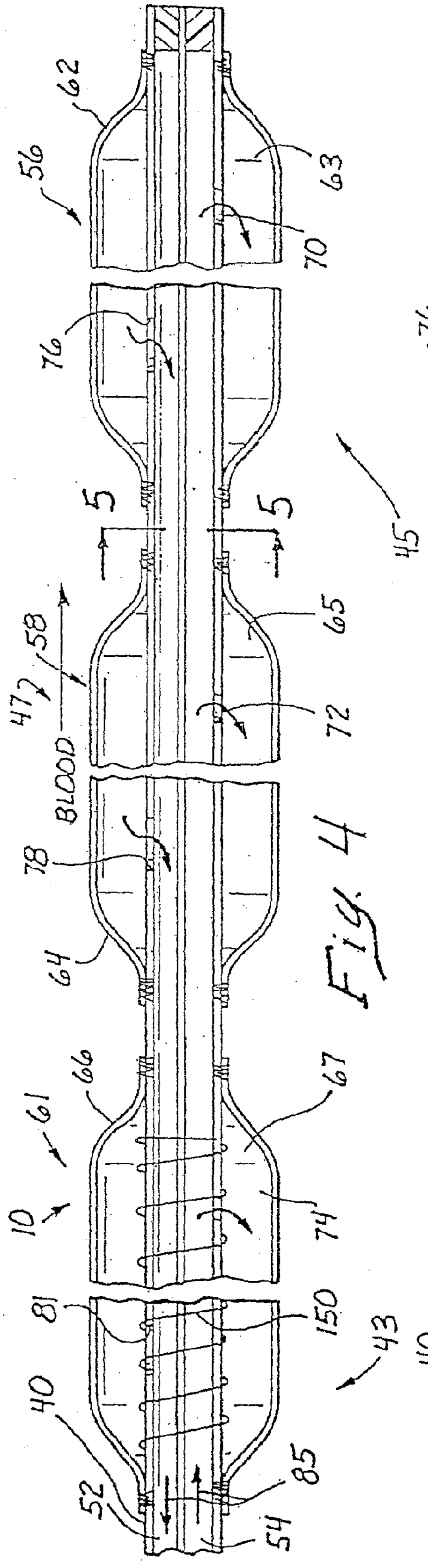
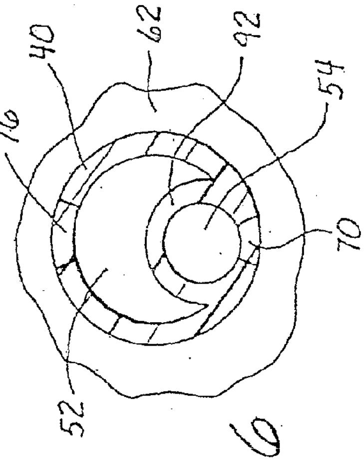


Fig. 4



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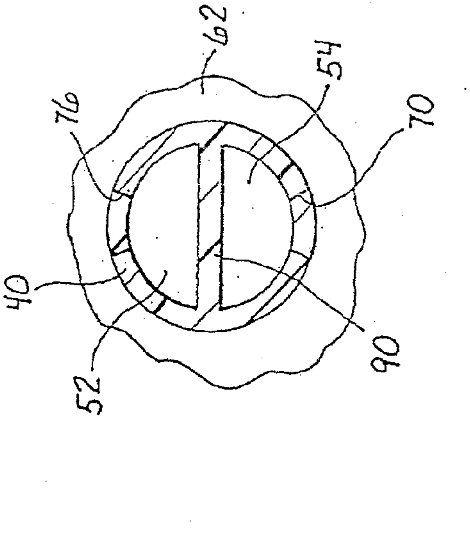

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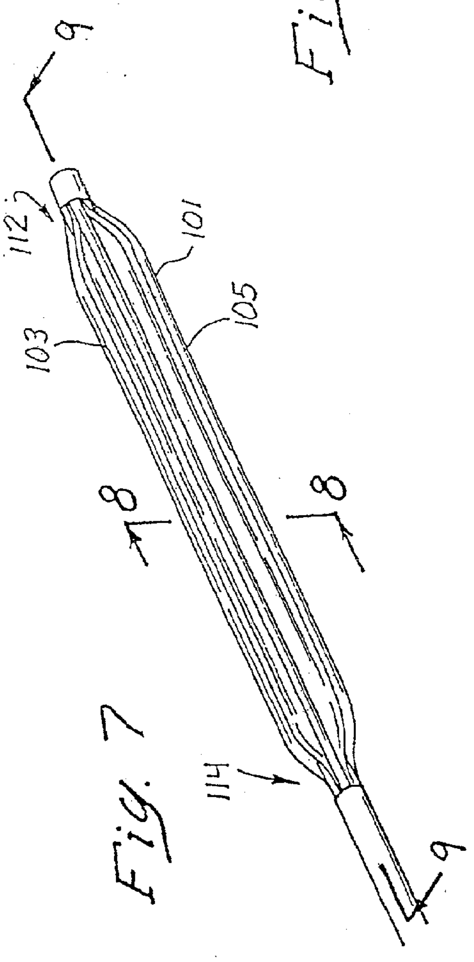

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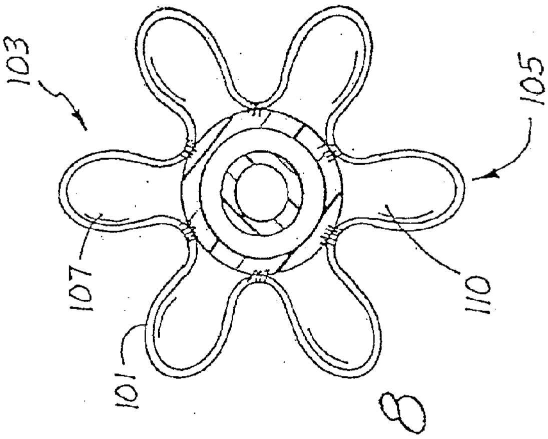

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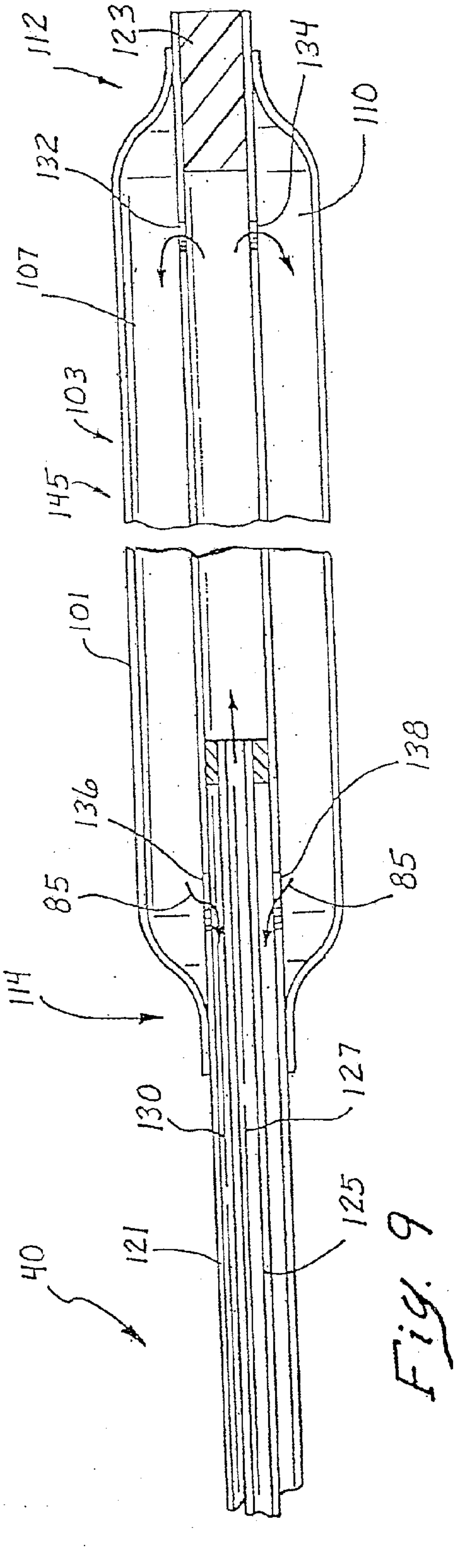

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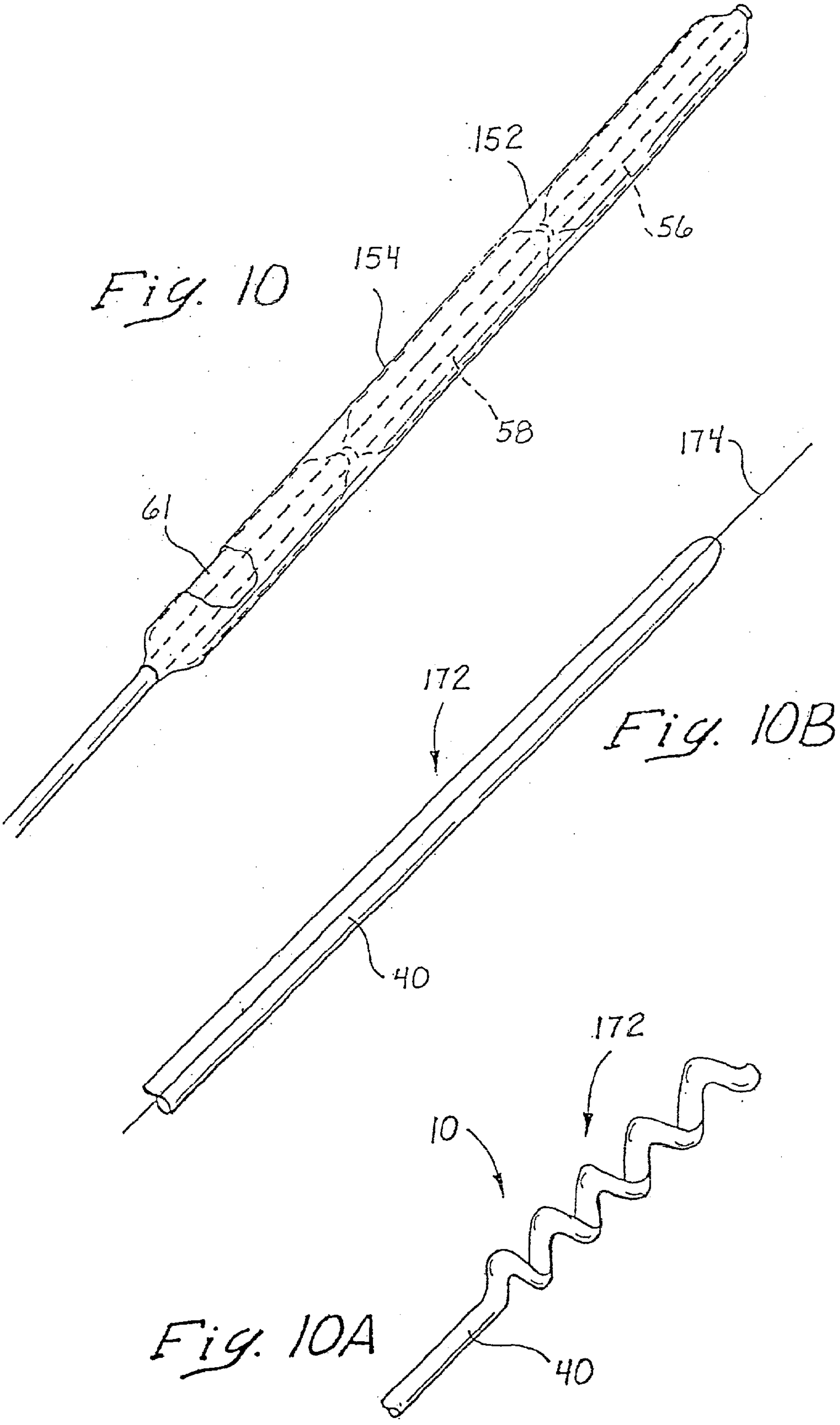
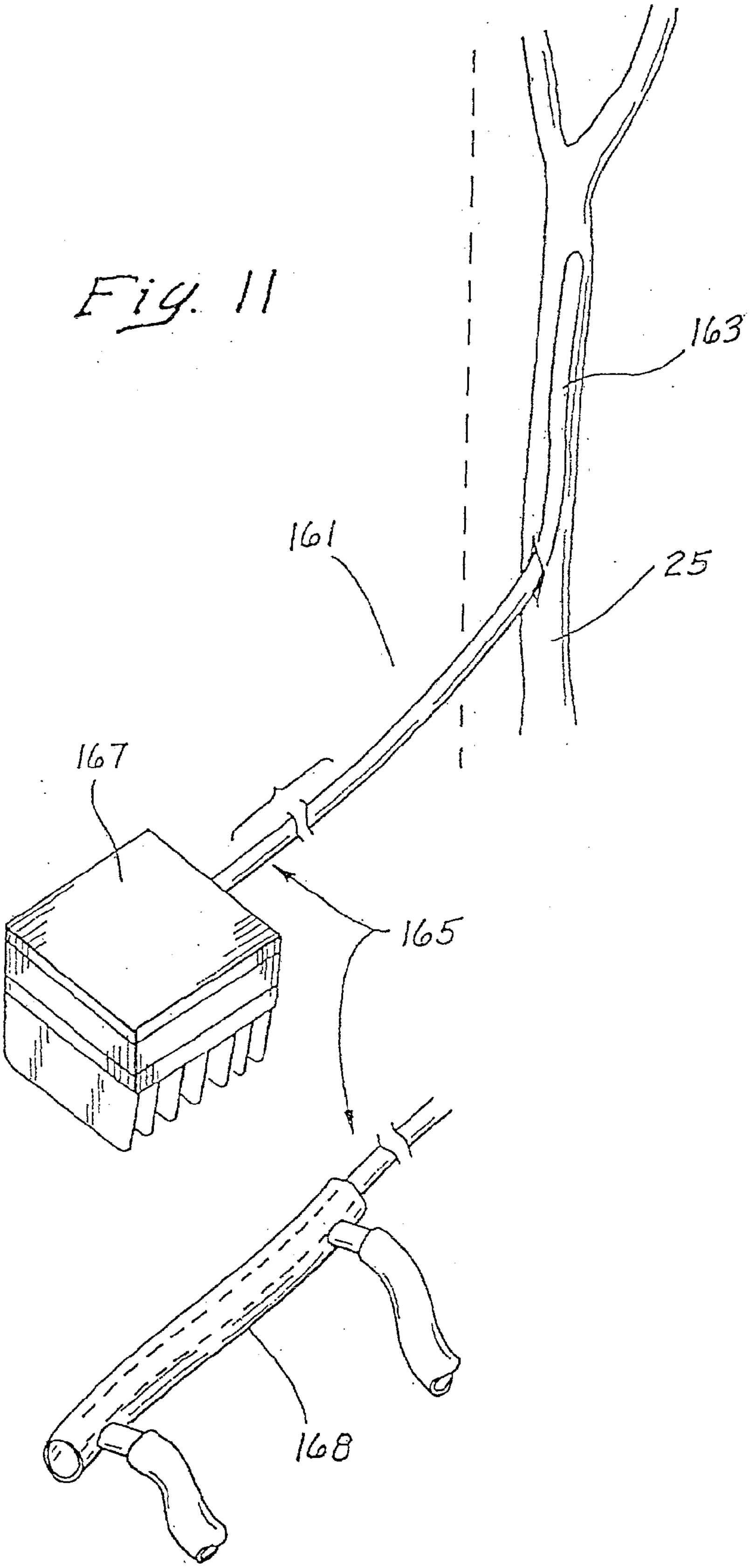


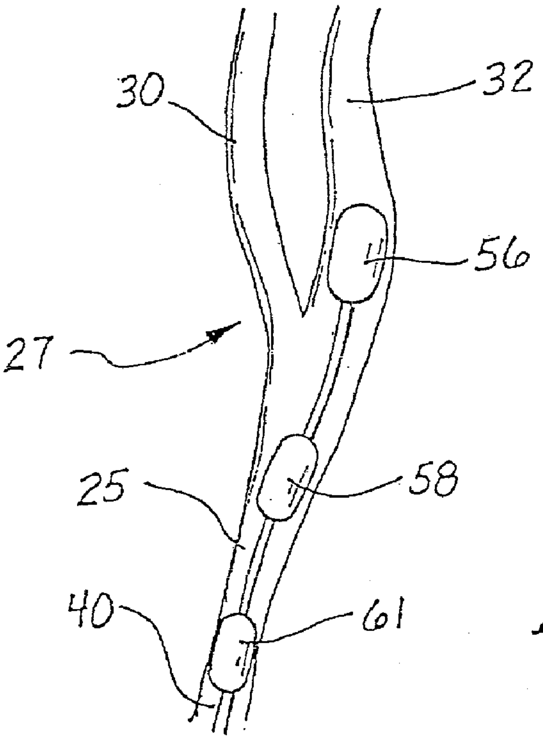
Fig. 10

Fig. 10B

Fig. 10A

Fig. 11





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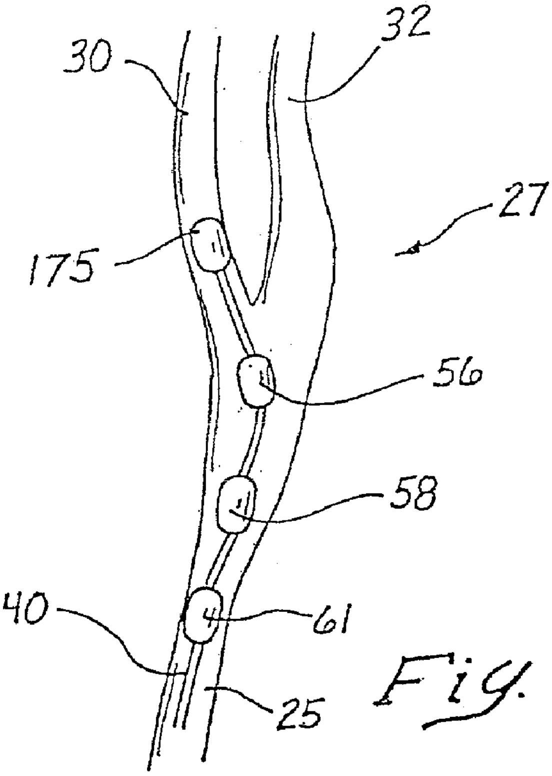

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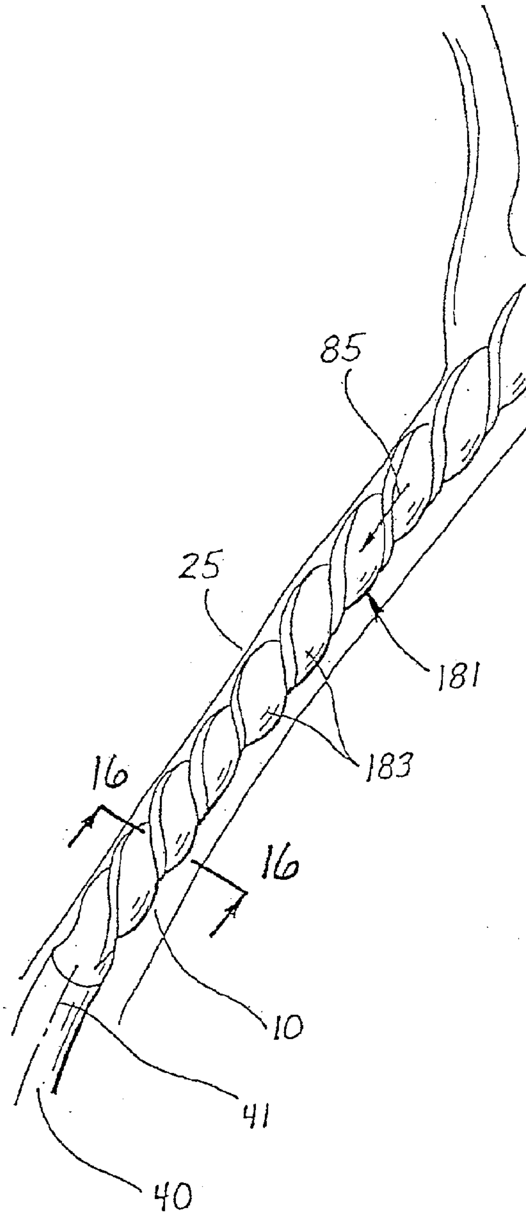

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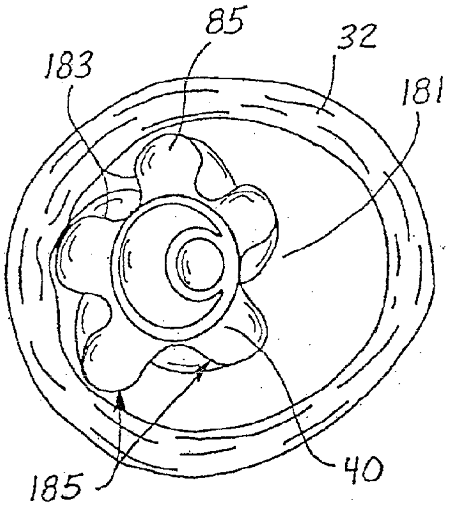

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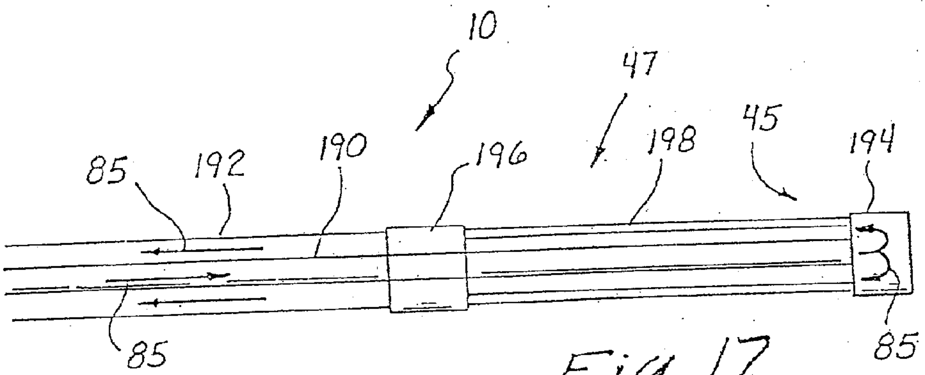

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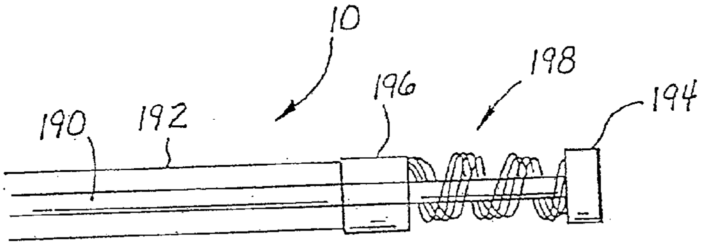

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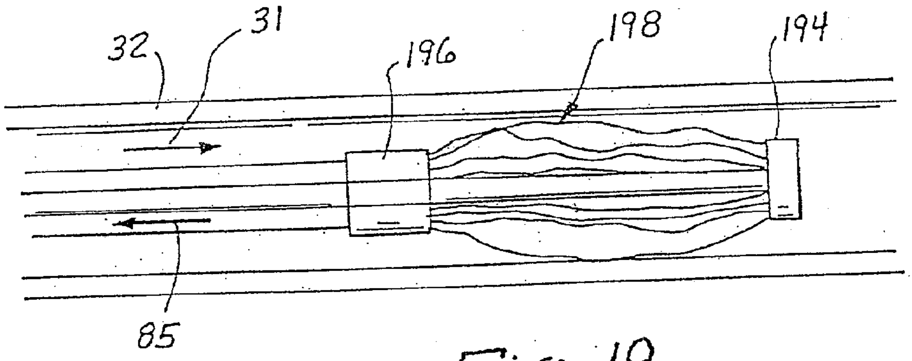

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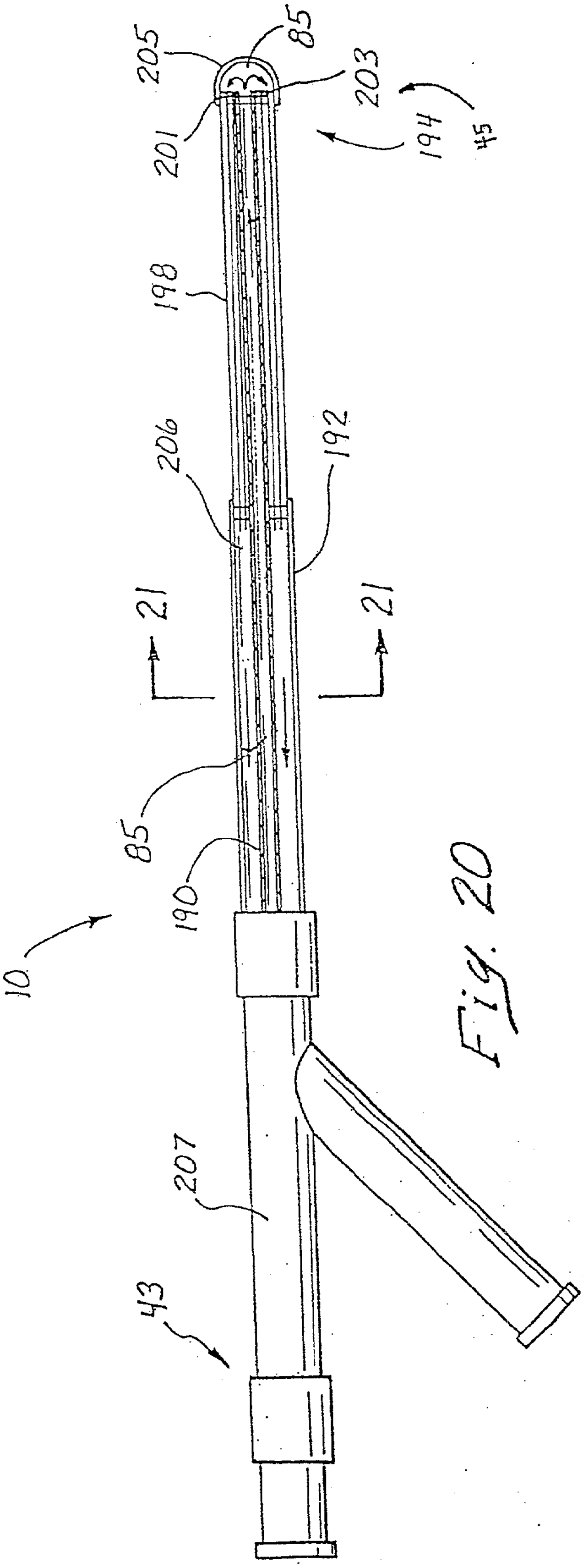

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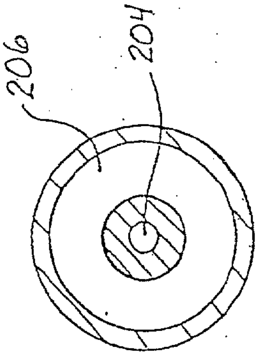

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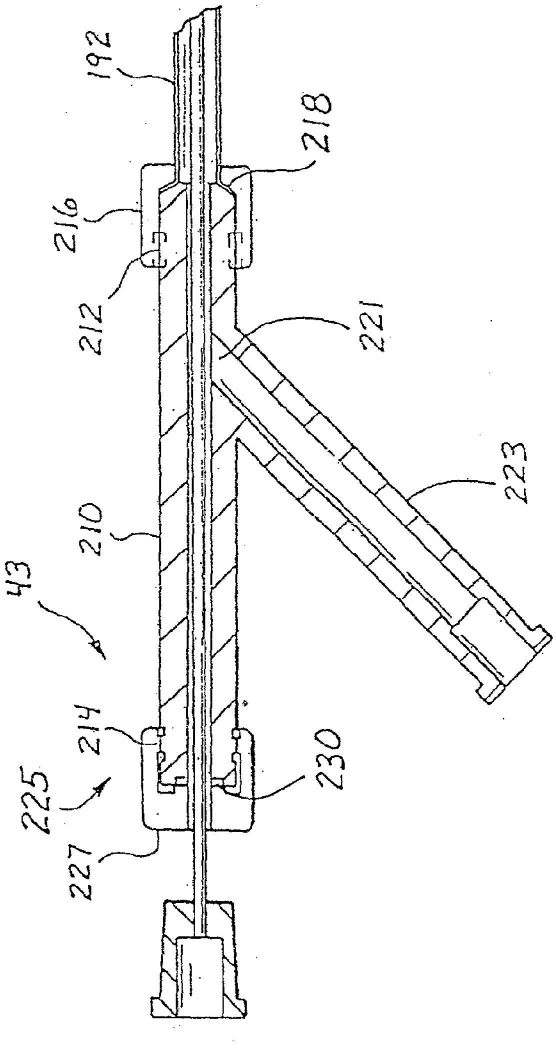

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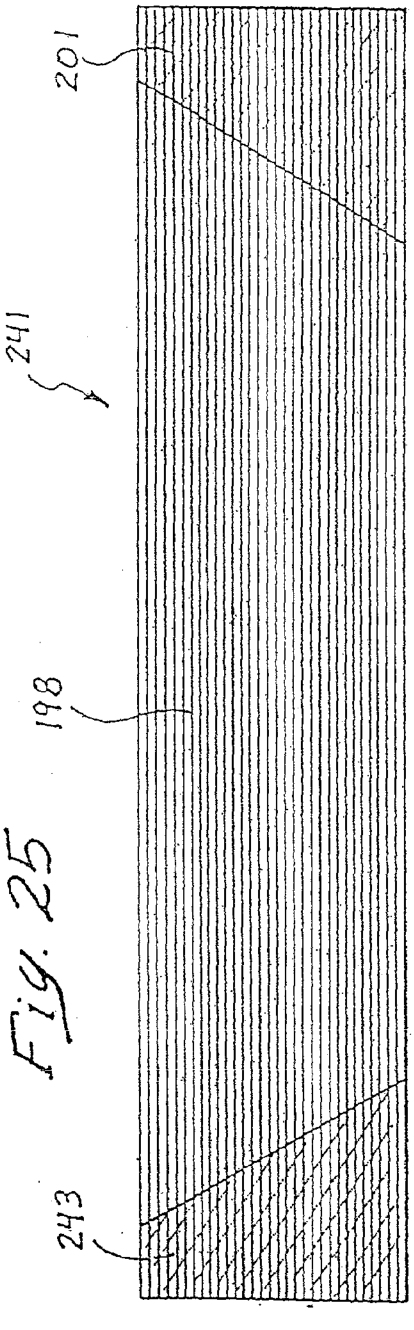

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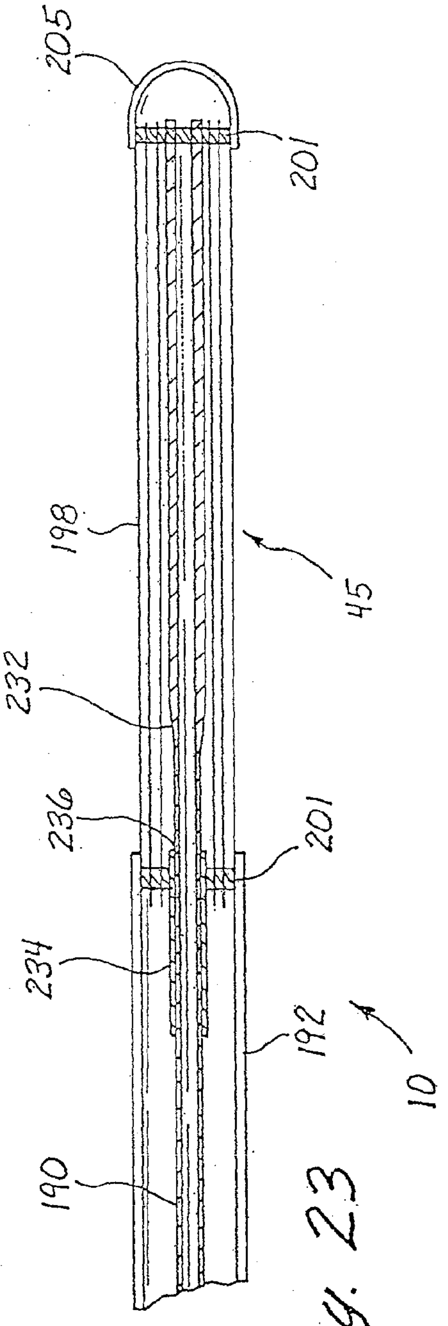
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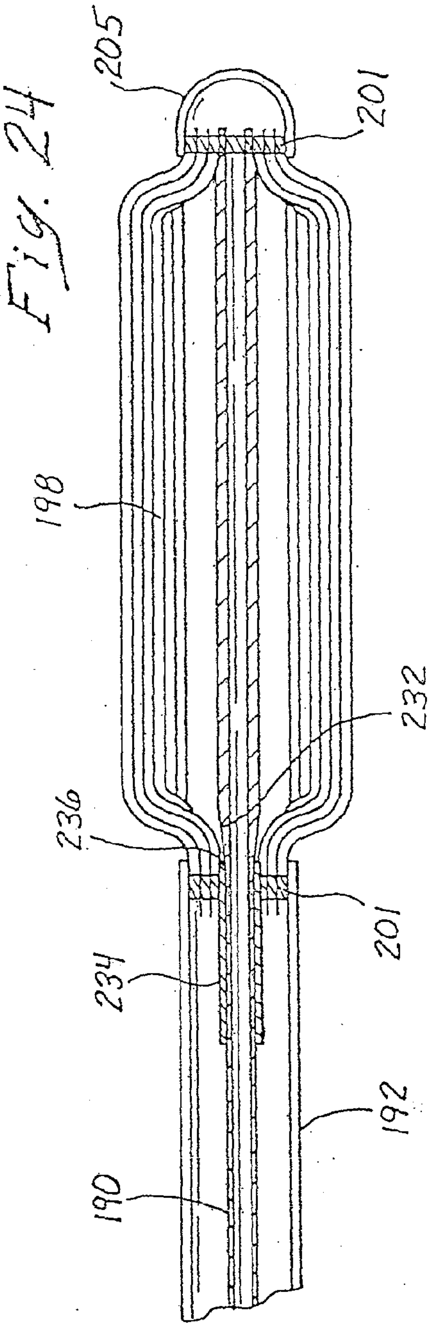
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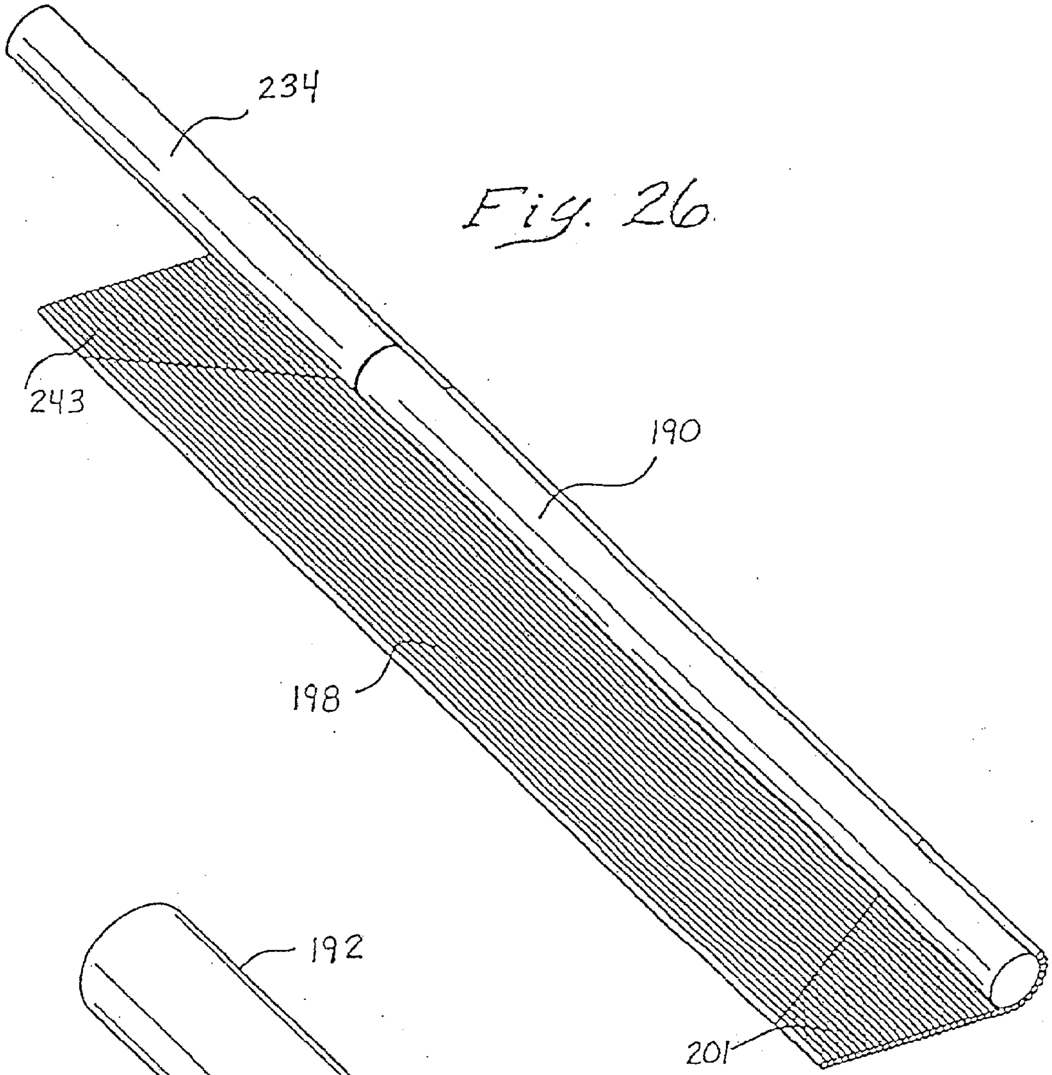

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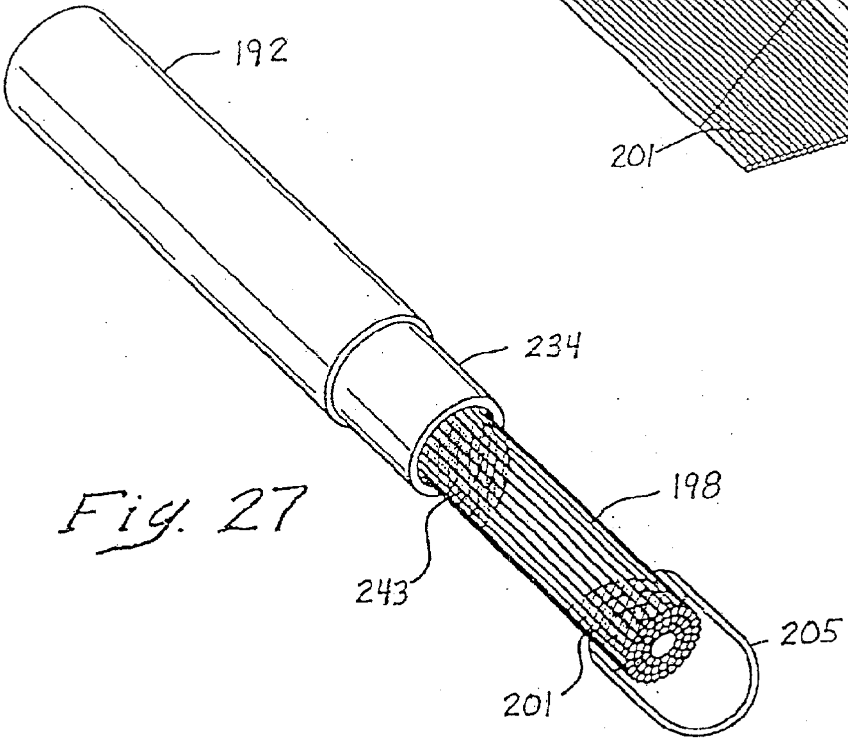

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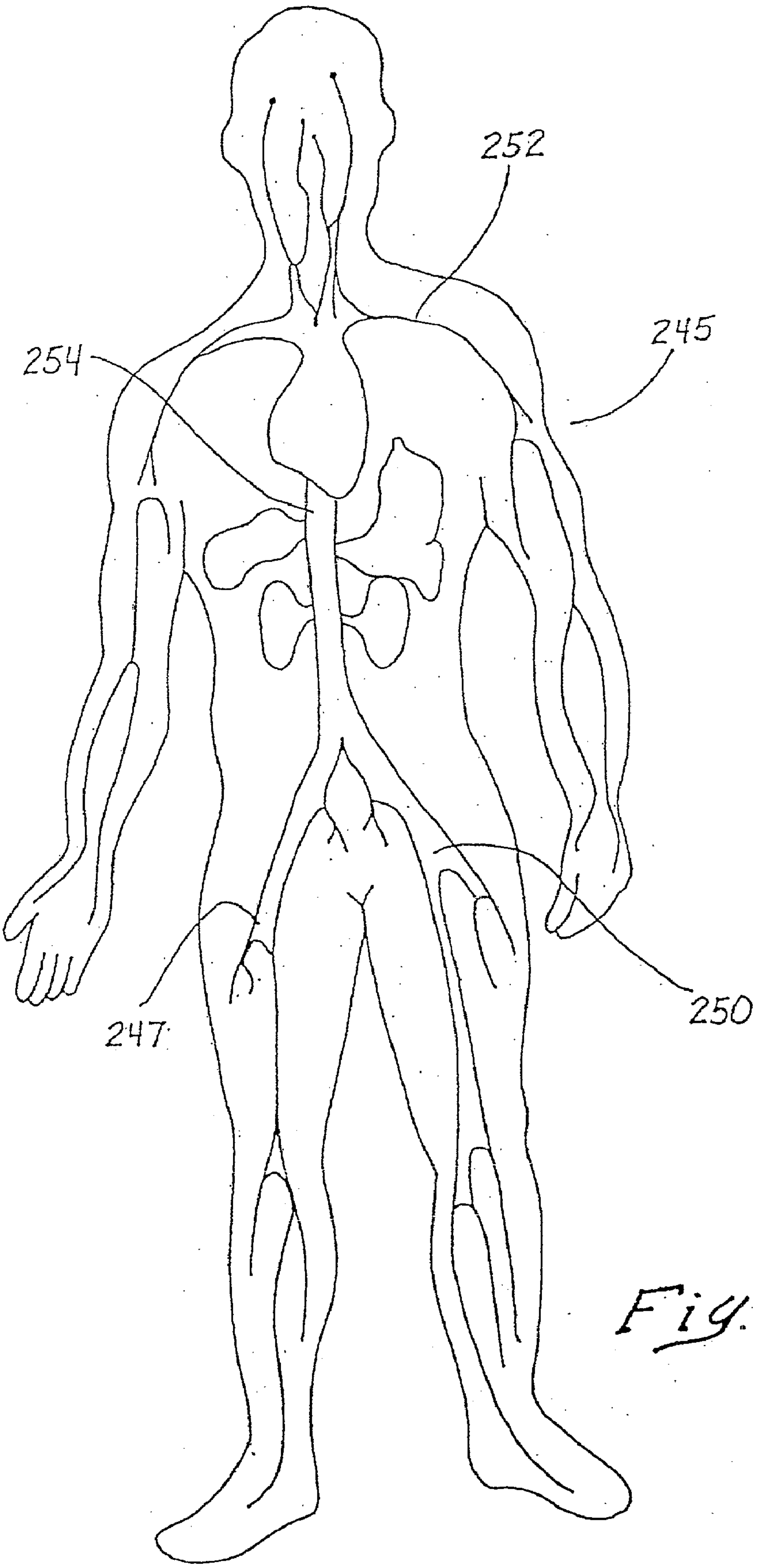

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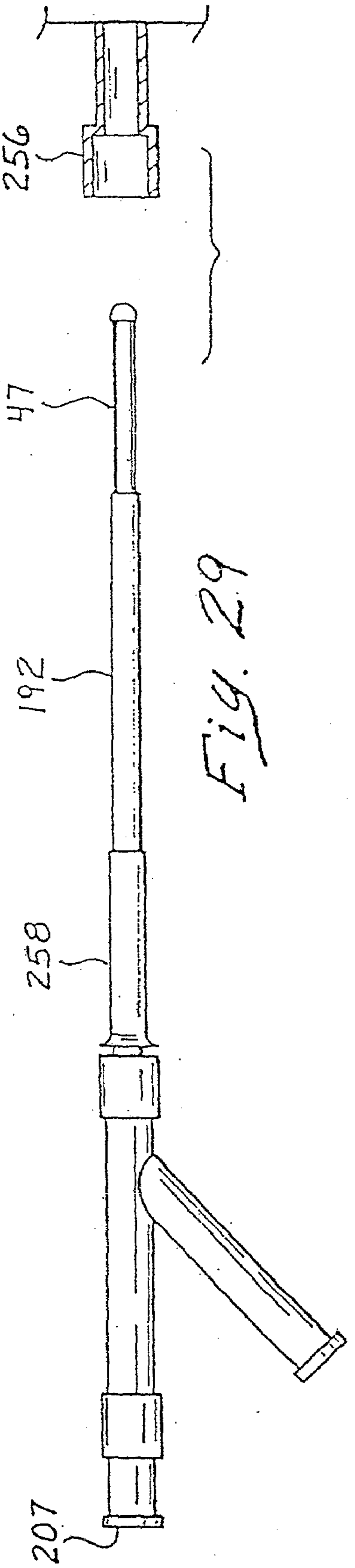

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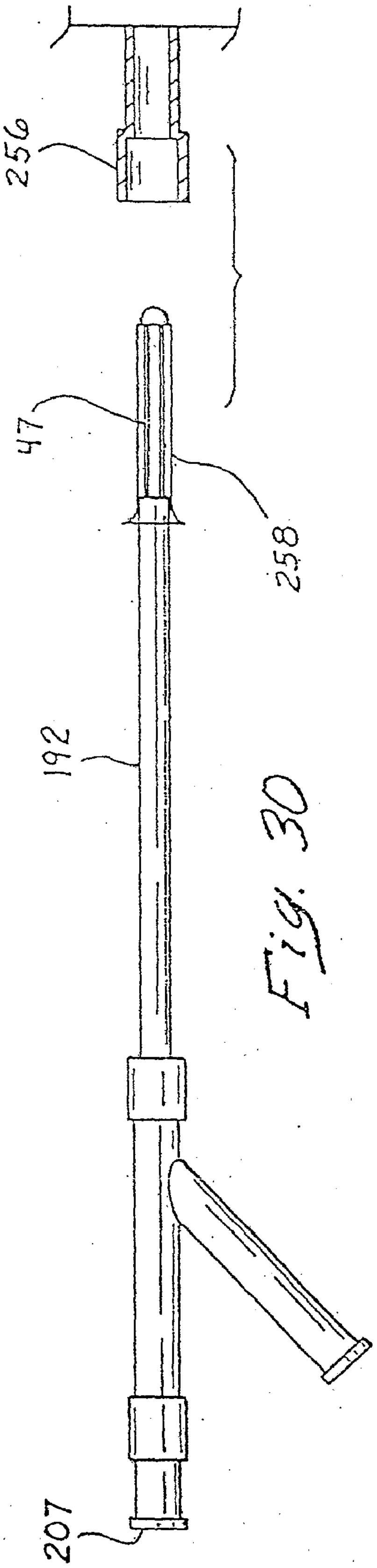

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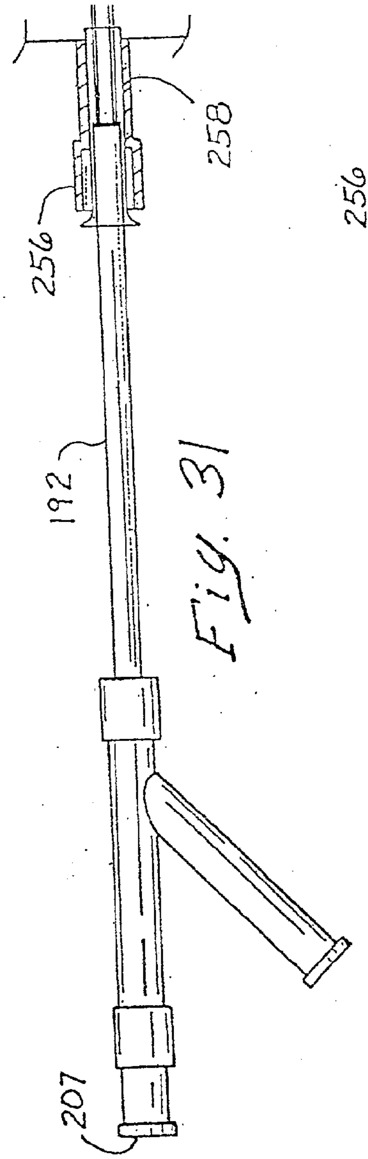

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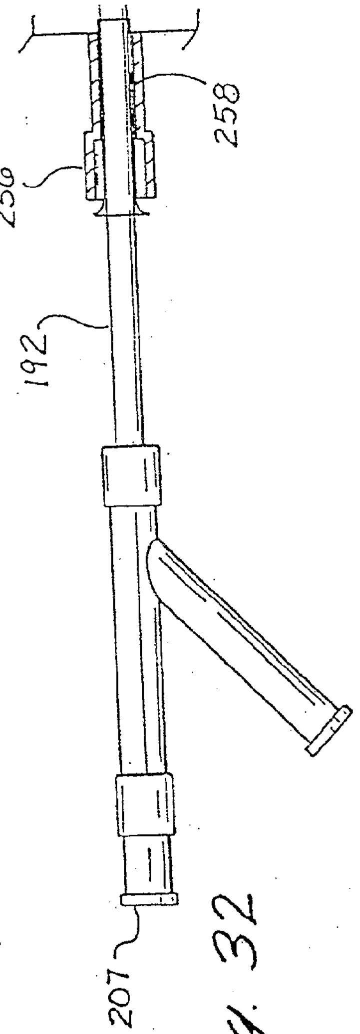

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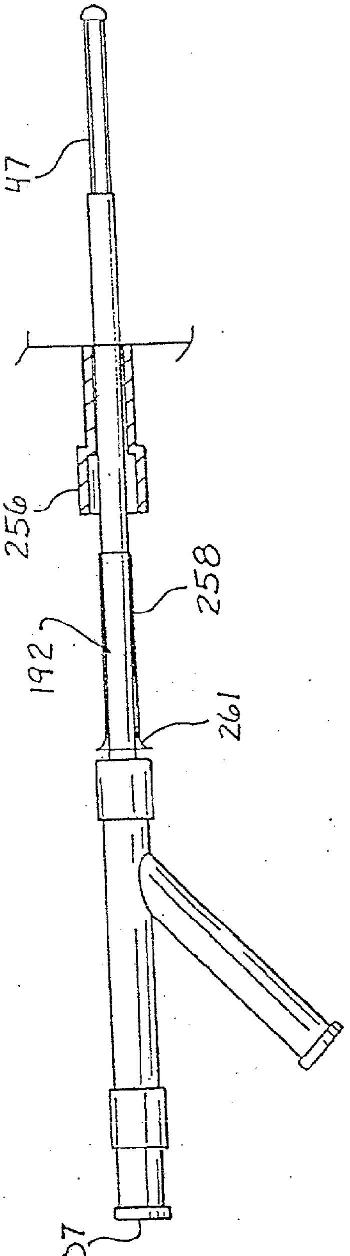

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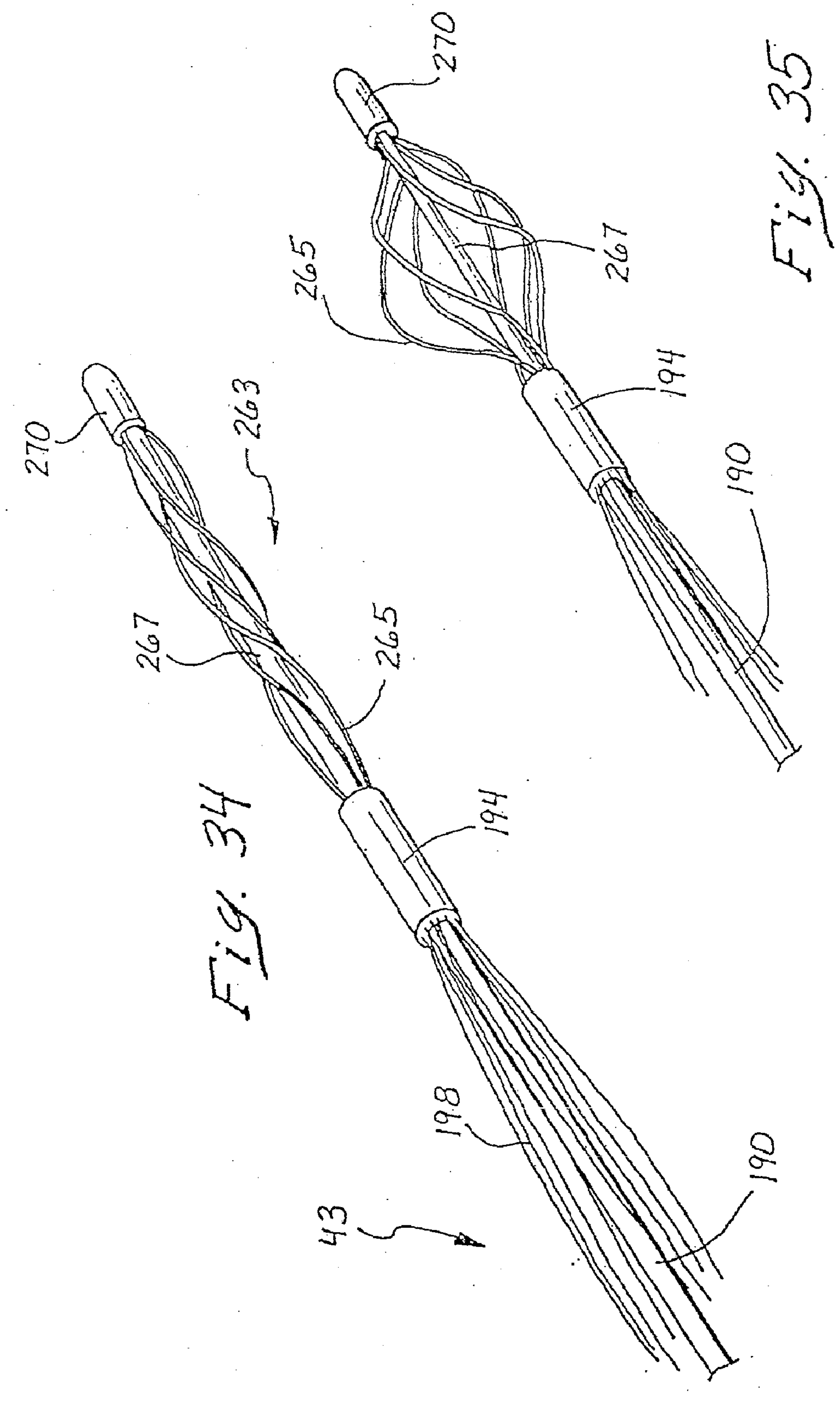
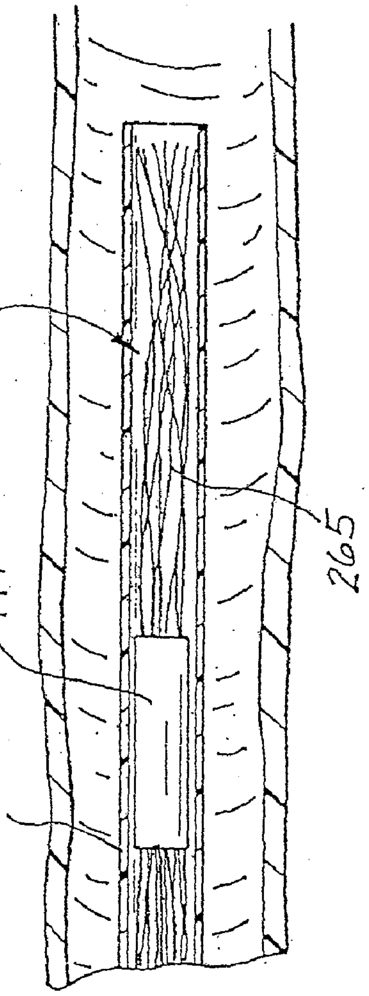


Fig. 34

Fig. 35

Fig. 37



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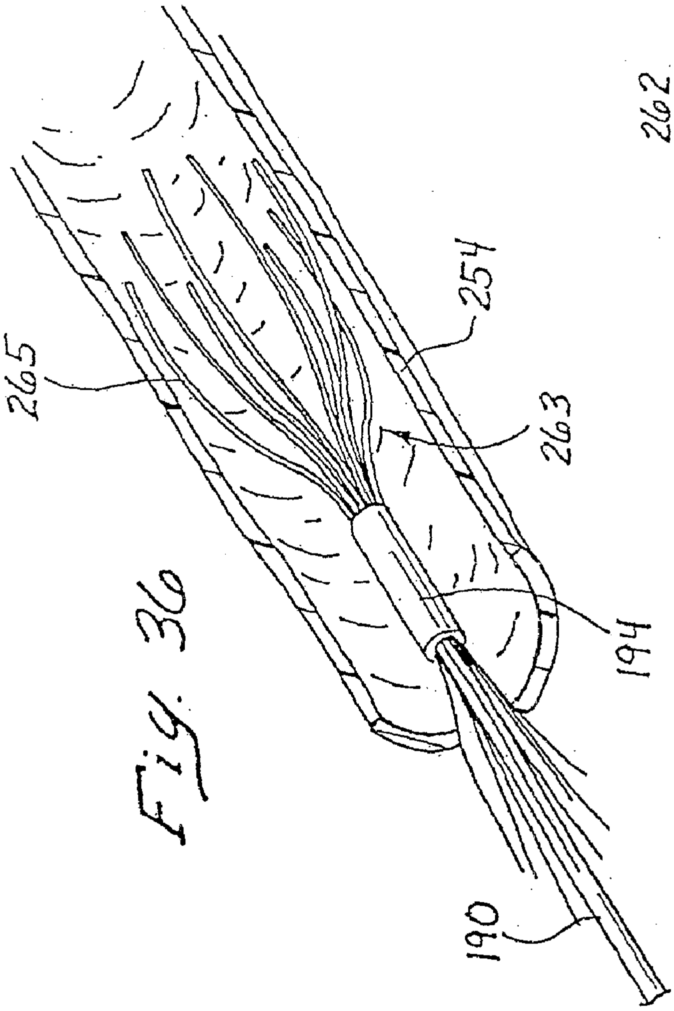

INDWELLING HEAT EXCHANGE CATHETER AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] This invention relates generally to apparatus and methods for producing heat exchange with body tissue, and more specifically to methods and apparatus for the hypothermic treatment of a body fluid in a body conduit.

[0003] 2. Discussion of the Prior Art

[0004] Many of the advantages of hypothermia are well known. By way of example, it has been found particularly desirable to lower the temperature of body tissue in order to reduce the metabolism of the body. In stroke, trauma and several other pathological conditions, hypothermia also reduces the permeability of the blood/brain barrier. It inhibits release of damaging neurotransmitters and also inhibits calcium-mediated effects. Hypothermia inhibits brain edema and lowers intracranial pressure.

[0005] In the past, hypothermic treatment has been typically addressed systemically, meaning that the overall temperature of the entire body has been lowered to achieve the advantages noted above. This has been particularly desirable in surgical applications where the reduced metabolism has made it possible to more easily accommodate lengthy operative procedures. An example of this systemic approach includes catheters for transferring heat to or from blood flowing within a patient's vessel, as disclosed by Ginsburg in U.S. Pat. No. 5,486,208. A closed loop heat exchange catheter is also disclosed by Saab in U.S. Pat. No. 5,624,392. A cooling device for whole-body hyperthermia that utilizes the circulatory system of the body is known to be more efficient since the entire volume of the body is constantly perfused with the cold fluid at a capillary level.

[0006] Likewise, various other means of cooling the body have been tried with cooling blankets, ice water bladder lavages, ice baths, esophageal catheters and their associated methods. All of these devices require a considerable time to cool the body since the primary heat transfer occurs through the skin or the skull. A more efficient body cooling device that can quickly cool and accurately control the body temperature is required.

SUMMARY OF THE INVENTION

[0007] A heat exchange catheter and method of operation are included in the present invention. The method is adapted to produce hypothermia or hyperthermia, typically in a selected portion of the body without substantially varying the temperature of the remaining portions of the body. The selected body portion will usually be associated with a body conduit which conveys a body fluid to the selected body portion. Of particular interest are the organs of the body which are commonly nourished and maintained by a flow of blood in the arterial system. For example, a flow of blood is introduced to the brain through the carotid artery. Of course the temperature of this blood is usually at the normal body temperature.

[0008] By positioning a heat exchange catheter in the body conduit, heat can be added to or removed from the body fluid to heat or cool the selected body portion. For example, the heat exchange catheter can be disposed in the carotid artery where the arterial blood flowing to the brain can be cooled. The flow of cooled blood to the brain reduces the temperature of the brain thereby resulting in cerebral hypothermia. Importantly, this temperature reduction occurs primarily and selectively in the brain; the remaining portions of the body maintain a generally normal body temperature. In accordance with this method, the selected body portion, such as the brain, can be cooled thereby providing the advantages associated with hypothermia for this body portion. The remainder of the body, such as the portions other than the brain, do not experience the reduction in temperature. Furthermore, the invention is intended to remotely alter temperature in a region other than the point of introduction into the body. This is different than devices intended for systemic temperature control.

[0009] Several factors are of interest in effecting heat transfer in a heat exchanger. These factors include, for example, the convection heat transfer coefficient of the two fluids involved in the heat exchange, as well as the thermal conductivity and thickness of the barrier between the two fluids. Other factors include the relative temperature differential between the fluids, as well as the contact area and residence time of heat transfer. The Reynolds number for each fluid stream affects boundary layers, turbulence and laminar flow.

[0010] Notwithstanding the need for localized hypothermia, there will always be those procedures which call for systemic hypothermia. Many of the advantages associated with the present invention will greatly facilitate those procedures, for example, by decreasing the number and complexity of operative steps, increasing the heat transfer capacity of the device, and addressing other concerns such as the formation of blood clots.

[0011] In one aspect of the invention a catheter is provided with an elongate configuration, a proximal end and a distal end. An outer tube having a first lumen extends between the distal end and proximal end of the catheter, and an inner tube having a second lumen is disposed within the first lumen of the outer tube. Portions of the inner tube define a first flow path extending along the second lumen, while portions of the tubes define a second flow path extending between the first tube and the second tube. A plurality of hollow fibers provide fluid communication between the first and second flow paths, and a heat exchange fluid is disposed in the hollow fibers to cool the fibers.

[0012] In another aspect of the invention, a method for making a heat exchange catheter includes the steps of providing first and second tubes having first and second lumens, respectively. A plurality of hollow fibers are connected between a first flow path extending along the second lumen and a second flow path extending along the first lumen outwardly of the second tube. The method further comprises the step of insuring that the second tube is axially or rotationally movable relative to the first tube in order to vary the configuration of the hollow fibers.

[0013] In a further aspect of the invention, a method for operating a heat exchange catheter includes the steps of inserting into a body conduit the catheter with an inner tube disposed within an outer tube and defining a first flow path interiorly of the inner tube and second flow path between the inner tube and the outer tube. This inserted catheter also includes a plurality of hollow fibers disposed in fluid communication with the first and second flow paths. The method further includes steps for creating a flow of heat exchange fluid through the first and second flow paths, and moving the inner tube relative to the outer tube to change the profile of the hollow fibers.

[**0014**] In a further aspect of the invention, a heat exchange catheter includes an elongate shaft with first portions defining an inlet lumen and second portions defining an outlet lumen. A first manifold is disposed in fluid communication with the inlet lumen and a second manifold disposed in fluid communication with the outlet lumen. A plurality of hollow fibers are disposed between the manifolds in fluid communication with the inlet and outlet lumens. The catheter is adapted to receive a heat exchange fluid and to direct the heat exchange fluid through the hollow fibers to exchange heat through the hollow fibers.

[**0015**] In still a further aspect of the invention, a catheter is adapted to exchange heat with the body fluid flowing in a first direction through a body conduit. The catheter includes a shaft having an input lumen and an output lumen. A plurality of hollow fibers define a heat exchange region and collectively define an output surface of the heat exchange region. The input lumen of the shaft is coupled to the hollow fibers at a first location while the output lumen of the shaft is coupled to the hollow fibers at a second location disposed in the first direction from the first location.

[**0016**] Another aspect of the invention includes a method for exchanging heat with a body fluid in a body conduit. In this case, a catheter is provided with a plurality of hollow heat exchange fibers extending in fluid communication with an inlet lumen and an outlet lumen of the catheter. The heat exchange fibers collectively define a first cavity in heat transfer relationship with a body fluid in a body conduit.

[**0017**] In an additional aspect of the invention, an operative area of the catheter is sized and configured for disposition in a vessel containing blood. The operative area is adapted to perform a predetermined function, and the blood in the vessel has a tendency to form clots. In this aspect of the invention, the catheter is provided with a snare disposed relative to the operative area and being operable from a proximal end of the catheter to move from a low-profile state facilitating insertion of the catheter, to a high-profile state facilitating the capture of blood clots.

[**0018**] In still a further aspect of the invention, a heat exchange catheter is adapted for cooling the blood of a patient. The catheter includes a heat exchange region with a plurality of fibers each having a hollow configuration. A heat exchange fluid is disposed in the hollow fibers to cool the fibers and a coating is disposed on the outer surface of the fibers to inhibit formation of blood clots.

[**0019**] These and other features and advantages of the invention will be better understood with a description of the preferred embodiments of the invention and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

[**0020**] **FIG. 1** is side elevation view of a patient lying in a prone position with a heat exchange catheter of the present invention appropriately inserted to facilitate hypothermic treatment of the patient's brain;

[**0021**] **FIG. 2** is an enlarged side elevation view showing the vasculature associated with the patient's head and brain;

[**0022**] **FIG. 3** is a perspective view partially in section of a heat exchange region of the catheter;

[**0023**] **FIG. 4** is an enlarged axial cross section view of a plurality of balloons disposed in the heat exchange region of the catheter;

[**0024**] **FIG. 5** is a radial cross section view of the catheter taken along lines **5-5** of **FIG. 4**;

[**0025**] **FIG. 6** is a radial cross section view similar to **FIG. 5** of a further embodiment of the catheter;

[**0026**] **FIG. 7** is a perspective view of a further embodiment of the catheter wherein multiple balloons are provided with a longitudinal configuration;

[**0027**] **FIG. 8** is a radial cross section view taken along lines **8-8** of **FIG. 7**;

[**0028**] **FIG. 9** is an axial cross section view taken along lines **9-9** of **FIG. 7**;

[**0029**] **FIG. 10** is a perspective view of the catheter illustrated in **FIG. 3** further illustrating structures which can facilitate mixing and heat exchange;

[**0030**] **FIG. 10A** is a perspective view of ant embodiment of the catheter having a distal end with a pigtail configuration;

[**0031**] **FIG. 10B** is a perspective view of the catheter illustrated in **FIG. 10A** with the distal end straightened by a stylet **174** to facilitate insertion of the catheter;

[**0032**] **FIG. 11** is a schematic view of an embodiment including a heat pipe;

[**0033**] **FIG. 12** is a schematic view, partially in section, of a heat pipe adapted for use in the embodiment of **FIG. 11**;

[**0034**] **FIG. 13** is a top plan view of carotid artery branch illustrating one method of operation associated with the catheter;

[**0035**] **FIG. 14** is a top plan view similar to **FIG. 13** and showing a further method of operation with the catheter;

[**0036**] **FIG. 15** is a top plan view of the carotid branch similar to **FIG. 13** and showing a further method of operating a heat exchange catheter;

[**0037**] **FIG. 16** is a radial cross section of the catheter taken along lines **16-16** of **FIG. 15**;

[**0038**] **FIG. 17** is an axial cross section view of a further embodiment of the invention including hollow fibers in the heat exchange region;

[**0039**] **FIG. 18** is a side elevation view similar to **FIG. 17** and illustrating the hollow fibers in a compacted configuration; and

[0040] **FIG. 19** is an axial cross section view of the catheter of **FIG. 17** operatively disposed and configured to permit the hollow fibers to float and undulate within a blood stream.

[0041] **FIG. 20** is a side elevation view partially in section and illustrating a further embodiment of the catheter of the present invention;

[0042] **FIG. 21** is a radial cross-section view taken along the lines **21-21** of **FIG. 20**;

[0043] **FIG. 22** is an axial cross-section view of the proximal end of the catheter illustrated in **FIG. 20**;

[0044] **FIG. 23** is an axial cross-section view of the distal end of a further embodiment illustrating the heat exchange region in a low-profile state;

[0045] **FIG. 24** is an axial cross-section view similar to **FIG. 23** and illustrating the heat exchange region in a high-profile state;

[0046] FIGS. **25-27** illustrate a preferred method for manufacturing the heat exchange region of a hollow fiber embodiment of the cavity;

[0047] **FIG. 25** is a top plan view of a mat formed of the heat exchange fibers;

[0048] **FIG. 26** is a perspective view illustrating formation of the mat around the distal ends of the concentric tubes;

[0049] **FIG. 27** is a side elevation view illustrating attachment of the mat assembly to an outer tube of the catheter;

[0050] **FIG. 28** is a top-plan view of a patient illustrating portions of the blood circulatory system;

[0051] FIGS. **29-33** illustrate a method for introducing the catheter of the present invention;

[0052] **FIG. 29** is a side elevation view illustrating a introducing sheath in a first position removed from the heat exchange region;

[0053] **FIG. 30** is a side elevation view illustrating the sheath in a second position over the heat exchange region of the catheter;

[0054] **FIG. 31** is a side elevation view illustrating the catheter and sheath being inserted into an introducer;

[0055] **FIG. 32** is a side elevation view illustrating the catheter further inserted with the sheath maintained in the introducer;

[0056] **FIG. 33** is a side elevation view illustrating removal of the sheath to the first position;

[0057] **FIG. 34** is a perspective view of a further embodiment of the catheter including a distal clot filter in a low-profile state;

[0058] **FIG. 35** is a perspective view illustrating the catheter of **FIG. 34** with the clot filter in a high-profile state;

[0059] **FIG. 36** is a perspective view of a catheter with a clot filter having free ends and automatically deployable to a high-profile state; and

[0060] **FIG. 37** is a side elevation view of the catheter of **FIG. 36** with a sheath maintaining the clot filter in a low-profile state.

DESCRIPTION OF THE PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

[0061] A heat exchange catheter is illustrated in **FIG. 1** and designated generally by the reference numeral **10**. The catheter **10** is operatively disposed with respect to a body **12** of patient having a groin **14**, a head **16**, and a brain **18**. More specifically, the catheter **10** can be inserted percutaneously through a puncture or surgical cut down at the groin **14**, and into the femoral artery **21**. Following this initial introduction, the catheter **10** can be moved through the femoral artery **21** and the aortic arch **23**, into the common carotid artery **25** best illustrated in **FIG. 2**. This common carotid artery **25** divides at a carotid branch **27** into an external carotid artery **30**, which primarily supplies blood **31** to the face of the patient, and an internal carotid artery **32**, which primarily supplies blood to the brain **18** of the patient.

[0062] In the concept of this invention, the brain **18** is merely representative of a portion of the body **12** of the patient, and the arteries **21**, **25**, **30** and **32** are merely representative of conduits which supply a body fluid, such as blood, to a selected portion of the body **12**, such as the brain **18**. By cooling the body fluid, such as blood **31**, in the body conduit, such as the artery **32**, the specific body portion, such as the brain **18**, can be selectively cooled without significantly affecting the temperature of the remaining portions of the body **12**.

[0063] Selective hypothermic treatment of the brain **18** is initially of particular interest as it captures the advantages of hypothermia during operative procedures associated with the brain **18** without also capturing the disadvantages of hypothermia with respect to other areas of the body **12**. Thus, a surgeon operating to treat an aneurysm in the brain **18**, for example, can initially cool the brain **18** in order to facilitate that procedure. This selective hypothermia will be particularly appreciated in those surgical procedures which are primarily directed to the brain **18**. Procedures such as stroke, trauma, and other brain related injuries will also benefit up to and during from this selective hypothermia treatment.

[0064] A preferred embodiment of the catheter **10** of the present invention is illustrated in **FIGS. 3 and 4**. From this perspective view, it can be seen that the catheter **10** includes a shaft **40** having an axis **41** which extends between a proximal end **43** and a distal end **45**. When operatively disposed, a heat exchange region **47** at the distal end **45** is operatively disposed within the body **12**, and a hub **50** at the proximal end **43** is disposed outside of the body **12**. Within the shaft **40**, a plurality of lumens **52** and **54** extend in fluid communication with the hub **50** and the heat exchange region **47**.

[0065] A preferred embodiment of the heat exchange region **47** is illustrated in greater detail in **FIG. 4** where three balloons **56**, **58** and **61** are individually, separately and axially disposed along the shaft **40**. It will be appreciated that although the illustrated embodiment includes three balloons, a single balloon or double balloon embodiment may offer further advantages in a particular procedure. All of the balloons **56**, **58** and **61** are illustrated to have a significantly larger diameter than the shaft **40**. This may not be the case in other embodiments. More specifically, it may be desirable to maximize the dimension of the shaft **40** in order to facilitate flow of the heat exchange fluid. This will also minimize the volume of fluid in the balloon and promote a more rapid heat exchange. In one such embodiment, the diameter of the shaft **40** is in a range between 50 and 90 percent of the diameter of the balloons **56**, **58** and **61**.

[0066] Each of the balloons **56**, **58** and **61** can be formed from a piece of sheet material **62**, **64** and **66** which is bound or otherwise fixed to the shaft **40** to form a cavity **63**, **65** and **67**, respectively. An inlet hole **70** provides fluid communication between the lumen **54** and the cavity **63** of the balloon **56**. Similar inlet holes **72** and **74** are provided for the balloons **58** and **61**. In a like manner, an outlet hole **76** can be formed in the wall of the shaft **40** to provide fluid communication between the lumen **52** and the cavity **63** of the balloon **56**. Similar outlet holes **78** and **81** are provided for the balloons **58** and **61**, respectively. With this structure, it can be seen that the lumen **54** functions primarily as an inlet lumen for a heat exchange fluid which is illustrated generally as a series of arrows designated by the reference numeral **85**.

[0067] Initially, the heat exchange fluid **85** is introduced through the hub **50** (**FIG. 3**) and into the inlet lumen **54**. From the lumen **54**, the heat exchange fluid **85** passes through the inlet holes **70**, **72**, **74** and into the respective balloon cavity **63**, **65** and **67**. The heat exchange fluid **85** then passes into the outlet hole **76**, **78**, **81** and into the outlet lumen **52** and the hub **50** to regions exterior of the catheter **10**.

[0068] After the heat exchange fluid **85** is remotely cooled, it is circulated through the balloon cavities **63**, **65** and **67** to provide a cold temperature fluid on the inner surface of the sheet materials **62**, **64** and **66** which form the walls of the balloons **56**, **58** and **61**, respectively. With a body fluid, such as blood **31**, flowing exteriorly of the balloons **56**, **68** and **61**, heat transfer occurs across the sheet materials **62**, **64** and **66**, respectively.

[0069] It can be appreciated that this circulation of the heat exchange fluid **85** can be formed with any structure of the shaft **40** which provides two lumens, such as the lumens **52** and **54**, each of which can have access to the balloon cavities, such as the cavities **63**, **65** and **67**. In one embodiment of the shaft **40** illustrated in **FIG. 5**, **a** septum **90** is provided which separates the cylindrical shaft **40** into two equally sized lumens **52** and **54**. In the embodiment of **FIG. 6**, the cylindrical shaft **40** is provided with a cylindrical septum **92** which provides the lumen **54** with a circular cross section and the lumen **52** with a moon-shaped cross section. In such an embodiment, the lumen **54** must be defined off-axis from the shaft **40** in order to have access to the balloon cavities, such as the cavity **63**.

[0070] One of the advantages of a multiple balloon embodiment of the catheter **10** is that the flow and temperature of the heat exchange fluid **85** can be more easily controlled along the entire length of the heat exchange region **47**. Realizing that the heat exchange fluid **85** will be coolest prior to entering into a heat exchange with the blood **31**, and warmest after that heat exchange, one can advantageously control not only the velocity and volume of flow, but also the direction of flow within each, discrete balloons **56**, **58** and **61**. Another advantage of a multiple balloon design is the ability of the catheter to bend and flex when placed in a curved vasculature. Single balloon designs would be rigid, stiff and inflexible by comparison.

[0071] In order to facilitate the maximum heat exchange between the fluid **85** and the blood, it is desirable to provide a balanced flow of the heat exchange fluid **85** along the entire length of the heat exchange region **47**. In the embodiment illustrated in **FIG. 4**, efficient heat transfer is facilitated by countercurrent flow where the heat exchange fluid **85** is directed to flow counter to the flow of the blood **31**. To that end, the inlet holes **70**, **72** and **74** are positioned distally of the outlet holes **76**, **78** and **81**, respectively. As the blood hi flows distally along the outer surface of the catheter **10**, this relative position of the inlet holes and outlet holes causes the heat exchange fluid to flow in the opposite direction, proximally in each of the balloons **56**, **58** and **61**.

[0072] The amount of flow within each of the balloons **56**, **58** and **61** can also be controlled by the size of the inlet holes **70**, **72**, **74** and outlet holes **76**, **78** and **81**. In a preferred embodiment, this flow control is provided solely by the inlet holes **70**, **72** and **74**; the outlet holes **76**, **78** and **81** are sized larger than their respective inlet holes so that they offer little resistance to flow. In this embodiment, the inlet holes **70**, **72** and **74** are sized to be progressively smaller from the distal end **45** to the proximal end **43**. Thus the hole **70** is larger than the hole **72** which is larger than the hole **74**. As a result, the resistance to the flow of heat exchange fluid **85** in the most distal balloon **56** is less than that in the most proximal balloon **61**. This ensures that the coolest heat exchange fluid **85** is shared equally among all of the balloons **56**, **58** and **61** regardless of their position along the shaft **40**. In an embodiment wherein the flow is controlled by the outlet holes **76**, **78** and **81**, these holes can also be provided with a relatively reduced size from the distal end **45** to the proximal end **43**. With any of these structures, a more balanced flow of the heat exchange fluid can be achieved in order to facilitate the highest degree of heat exchange along the entire heat exchange region **47**. Alternatively, the flow of heat exchange fluid can also be balanced by providing the holes **76**, **78** and **81** with non-circular configurations. For example, these holes may be formed as longitudinal slits extending axially of the catheter.

[0073] A further embodiment of the invention is illustrated in **FIG. 7** wherein a single sheet of material **101** is used to form separate and distinct individual balloons, two of which are designated by the reference numerals **103** and **105**. As opposed to the radial balloons **56**, **58** and **61** of the previous embodiment, the balloons **103** and **105** extend axially along the surface of the shaft **40**. For example, the balloons **103** and **105** form individual balloon cavities **107** and **110**, respectively, which extend from a distal end **112** to a proximal end **114**.

[0074] This embodiment of the catheter containing the axial balloons **103** and **105** may include a shaft **40** with a slightly different configuration. As best illustrated in **FIG. 9**, the shaft **40** may include an outer tube **121** having an outer surface to which the sheet material **101** is attached and within which is disposed a distal sealing plug **123**. An inner tube **125**, which can be disposed coaxially with the outer tube **121**, has an inner lumen **127** and defines with the outer tube **121** an outer lumen **130**. A pair of inlet holes **132** and **134** provide flow fluid communication between the inner lumen **127** and the balloon cavities **107** and **110**, respectively. Similarly, a pair of outlet holes **136** and **138** provide fluid communication between the balloon cavities **107** and **110** and the outer lumen **130**, respectively. An inner plug **141**

disposed between the inner tube **125** and outer tube **121** to seal the outer lumen **130** between the inlet holes **132**, **134** and outlet holes **136**, **138**. For the reasons previously noted, a preferred embodiment has inlet holes **132**, **134** which are disposed distally of and sized smaller than the outlet holes **136**, **138**, respectively. This orientation will provide countercurrent flow in a catheter **10** which is inserted downstream into an artery, such as the carotid artery **25**.

[**0075**] Embodiments which are intended to maximize heat transfer will take advantage of the fact that heat exchange is enhanced when either, or both, the body fluid or the heat exchange fluid is provided with well mixed flow. Mixing can be enhanced by providing irregular surfaces next to which either of these fluids flow. For example, with reference to **FIG. 4**, it will be noted that a spring **150** can be disposed around the shaft **40** inside each of the balloons, such as the balloon **61**. In this embodiment, the spring **150** upsets the laminar flow of the heat exchange fluid **85** thereby producing the desired mixing of this fluid. Other structures can be positioned within the cavities formed by the balloons **56**, **58** and **61**.

[**0076**] Mixing can also be enhanced within the body fluid which flows along the outer surface of the catheter **10**. In this case, the multiple radial balloon embodiment illustrated in **FIG. 4** is of advantage as each of the balloons **56**, **58** and **61** represents a peak and defines with the adjacent balloon a valley along which the blood **31** flows. This series of peaks and valleys also upsets the laminar flow of the body fluid. Mixing of the body fluid can also be enhanced by providing other structures along the outer surface of the sheet material **62**, **64** and **66** which form the balloons as well as any exposed areas of the shaft **40** in the heat exchange region **47**. By way of example, a multiplicity of granules **145** can be adhered to the outer surface of the radial balloons **56**, **58** and **61** or the axial balloons **103** and **105** as illustrated in **FIG. 9**. Ridges can also be provided along these surfaces.

[**0077**] With some body fluids, it may be desirable to inhibit turbulent flow and facilitate laminar flow. This may be true for example in the case of blood where undesirable hemolysis may occur in response to increased turbulence. Such an embodiment might be particularly desirable for use with radial balloons where an outer balloon **152** would promote laminar flow by reducing the height differential between the peaks and valleys defined by the balloons **56**, **58** and **61**. This outer balloon **152** is best illustrated in **FIG. 10**. To further promote laminar flow, the outer surface of any structure in the heat exchange region **47** can be provided with a coating **154**, such as a hydrophilic or a hydrophobic coating to modify the boundary layer. Thus The outer surface of the shaft **40** as well as the outer surface of any of the balloons **56**, **58**, **61**, **103**, **105** and **152** can be provided with the coating **154**. The coating **154** may also include other ingredients providing the catheter **10** with additional advantageous properties. For example, the coating **154** may include an antithrombogenic ingredient such as heparin or aspirin. Such a coating **154** would not only inhibit platelet deposition but also the formation of blood clots.

[**0078**] As previously noted, the characteristics of the heat exchange fluid **85** may also be of importance in a particular heat exchange environment. Although the heat exchange fluid **85** may include various liquids, it is believed that gases may provide the greatest temperature differential with the body fluid. Particularly if this fluid includes blood, gases that are inert or otherwise compatible with the vascular system will be appreciated. Although several inert gases might fulfill these requirements, carbon dioxide is used for the heat exchange fluid **85** in a preferred embodiment of the invention.

[**0079**] A further embodiment of the catheter **10** is contemplated for maximizing the surface area available for heat exchange. As illustrated in **FIGS. 10A and 11B** the catheter **10** can be formed with a distal end **45** of the shaft **40** disposed in the natural configuration of a spiral or pigtail **172**. The relatively large diameter of the pigtail **172** facilitates heat exchange, but tends to deter from a low profile desire for insertion. Under these circumstances, it may be advantageous to insert the catheter **10** over a stylet or guidewire **174** in order to straighten the pigtail **172** as illustrated in **FIG. 10B**.

[**0080**] Hyperthermia and hypothermia for selective regions of the body can also be achieved by placing in the body conduit, such as the carotid artery **25**, a heat pipe **161** best illustrated in the schematic view of **FIG. 11**. In this embodiment, the heat pipe **161** includes a distal end **163** and proximal end **165**. The distal end **163** is adapted to be placed within the body conduit, such as the carotid artery **25**. The proximal end **165** of the heat pipe **161** is adapted to be connected to an external heat sink or cooler, such as a thermoelectric cooler **167** or water jacket **168**. A wick structure **170** is provided in the heat pipe **161** to facilitate a flow of heat exchange fluid from the cooler **167** to the distal end **163**.

[**0081**] In a process involving the heat pipe **161**, illustrated in **FIG. 12**, the heat exchange fluid is moved from the proximal end **165** of the heat pipe **161** either by gravity or by capillary action of the wick structure **170** to the distal end **163**. At the distal end **163** of the heat pipe **161**, heat is transferred from the body fluid, such as blood, to the heat exchange fluid in its liquid state. This heat exchange liquid absorbs a heat of vaporization as it passes into a vapor state in the heat pipe **161**. The heat exchange fluid in its vapor state creates a pressure gradient between the ends **163** and **165** of the heat pipe **161**. This pressure gradient causes the vapor to flow to the cooler **165** where it is condensed giving up its latent heat of vaporization. The heat exchange fluid in its liquid state then passes back through the heat pipe **161** through the wick structure **170** or by gravity. The passive heat exchange system provided by the heat pipe **161** is vacuum-tight and can be operated with a minimum amount of the heat exchange fluid.

[**0082**] Although the heat exchange catheter **10** will be advantageous in the hyperthermic or hypothermic treatment of any portion of the body **12**, it is believed that it will be particularly appreciated in those procedures which can benefit from the hypothermic treatment of the brain **18**, such as the treatment of ischemic stroke and/or head trauma. As previously noted in comments directed to **FIG. 1**, the catheter **10** can be inserted into the femoral artery in the groin **14** and directed through the aortic arch **23** into the common carotid artery **25**. As illustrated in **FIG. 13**, the catheter **10** can then be moved into the region of the arterial branch **27** where it will encounter the external carotid artery **30** and the internal carotid artery **32**. Since the external carotid artery **30** is directed primarily to the facial regions, it does not supply a significant amount of blood to the brain **18**. In contrast, the internal carotid artery **32** is almost solely responsible for feeding the capillary bed of the brain **18**. Based on these considerations, hypothermic treatment of the brain **18** is best addressed by cooling the blood in the internal carotid artery **32** without wasting any of the cooling properties on the external carotid artery **30**. In a method associated with one embodiment of the invention, the most distal of the balloons, such as the balloon **56** in **FIG. 13** is preferably positioned within the internal carotid artery **32**. The more proximal balloons **58** and **61** can be disposed along the common carotid artery **25**. This embodiment of the catheter **10** and its associated method will achieve a higher degree of heat transfer within the internal artery **32** than the external artery **30**.

[**0083**] In another embodiment of the catheter **10** best illustrated in **FIG. 14**, an occlusion balloon **175** is provided distally of the heat exchange region **47**. In this embodiment, the occlusion balloon **175** will preferably be inflatable through a separate lumen in the shaft **40**. As the catheter **10**, approaches the carotid branch **27**, the occlusion balloon **81** is directed, into the external carotid artery **30** and inflated in order to at least partially occlude that artery. The remaining proximal balloons **56**, **58** and **61** in the heat exchange region **47** are left within the common carotid artery **25** to promote heat exchange with the blood flowing to the branch **27**. With the external artery **30** at least partially occluded, heat transfer occurs primarily with the blood flowing into the internal carotid artery **32**.

[**0084**] A further embodiment of the invention is illustrated in **FIG. 15** operatively disposed in the common carotid artery **25** and internal carotid artery **32**. In this case, the catheter **10** includes a balloon **181** which is attached to the distal end of the shaft **40** and provided with a spiral configuration. More specifically, the balloon **181** may be formed from several individual balloons, as with the embodiment of **FIG. 7**, for as individual flutes **183** on the single balloon **181**. In either case, the separate balloons (such as the balloons **103**, **105** of **FIG. 7**) or the flutes **183** are oriented in a spiral configuration around the axis **41** of the catheter **10**. The shaft **40** can be provided with any of the configurations previously discussed such as the eccentric configuration of **FIG. 6**.

[**0085**] By providing the balloon **181** with a spiral configuration, heat exchange is enhanced by at least two of the factors previously discussed. Notably, the surface area of contact is increased between the blood **31** flowing externally of the balloon **181** and the heat exchange fluid flowing internally of the balloon **181**. The spiral configuration also enhances the mixing properties of both the blood **31** and the heat exchange fluid **85**.

[**0086**] As noted, the heat exchange fluid **85** may be cooled to a sub-zero temperature. In order to thermally protect the internal lining of the artery **32** from direct contact with the sub-zero coolant, it may be desirable to provide the tips of the flutes **183** with a thicker wall **185**, as shown in **FIG. 16**. This thicker wall **185** might be advantageous in any of the balloon configurations previously discussed, but would appear to be most advantageous in embodiments of **FIG. 7** and **15** where the contact with the artery **32** tends to be more localized by the longitudinal balloons **103**, **105** (**FIG. 7**) on the spiral flutes **183** (**FIG. 15**).

[**0087**] Still a further embodiment of the invention is illustrated in **FIG. 17**. In this embodiment, the shaft **40** includes an inner tube **190** disposed within an outer tube **192**. These tubes **190**, **192** may be concentric and longitudingly movable relative to each other. The tubes **190**, **192** terminate respectively in manifolds **194**, **196**. Between these manifolds **194**, **196**, a multiplicity of hollow fibers **198** can be disposed at the distal end **45** to define the heat exchange region **47** of the catheter **10**. The hollow fibers **198** each include an internal lumen which provides fluid communication between the manifolds **194** and **196**. In operation, the heat exchange fluid **85** flows distally along the inner tube **190** into the distal manifold **194**. From this manifold **194**, the heat exchange fluid **85** flows into the internal lumens of the hollow fibers **198** proximally to the proximal manifold **196**. The warmer heat exchange fluid **85** flows proximally from the manifold **196** between the inner tube **190** and outer tube **192**.

[**0088**] Preferably, the hollow fibers **198** have a wall thickness that is thin enough to allow maximum heat transfer, yet strong enough to withstand the pressure requirements of the heat exchange fluid **85**. The hollow fibers **198** are further adapted to achieve ideal heat transfer by the maximization of both surface area and coolant flow. The smaller the diameter of the fibers **198**, the more fibers can be fit into the catheter **10** with a corresponding increase in surface area. As the diameter of the fibers **198** is decreased, however, the resistance to fluid flow increases thus lowering the coolant flow rate. The effect of the inflow and outflow lumens must also be considered in determining the fluid resistance. Ideally, the wall thickness of the hollow fibers **198** is in a range between 0.00025 inches and 0.003 inches. In a preferred embodiment the wall thickness is in a range between 0.00075 inches and 0.002 inches, and ideally 0.00125 inches. The outer diameter of the hollow fibers **198** will typically be between 0.008 inches and 0.035 inches. In a preferred embodiment the outer diameter is in a range between 0.010 inches and 0.018 inches, and ideally 0.015 inches.

[**0089**] It will be noted that the heat exchange fluid **85** flowing in the inner tube **190** is insulated in several respects from the blood stream outside the catheter **10**. This flow channel in the inner tube **190** is insulated not only by the wall of the outer tube **192**, but also by the coolant returning in the flow channel associated with the outer tube **192**. The heat exchange fluid **85** in the inner tube is further insulated by the thickness of the inner tube wall.

[**0090**] In the heat exchange region **47**, the wall thicknesses associated with the inner tube **190** and the outer tube **192** is preferably reduced in order to provide additional volume for the hollow fibers **198**. With a reduced wall thickness, the inner tube **190** also contributes to the heat exchange occurring in the region **47**.

[**0091**] The hollow fibers **198** offer several advantages to this embodiment of the catheter **10**. Notably, they provide a vet high surface area between the blood **31** and the heat exchange fluid **85**. This greatly enhances the heat exchange characteristics of this embodiment. Countercurrent flow can also be maintained further facilitating the heat exchange capabilities of this catheter.

[**0092**] The hollow fibers **198** can be spiraled as illustrated in **FIG. 18** by twisting the inner tube **190** with respect to the outer tube **192**. This characteristic can be used to provide a shorter and lower profile heat exchange region **47** in order to facilitate introduction of the catheter **10**. A lower profile may also be obtained by separating the manifolds **194** and **196** a distance substantially equal to the length of the fibers **198**. This will tend to hold the fibers in a straight, parallel relationship and thereby facilitate introduction of the catheter **10**. The spiraled configuration of the hollow fibers **198** can be maintained during heat exchange in order to further increase the heat exchange area per unit length of the catheter **10**. Alternatively, the fibers **198** can be positioned to loosely float and undulate between the manifolds **194** and **196** as illustrated in **FIG. 19**. This characteristic of the fibers **198** will not only provide the increased heat exchange area desired, but also promote mixing within the blood **31**.

[**0093**] The fibers **198** will typically be formed of common materials such as polyolefin nylon and polyurethane. The fibers can be coated with a clot-inhibiting material such as heparin. Other materials advantageous for inhibiting the formation of blood clots might include those which form polymer surfaces with **16** or **18** carbon alkyl chains. These materials attract albumin and thereby inhibit clot formation. In a further embodiment, the fibers **198** can be provided with micropores which permit the leaching of such clot inhibiting pharmaceuticals as heparinized saline which could also serve as the heat exchange fluid **85**.

[**0094**] The embodiment of **FIG. 20** also takes advantage of the significant heat exchange characteristics associated with the hollow fibers **198**. In this embodiment, the manifold **194** at the distal end **45** of the catheter **10** includes a potting seal **201** with a distal surface **203**. The fibers **198** are held in the potting seal **201** with the lumens of the fibers **198** exposed at the surface **203**. The distal end of the inner tube **190** is also held in the potting seal **201** with its lumen exposed at the distal surface **203**. In this embodiment, the manifold **194** includes a cap **205** which may have a hemisphere configuration. This cap extends over the distal surface **203** of the potting seal **201** and provides fluid communication between the lumen of the inner tube **190** and the lumens of the hollow fibers **198**. This cap **205** may also be constructed of materials and wall thicknesses that insulate the blood vessels from potential contact with a cold catheter tip.

[**0095**] **FIG. 21** illustrates in a cross-sectional view a first flow channel **204** which extends along the lumen of the inner tube **190** and a second flow channel **206** which extends along the lumen of the outer tube **192** outwardly of the inner tube **190**. As the heat exchange fluid **85** is introduced into the first flow channel **204**, its direction is reversed in cap **205** so that the flow of the fluid **85** in the hollow fibers is counter to the flow of the body fluid, such as blood, in the body conduit, such as the artery **32**. After moving through the fibers **198**, the heat exchange fluid **85** passes along the second flow channel **206** between the inner tube **190** and outer tube **192**, and exits the catheter **10** at the proximal end **43**.

[**0096**] The embodiment of **FIG. 20** also includes a Y-connector **207** disposed at the proximal end **43** of the catheter **10**. This connector **207** is shown in greater detail in the enlarged view of **FIG. 22**. In this view it can be seen that the connector **207** includes a body **210** with screw threads **212** at its distal end and screw threads **214** at its proximal end. At the distal end of the body **210**, a screw cap **216** mates with the screw threads **212** to engage an annular flange **218** at the proximal end of the outer tube **192**. In this manner, the Y-connector **207** forms a seal with the proximal end of the outer tube **192** and provides fluid communication between the second flow channel **206** and a lumen **221** of the Y-connector **207**. A side port **223** communicates with .this lumen **221** and provides an exit port for the secondary flow channel **206**.

[**0097**] In order to prevent leakage from the lumen **221** at the proximal end **43** of the Y-connector **207**, a releasable seal **225** can be formed at the proximal end of the body **210**. In the illustrated embodiment, the releasable seal **225** includes a cap **227** which is threaded to register with the threads **214** of the body **210**. This cap **227** extends around the proximal end of the body **210** and compresses an elastomeric washer **230** against the body **210** and the outer surface of the inner tube **190**. By tightening the cap **227**, the washer **230** is compressed to seal the lumen **221**. This compression also functions to inhibit, but not necessarily prevent, axial movement between the outer tube **192** and inner tube **190**. The releasability of the seal **225** can be appreciated in order to facilitate this relative movement between the tubes **190** and **192** for the reasons previously discussed. This form of a releasable seal **225** is commonly referred to as a Tuohy-Borst seal.

[**0098**] The relative movement between the inner and outer tubes **190** and **192**, respectively, will be appreciated in order to provide the tubes **190** and **192** with a first position wherein the fibers **198** have a low profile configuration as illustrated in **FIG. 23**. The relative movement will also be appreciated in order to provide the tubes **190** and **192** with a second position wherein the hollow fibers **198** form an increased profile as illustrated in **FIG. 24**. It can be appreciated that this profile will facilitate heat exchange by providing an increased spacing of the individual hollow fibers in the body fluid.

[**0099**] Another feature associated with these two positions is illustrated in **FIG. 23** where the inner tube **190** is expanded in thickness at its distal end in order to form a ramp or taper **232**. In this embodiment, the taper **232** is annular and extends radially outward with progressive distal positions along the tube **190**. As the inner tube **190** is drawn proximally relative to the outer tube **192**, the taper **232** is brought into sealing engagement with the proximal end of the hollow fibers **198** and potting seal **201**. This effectively seals the distal end of the outer tube **192** against the outer surface of inner tube **190**, and prohibits any loss of the heat exchange fluid **85** between the inner and outer tubes **190** and **192** at the distal end **45**.

[**0100**] This loss of the heat exchange fluid **85** can also be addressed with a seal tube **234** which can be positioned between the inner and outer tubes **190**, **192** and inwardly of the hollow fibers **198**. In this embodiment, a distal end **236** of the seal tube **234** is generally coextensive with the distal end of the outer tube **192**. The seal tube **234** is preferably provided with an inner diameter greater than the outer diameter of the inner tube **190**. As a result, the inner tube **190** is free to move relative to the outer tube **192** to achieve the advantages previously discussed. However, when the inner tube **190** is drawn sufficiently proximal of the outer tube **192**, the taper **232** will contact the distal end **236** of the seal tube **234**. This effectively forms the seal between the inner and outer tubes **190** and **192**, respectively at the distal end of the outer tube **192**. With the taper **232** wedged against the seal tube **234**, the fibers **198** are maintained in their operative free-floating configuration as illustrated in **FIG. 24**.

[0101] Alternatively, a non-tapered inner tube **190**, can be mated with a closely fitted seal tube **234**. With very small and controlled differences between the outside diameter of the inner tube **190** and the inside diameter of the seal tube **234**, for example 0.0005 to 0.003 inches, an effective seal can be constructed without the taper **232**. This embodiment relies on the length of the seal tube **234**, the surface tension of the coolant fluid **85**, and the small capillary gap to create a resistance greater than the pressure of the coolant fluid during operation. This design does not require the inner tube to be moved a fixed distance relative to the outer tube and does not require a constant tension between the inner and outer tubes to effect a seal.

[0102] The seal tube **234** is preferably constructed of polyimide which allows for a precision and constant inner diameter. In addition, polyimide is available in very thin wall thicknesses so that the seal tube **234** will not occupy a significant portion of the annular space which is more appropriately dedicated to the fibers **198**.

[0103] A method for manufacturing the hollow fiber embodiments of the catheter **10** is illustrated in FIGS. **25-27**. In **FIG. 25, a** planar mat **241** of the hollow fibers **198** is formed with a generally planar configuration. In this mat **241**, the fibers **198** are oriented in a generally parallel configuration with angled potting seals **201** and **243** formed at opposite ends of the fibers **198**. This fiber mat **241** can be rolled onto the outer surfaces of the inner tube **190** and seal tube **234** as illustrated in **FIG. 26**. In this step, the potting seal **201** is formed around the distal end of the inner tube **190** while the potting seal **243** is formed around the distal end of the seal tube **234**.

[0104] By initially forming the fibers **198** into the mat **241**, a generally uniform thickness of the mat **241** can be maintained. Rolling the mat **241** onto the tubes **190** and **234** maintains this uniform thickness and also facilitates orientation of the fibers **198** onto the cylindrical tubes **190** and **234**. This technique also forms an inwardly spiraling helical bond joint profile that aids in directing the blood flow in order to inhibit clot formation by preventing stagnant blood flow areas at the bond joint. With the potting seals **201** and **243** suitably bonded to the tubes **190** and **234**, respectively, the cap **205** can be mounted over the distal end of the fibers **198** as previously discussed. At the proximal end of the fibers **198**, the seal tube **234** can be mounted in the distal end of the outer tube **192** as illustrated in **FIG. 27**.

[0105] The seal tube **234** offers some interesting possibilities for the infusion of fluids at the distal end **45** of the catheter **10**. Of course, it is always possible to provide an additional lumen within the shah of the catheter **10**. In such an embodiment, the fluid to be infused could be injected into the additional lumen at the proximal end **43** to exit the catheter at the distal end **45**. Alternatively, the fluid to be infused might be included in the heat exchange fluid **85**. The tolerance between the seal tube **234** and the outer diameter of the inner tube **190** could then be controlled to provide a calibrated leak of the heat exchange fluid **85** at the distal end **45** of the catheter **10**. Micro holes might also be drilled into the outer tube **192** or inner tube **190** to provide for a controlled leakage of the infusion fluid.

[0106] Each of the foregoing embodiments of the heat exchange catheter **10** is adapted for use in cooling the entire human body, or perhaps only a portion of the total body. Methods of operation will vary widely depending on the focus of a particular procedure. By way of example, it will be noted with reference to **FIG. 28** that the catheter **10** is particularly adapted for cooling blood in a procedure which may involve as many as three of the catheters **10**. In **FIG. 28, a** human body **245** is illustrated along with a portion of the blood circulatory system including a pair of femoral veins **247, 250** and a subclavian vein **252**. These veins **247, 250** and **252** all extend into the vena cava **254** of the body **245**. In this procedure, separate catheters, such as the heat exchange catheter **10**, can be introduced into each of the femoral veins **247, 250** and the subclavian vein **252** with their respective heat exchange regions disposed in the vena cava **254**. Alteratively, and preferably, only two such catheters would be introduced from two of the three veins **247, 250** and **252**.

[0107] A systemic version of the catheter might have a diameter in a range of between 9 and 15 French, and a length of approximately 20 to 80 centimeters long. It is contemplated that this design could conceivably cool the body in several hours. The use of two such catheters inserted into the vena cava **254** as mentioned above could be expected to reduce the time required to cool the body by a factor of 2. It will be appreciated that similar catheters and methods can be used to lower the temperature of blood in the native carotid or in the vertebral circulatory system. The amount of blood heat lost is directly proportional to the temperature differential, the blood velocity and the blood-to-catheter surface area.

[0108] Particularly in an operative setting wherein the heat exchange catheter **10** is to be inserted into a blood vessel, a further design feature best illustrated in FIGS. **29-33** will be of particular interest. In these views, an introducer **256** is positioned for percutaneous insertion into a blood vessel such as the femoral vein **250**. A sleeve **258** is provided on the catheter **10** and slidable along the outer tube **192** between two positions. The first position is illustrated in **FIG. 29** wherein the sleeve **258** is disposed in a spaced relationship with the heat exchange region **47**. The second position of the sleeve **258** is illustrated in **FIG. 30** where the sleeve **258** covers the heat exchange region **47**. In this position the balloons or fibers associated with the region **47** are compressed to a low profile state greatly facilitating introduction of the catheter **10** into the introducer **256**. In addition, the covered heat exchange region **47** is stiffened for easier introduction into the introducer **256**. The fibers and/or balloons are also protected from the interior surface of the introducer **256**. Optionally, a stiffening mandril may be inserted down one or more of the tubes **190, 192** to facilitate introduction of the catheter **10** into the introducer **256**.

[0109] After this initial insertion, the sleeve **258** remains within the introducer **256** while the remainder of the heat exchange region **47** is moved distally into the conduit as illustrated in **FIG. 31**. At this point, the sleeve **258** can be removed from the introducer **256** by sliding it proximally to its first position as illustrated in **FIG. 33**.

[0110] This method of introduction is facilitated by providing the sleeve **258** with a generally cylindrical confguration. The diameter of the cylindrical sheath should be less that the inside diameter of the introducer **256**. However, at the proximal end of the sheath **258**, an annular flange **261** or other enlargement can be provided to ensure that the sheath **258** does not pass beyond the introducer **256**.

[**0111**] Another feature associated with the present invention relates to a blood clot basket or snare **263**, best illustrated in **FIGS. 34 and 35**. This snare **263** is preferably positioned downstream of the heat exchange region **47** associated with the catheter **10**. It being appreciated that any structure disposed in a blood vessel may tend to generate blood clots, it is the purpose of the snare **263** to capture any such clots. The snare **263** of the preferred embodiment includes a plurality of wires **265** which extend along a shaft **267** with their opposing ends fixed in the manifold **194** and a distal cap **270**. The wires **265** in a preferred embodiment are formed of stainless steel or a nickel titanium alloy.

[**0112**] In the illustrated embodiment, the shaft **267** extends to the proximal end **43** of the catheter **10** either through the lumen of the inner tube **190** or alternatively through a second, separate lumen in the inner tube **190**. In the former case, a seal would be required at the distal end of the manifold **194** to prevent any leakage of heat exchange fluid **85** around the shaft **267**.

[**0113**] In either case, the shaft **267** is free to move relative to the concentric tubes **190** and **192**. When the shaft **267** is moved relatively distally, the snare wires **265** are provided with a generally low profile. When the shaft **267** is moved relatively proximally, the wires **265** deploy to provide the snare with an enlarged high-profile configuration as illustrated in **FIG. 35**.

[**0114**] In a further embodiment of the snare **263**, the wires **265** are connected to the manifold **194** and extend to distal ends which are unattached or free. The wires **265** in this embodiment, best illustrated in **FIG. 36**, are bent to a deployed enlarged configuration. With such an embodiment, insertion is facilitated by providing a delivery sheath which is movable to maintain the wires **265** in a low-profile state. Once the catheter **10** is in place, the sheath **262** can be removed thereby permitting the wires **265** to automatically expand to their enlarged high-profile state.

[**0115**] With respect to the forgoing disclosure as a whole, it will be apparent that many variations from these preferred embodiments will now be apparent to those skilled in the art. For example, with respect to the balloon embodiments previously discussed, it will be appreciated that the advantages of this invention can be derived with only a single balloon. On the other hand, there seem to be several advantages associated with multiple balloon embodiments. Notably, a more even and balanced transfer of heat exchange can be achieved with multiple balloons. In addition, there appears to be better mixing with respect to both the blood **31** as well as the heat exchange fluid **85**. Multiple balloons also provide an increased surface area relative to single balloon embodiments. Furthermore, the overall flexibility of the catheter **10** is enhanced with multiple balloons separated by interruptions which provide natural flex points for the catheter. When the balloons experience the high perfusion pressure, they become more stiff. The reduced diameter interruptions provide for increased flexibility at these joints.

[**0116**] Additional flexibility can be derived by providing the shaft **40** with variable stiffness. This variability can be produced by different materials forming the shaft **40** along its length or alteratively, tapering or otherwise varying the diameter of the shaft **40**. For example, the shaft **40** can be progressively tapered from its proximal end **43** to its distal end **45** in order to provide a softer and more flexible heat exchange region **47**.

[**0117**] In any of the foregoing embodiments of the catheter **10**, the inner tube **190** can be provided with a central lumen facilitating introduction over a guidewire and providing a capability for the infusion of fluids through the catheter **10**.

[**0118**] With the intent of maximizing heat transfer with the body fluid in a conduit feeding a specific region of the body, any of the factors previously noted can be addressed to provide structural modifications to the foregoing embodiments. Of course changes in the material or size of any of the structural elements described can be varied to achieve various heat exchange properties. Realizing the many changes which might be contemplated, one is cautioned not to limit this concept only to the specific embodiments illustrated and disclosed, but rather to determine the scope of the invention with reference to the following claims.

1. A catheter having an elongate configuration with a proximal end and a distal end, the catheter comprising:

an outer tube having an elongate configuration and a first lumen;

an inner tube disposed in the first lumen of the outer tube and having a second lumen extending between the proximal end and the distal end of the catheter;

portions of the inner tube defining a first fluid flow path extending along the second lumen between the proximal end and the distal end of the catheter;

portions of the outer tube and the inner tube defining a second flow path extending between the first tube and the second tube; and

a plurality of hollow fibers providing fluid communication between the first fluid flow path and the second fluid flow path.

2. The catheter recited in claim 1, wherein:

each of the hollow fibers has a proximal end and a distal end;

the distal end of each of the hollow fibers has a fixed relationship with the distal end of the inner tube; and

the proximal end of each of the hollow fibers has a fixed relationship with the distal end of the outer tube.

3. The catheter recited in claim 2, wherein the inner tube has properties for moving relative to the outer tube to vary the configuration of the hollow fibers extending between the inner tube and the outer tube.

4. The catheter recited in claim 3, wherein:

portions of the inner tube define a taper, the inner tube being axially movable to bring the portions of the inner tube into sealing proximity with the hollow fibers.

5. The catheter recited in claim 1 further comprising:

a cap disposed over the distal ends of the inner tube and the hollow fibers.

6. The catheter recited in claim 1, further comprising:

a seal tube disposed inwardly of the proximal end of the hollow fibers and forming a seal with the distal end of the outer tube and the proximal ends of the hollow fibers.

7. The catheter recited in claim 6, wherein the seal tube extends proximally of the proximal end of the hollow fibers.

8. The catheter recited in claim 4, further comprising:

a seal tube disposed inwardly of the proximal end of the hollow fibers and forming a seal with the distal end of the outer tube and the proximal end of the hollow fibers; and

the portions of the inner tube which define the taper are axially movable relative to the outer tube in the sealing engagement with the hollow fibers.

9. The catheter recited in claim 1, wherein the hollow fibers are adapted to receive a heat exchange fluid from the first flow path and to release the heat exchange fluid into the second flow path.

10. The catheter recited in claim 3, further comprising:

a seal tube disposed between the hollow fibers and the inner tube and having an inner diameter greater than the outer diameter of the inner tube, but sufficiently close to the outer diameter of the inner tube to form a liquid seal between the seal tube and the inner tube by capillary action.

11. The catheter recited in claim 10, wherein:

portions, of the inner tube define a taper, the inner tube being axially movable to bring the portions of the inner tube into sealing proximity with the distal end of the seal tube.

12. The catheter recited in claim 5, farther comprising:

a coating of insulation covering the cap at the distal end of the catheter.

13. The catheter recited in claim 1, wherein the hollow fibers are adapted to receive a heat exchange fluid from the second flow path and to release the heat exchange fluid into the first flow path.

14. A method for making a heat exchange catheter, comprising the steps of:

providing a first tube having a first lumen extending between a proximal end and a distal end;

inserting a second tube into the lumen of the first tube, the second tube having a second lumen;

connecting a plurality of hollow fibers in fluid communication with a first flow path extending along the second lumen of the second tube, and a second flow path extending along the first lumen of the first tube outwardly to the second tube; and

insuring that the second tube is at least one of axially and rotationally movable relative to the first tube to vary the configuration of the hollow fibers in order to facilitate heat exchange with the heat exchange catheter.

15. The method recited in claim 14, wherein the insuring step includes the steps of:

moving the second tube distally relative to the first tube to change the hollow fibers to a low profile state; and

moving the second tube proximally relative to the first tube to change the hollow fibers to a high profile state.

16. The method recited in claim 14, wherein the connecting step further comprises the steps of:

forming the hollow fibers in a stack having a generally planar configuration;

wrapping the hollow fibers stack around the second tube; and

inserting the hollow fibers into the distal end of the first tube.

17. The method recited in claim 14, further comprising the steps of:

fixing to the proximal end of the first tube a Y-connector having fluid communication with the second flow path.

18. The method recited in claim 17, further comprising the steps of:

attaching a locking device to the Y-connector, the locking device being operable between a first position permitting movement of the second tube relative to the first tube, and a second position inhibiting movement of the second tube relative to the first tube.

19. The method recited in claim 16, further comprising the step of:

potting the hollow fiber stack to form an end seal tapered radially inwardly to inhibit formation of stagnant flow regions around the fibers of the stack.

20. A method for operating a heat exchange catheter within a body conduit containing a body fluid, the method comprising the steps of:

inserting into the body conduit the heat exchange catheter with an inner tube disposed within an outer tube to define a first flow path interiorly of the inner tube and a second flow path between the inner tube and the outer tube, and a plurality of hollow fibers disposed in fluid communication between the first flow path and the second flow path; and

creating a flow of heat exchange fluid by introducing the heat exchange fluid into one of the first flow path and the second flow path.

21. The method recited in claim 20, wherein the inserting step includes the step of pushing the inner tube distally relative to the outer tube to provide the hollow fibers with a lower profile.

22. The method recited in claim 20, wherein the creating step further comprises the step of reciprocating the inner tube relative to the outer tube to create a continuous movement of the hollow fibers in order to facilitate heat exchange between the hollow fibers and the body fluid.

23. The method recited in claim 20, further comprising the steps of:

removing the catheter from the body conduit, and prior to the removing step, pushing the inner tube distally relative to the outer tube to provide the hollow fibers with a lower profile.

24. The method recited in claim 20, wherein prior to the inserting step the method comprises the steps of:

providing a sheath outwardly of the outer tube and movable between a first position spaced from the hollow fibers and a second position proximate to the hollow fibers; and moving the sheath to the second position and over the hollow fibers to maintain the fibers in a low profile state.

25. The method recited in claim 24, further comprising the steps of after the inserting step, moving the sheath from the second position to the first position.

26. The method recited in claim 25, further comprising the step of after the first moving step, moving the sheath from the first position to the second position and withdrawing the catheter.

27. The method recited in claim 20, wherein the heat exchange fluid is a cooling fluid.

28. A heat exchange catheter, including:

an elongate shaft extending along an axis between a proximal end a distal end;

first portions of the shaft defining an inlet lumen extending between the proximal end and the distal end of the shaft;

second portions of the shaft defining an outlet lumen;

a first manifold in fluid communication with the inlet lumen at the distal end of the shaft;

a second manifold in fluid communication with the outlet lumen of the shaft;

a plurality of hollow fibers disposed to extend between the first manifold and the second manifold in fluid communication with the inlet lumen and the outlet lumen; and

the catheter being adapted to receive a heat exchange fluid at the proximal end of the inlet lumen, and to direct the heat exchange fluid through the hollow fibers to exchange heat through the hollow fibers.

29. The heat exchange catheter recited in claim 28, wherein the first manifold is disposed distally of the second manifold.

30. The heat exchange catheter recited in claim 29, wherein the outlet lumen is disposed outwardly of the inlet lumen.

31. The heat exchange catheter recited in claim 28, wherein the shaft comprises:

an inner tube defining the input lumen; and

an output tube concentric with the input tube and defining with the input tube the output lumen.

32. The heat exchange catheter recited in claim 31, wherein:

the first tube has a fixed relationship with the first manifold;

the second tube has a fixed relationship with the second manifold; and

the first tube is axially movable relative to the second tube to vary the configuration of the hollow fibers.

33. The heat exchange catheter recited in claim 32, wherein the first tube is movable axially of the second tube to separate the first manifold and the second manifold, and to place the hollow fibers in a generally straight, parallel relationship.

34. The heat exchange catheter recited in claim 28, wherein the heat exchange fluid is a liquid.

35. A catheter adapted to exchange heat with a body fluid flowing through a body conduit, the catheter comprising:

a shaft having an axis extending between a proximal end and a distal end, the shaft having an input lumen and an output lumen;

a plurality of hollow fibers defining a heat exchange region of the shaft and collectively defining an outer surface of the heat exchange region;

the input lumen of the shaft coupled to the hollow fibers of the heat exchange region at a first location, the output lumen of the shaft being coupled to the hollow fibers of the heat exchange region at a second location such that a heat exchange fluid introduced into the input lumen will enter the hollow fibers of the heat exchange region at the first location and will exit the hollow fibers of the heat exchange region at the second location through the output lumen.

36. The catheter recited in claim 35, wherein the body fluid flows in a first direction through a body conduit and the heat exchange fluid flows through the hollow fibers in a second direction opposite to the first direction.

37. The catheter recited in claim 35, further comprising:

a clot inhibiting coating covering the hollow fibers.

38. The catheter recited in claim 36, further comprising:

a clot snare disposed in the first direction from the heat exchange region.

39. The catheter recited in claim 37, wherein portions of each hollow fiber defines a multiplicity of micro pores and the coating is formed by a clot inhibiting chemical included in the heat exchange fluid and leechable through the micro pores of the fibers.

40. A method for exchanging heat with a body fluid in a body conduit, comprising the steps of:

introducing into the body conduit a catheter having an inlet lumen and an outlet lumen;

providing the catheter with a first cavity in heat transfer relationship with a body fluid in the body conduit;

introducing a heat exchange fluid into the inlet lumen and into the first cavity;

exchanging heat between the heat exchange fluid and the body fluid in the body conduit;

removing the heat exchange fluid from the first cavity through the outlet lumen; and

during the providing step, providing the catheter with a plurality of hollow heat exchange fibers each extending in fluid communication with the inlet lumen and the outlet lumen, the heat exchange fibers collectively defining the first cavity in heat transfer relationship with the body fluid in the body conduit.

41. The method recited in claim 40, wherein the second introducing step includes the step of introducing the heat exchange fluid into the hollow fibers.

42. A catheter having a elongate configuration with a proximal end and distal end, comprising:

an operative area of the catheter sized and configured for disposition in a vessel containing blood flowing in a particular direction, the operative area being adapted to perform a predetermined function and the blood in the vessel having a tendency to form blood clots; and

a snare disposed in the particular direction from the operative area and being operable from the proximal end of the catheter to move from a low-profile state facilitating insertion of the catheter into the vessel, and a high-profile state facilitating capture of any blood clots.

43. The catheter recited in claim 42, wherein the snare is disposed distally of the operative area of the catheter.

44. The catheter recited in claim 42, wherein the operative area includes a heat exchange region of the catheter.

45. The catheter recited in claim 44, wherein the heat exchange region is a heat receiving region of the catheter.

46. The catheter recited in claim 42, wherein the snare includes:

a plurality of elongate filaments each having a first end attached to the operative region of the catheter and a second end.

47. The catheter recited in claim 46, wherein the second ends of the filaments are unattached.

48. The catheter recited in claim 46, wherein:

the catheter further comprises a cap disposed at the distal end of the catheter;

the second ends of the filaments are attached to the cap; and

movement of the cap relative to the operative region of the catheter changes the profile of the snare.

49. The catheter recited in claim 48, further comprising:

a shaft attached to the cap and extending to the proximal end of the catheter; whereby

the profile of the snare is changed by movement of the shaft relative to the operative region of the catheter.

50. The catheter recited in claim 42, wherein the filaments are formed of wire.

51. The catheter recited in claim 50, wherein the wire filaments include a nickel titanium alloy.

52. A heat exchange catheter having a elongate configuration and extending between a proximal end and a distal end, the catheter being adapted for cooling the blood of a patient, comprising:

a heat exchange region of the catheter;

a plurality of fibers included in the heat exchange region, with each of the fibers having a hollow configuration and being adapted to receive a heat exchange fluid; and

a coating disposed on the outer surface of the fibers to inhibit the formation of blood clots on the cooled fibers.

53. The heat exchange catheter recited in claim 52, further comprising a chemical included in the coating and having characteristics for inhibiting the formation of the blood clots.

54. The heat exchange catheter recited in claim 53, wherein the chemical includes heparin.

55. The heat exchange catheter recited in claim 53, wherein:

each of the fibers includes a multiplicity of micro pores extending between the hollow interior of the fibers and the outer surface of the fibers; and

the chemical is included in the heat exchange fluid and leached with the heat exchange fluid through the micro pores to coat the outer surface of the fibers.

56. The method recited in claim 20 farther comprising the step of:

moving the inner tube relative to the outer tube to change the profile of the hollow fibers.

57. The method recited in claim 20, wherein the creating step includes the step of:

providing a heat exchange fluid in the form of a liquid.

58. The method recited in claim 20, wherein the creating step includes the step of:

providing a heat exchange fluid in the form a gas.

59. The method recited in claim 20, wherein the creating step includes the step of:

heating the heat exchange fluid prior to introducing the heat exchange fluid into the catheter.

60. The method recited in claim 20, wherein the creating step includes the step of:

cooling the heat exchange fluid prior to introducing the fluid into the catheter.

61. The heat exchange catheter recited in claim 28, wherein the heat exchange fluid is a gas.

62. The heat exchange catheter recited in claim 28, wherein the heat exchange fluid is a cooling fluid.

63. The heat exchange catheter recited in claim 28, wherein the heat exchange fluid is a heating fluid.

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