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(54) **BLOOD-FLOW-OCCLUDING, TEMPERATURE-SENSING CATHETERS**

BLUTFLUSS-OKKLUDIERENDE, TEMPERATURMESSENDE KATHETER

CATHETER POUR DETECTION DE TEMPERATURE, BLOQUANT LE FLUX SANGUIN

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Description

FIELD OF THE INVENTION

[0001] This invention relates generally to medical instrumentation and appliances and, in particular, to temperature sensing catheters and methods of use.

BACKGROUND OF THE INVENTION

[0002] Arteriosclerosis is a major source of adult morbidity and mortality in industrialized countries. The condition may lead to a number of complications, including coronary thrombosis, myocardial ischemia, unstable angina, myocardial infarction and restenosis of stents and bypass grafts. The classification of atherosclerotic lesions by type can be valuable in predicting clinical complications, and the type of plaque is likely a better predictor of cardiovascular events than angiographic data.

[0003] Unstable plaque is well established as producing high risk for sudden myocardial infarction, either through plaque rupture and subsequent thrombotic response, or thrombosis generated at the inflamed surface of the plaque. The rupture of unstable plaque, and the subsequent generation of thrombus, has been estimated to account for 60 to 70 percent of fatal myocardial infarctions and up to 85 percent of all myocardial infarctions.

[0004] Unstable plaque is characterized by a lipid-rich core, chronic inflammation, thin fibrous cap, and activated macrophages. Angiography can identify the presence of a ruptured plaque after rupture, but not before rupture. Thus, it cannot determine the risk associated with a given plaque.

[0005] Due to chronic inflammation, the temperature of unstable plaque is typically elevated above the temperature of ambient blood flow. Extensive research has been conducted to confirm the elevated temperatures of unstable plaques, and to develop techniques to clinically identify them. It has been found that there is a correlation between the temperature of atherosclerotic plaque and the vulnerability to blood vessel rupture. In particular, it has been determined that inflamed, unstable deposits typically give off more heat than do healthy, non-inflamed tissues. Accordingly, there have been various apparatus and methods proposed to monitor the temperature of the vessel wall without occluding blood flow. U.S. Patent Nos. 5,871,449; 5,924,997; and 5,935,075 provide background with regard to the general approach.

[0006] To determine that thrombotic events could be predicted through thermal measurements on the plaque surface, Willerson et al. measured the intimal surface temperatures on 20 sites located on 50 samples of excised living carotid artery samples from 48 patients using a thermistor, and then conducted histological studies. The results showed 37 percent of plaque regions warmer by up to 2.2°C. These warmer regions could not be distinguished from cooler regions by visual observation, but correlated positively with cell density, a marker of inflammation.

[0007] Stefanadis et al. conducted human in vivo measurements of plaques using a Betatherm Microchip NTC 100K6 MCD368, 0.457 mm diameter thermistor on the end of a guide wire pressed against the vessel wall by a hydrofoil. They measured thermal heterogeneity of plaque temperatures repeatedly with an accuracy of 0.05°C and spatial and temporal resolutions of 500 um and 300 ms, in 90 patients with normal coronary arteries, stable angina, unstable angina, and with acute myocardial infarction. This group found artery-wall temperatures that increased progressively from normal patients, to stable angina patients, to unstable angina patients. The measurement of temperature differences in the inner lumen of coronary arteries shows great promise for identifying sites of unstable plaque.

[0008] Research on classification of plaque as stable or unstable has been carried out in three main areas: thermal, Ultra-Fast Magnetic Resonance Imaging (MRI) and Intravascular Ultrasound (NUS), with some work on a few others (e.g. Raman scattering, elastography, optical coherence tomography). While MRI and IVUS show promise, only thermal techniques offer a direct, inexpensive method of plaque classification that, due to its minimal hardware and disposable requirements, can be quickly and inexpensively implemented.

[0009] Plaque classification by MRI presents numerous obstacles. It brings the problems of requiring a special machine, typically located in other regions of the facility and not available on an ad hoc basis, into the cath lab as questions of plaque stability may arise. The ability of MRI to characterize human atherosclerotic plaque has been investigated by comparing MRI images of carotid artery plaque with histologic examination of the specimens after carotid endarterectomy. The studies indicated that MRI can discriminate the presence of a lipid core and fibrous cap in the carotid artery. The ability of MRI to characterize plaque composition of coronary arteries in the beating human heart has not been demonstrated. Even if the technical challenges of spatial and temporal resolution are solved, the cost of imaging coronary arteries using MRI is likely to be substantial.

[0010] While IVUS can accurately identify arteriosclerosis in its early stages, it is much less effective in the classification of plaque by type. Further, IVUS requires expensive and large equipment that also must be brought into the cath lab when needed. The main limitation of NUS is cost. IVUS enjoys an installed base in many cath labs, unlike other competing technologies to classify plaque, but it is problematic in this application. IVUS is very operator dependent and typically has a 300 micron resolution, the thickness of the fibrous cap on unstable plaque. Thus, IVUS does not have the needed resolution to identify unstable plaque. Although numerous clinical studies have been performed with IVUS, there are very limited follow-up data to suggest that IVUS examination of a coronary artery can be used to predict the probability that a plaque will rupture.

[0011] Yamagishi et al. performed IVUS examination of 114 coronary plaques in 106 patients. During an average follow-up period of 22 months, 12 patients had an acute coronary event related to a plaque that was previously examined by IVUS. Ten of the 12 plaques contained an echolucent zone consistent with a lipid-rich core. Only 4 of 90 sites not associated with acute events had an echolucent zone ($p<0.05$).

[0012] Optical Coherence Tomography (OCT) has problems due to its limited penetration distance, and the fact that it requires a saline flush to remove blood from the area and permit transmission of the optical radiation. Further, it can run only at -5 frames/sec., which does not provide adequate temporal resolution. This technique, and others, such as pulsed laser radiation and the use of Raman scattering spectroscopy, require the vessel be purged of blood with clear saline for the signals to propagate. Further, they are much less developed than other techniques.

[0013] Classification of atherosclerotic plaque stability by measurement of its surface temperature is direct. Due to the chronic inflammation, the surface temperature of unstable plaque is typically elevated above that of the adjacent sites on the inner lumen of the vessel. Measurements in vivo and ex vivo have been made of active plaque sites, with temperature differences from the adjacent normal artery wall ranging up to 2 to 3°C. The equipment associated with thermal measurements may be small and inexpensive, thus easily portable between cath labs or available in all cath labs in a single facility, as opposed to Magnetic Resonance Imaging (MRI) and Intravascular Ultrasound (IVUS). Identification of unstable plaques would permit the cardiologist to decide on treatment on a site-by-site basis during a single catheter insertion.

[0014] There are numerous potential treatments for these unstable lesions, including antiinflammatory and/or anti-microbial treatments, aggressive cholesterol lowering, and heating to generate apoptosis. Stenting techniques are influenced by the classification of the plaque being treated. As classification of plaques becomes established, other therapeutic techniques will no doubt develop.

[0015] While plaque temperature measurement and catheters therefore showed early promise in terms of early diagnosis and treatment, it has more recently been discovered that the temperature elevation to be identified as representative of unstable lesions is complicated by the"cooling affect"of blood flow. In particular, a recent paper by Stefanadis, entitled *Thermal Heterogeneity in Stable Human Coronary Atheroschlerotic Plaques is Underestimated in Vivo : The "Cooling Effect"of Blood Flow* postulates that the"cooling effect"of blood flow may lead to an underestimation of *in vivo* temperature measurements associated with atheroschlerotic plaques.

[0016] US2003/0028114 discloses a method and apparatus for detecting vulnerable atherosclerotic plaque. Thermocouple and thermistor basket cathereters are disclosed capable of detecting temperature heterogeneity along a vessel wall.

[0017] Accordingly, the need remains for an improved system and method for analyzing plaque tissues exhibiting an elevated temperature, both to predict rupture or other clinical events.

SUMMARY OF THE INVENTION

[0018] This invention improves upon the existing art by providing a catheter assembly for sensing the temperature of an arterial wall or other body lumen, the preferred embodiment including a blood-flow-occluding feature to increase the accuracy of the temperature measurements.

[0019] In terms of apparatus, the catheter includes a distal end with a temperature sensing structure and a proximal end including a manually operated expansion control. The temperature sensing structure includes a plurality of presentation elements, preferably in the form of a basket or braided structure having at least one temperature sensor supported thereon, each sensor being operative to generate an electrical signal indicative of temperature. The presentation elements are physically coupled to the manually operated expansion control, such that operation of the control causes the basket or braided structure to move between a collapsed state, enabling the temperature sensing structure to be positioned in a section of the vessel to be measured, and an expanded state, wherein at least one temperature sensor is in contact with, or immediately proximate to, the vessel wall.

[0020] The temperature-sensing structure is preferably in the form of an expandable basket or braid structure, and the temperature sensors are preferably thermistors. An elastic sleeve is used to cover the expandable basket or braid structure to further insulate the temperature sensors and provide structural strength. At least one thermal sensor may optionally be provided to measure a non-wall temperature.

[0021] The sensors are interfaced to a data unit operative to receive signals from the sensors and display information indicative of vessel wall temperature. Each sensor may be independently wired to the data unit or signal multiplexing may be used.

[0022] Given the independent control of the temperature-sensing structure and blood-occluding feature, a method unique to this invention permits a particular point being analyzed to serve as its own baseline reference. According to this aspect of the invention, the catheter is inserted into an area to be analyzed, and the presentation elements are expanded such that the temperature sensors contact one or more points of the vessel wall. The electrical signals from the sensors are read out to the data box and stored and/or displayed, these being indicative of wall temperature with at least a portion of blood flow being present. After this measurement is taken, the occluder feature is activated to interrupt or stop blood

flow, at which point the signals from the sensors are monitored to determine temperature rise, if any, as well as the difference between the temperature sensed during at least partial flow and that with stagnant fluid. This results in a much more accurate determination of ΔT, defined as $T_{occluded} - T_{flowing}$.

[0023] Unique to this method, the method may further include the steps of collapsing the basket or braided structure; moving the temperature-sensing up to a different location; and expanding the basket or braided structure to perform an additional temperature reading while the flow of blood remains occluded. In such a case, it may be advantageous to use an initial measurement with at least partial blood flow to serve as a baseline temperature measurement of the subsequent readings taken while the flow of blood is partially or fully occluded.

[0024] In an alternative embodiment, the occluding feature may not be provided, or may not be used. In such a case, the expandable basket or braid structure may be used to measure ambient blood flow temperature in a collapsed state, using the sensors provided for measuring wall temperature, non-wall temperature, or both. Once this baseline is taken, the basket or braid structure is expanded to take a reading of the wall temperature(s), and the wall temperature(s) is compared to the ambient reading. If a sensor is provided for measuring non-wall temperature, the wall and ambient reading may be taken simultaneously.

[0025] Another aspect of the invention involves the time it takes to obtain an accurate temperature reading. It has been experimentally determined that, even with flow occlusion, several seconds are required before the temperature(s) detected by the sensors have stabilized to the point of acceptable accuracy. Indeed, at least using one type of available thermistor, ten seconds or more may be required before an accurate measurement is obtained.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026]

FIGURE 1 is a rendering of a structure wherein temperature sensors are integrated into a braided structure according to the invention;

FIGURE 2 shows a braided structure and elastic cover;

FIGURE 3 is a perspective, simplified view of an experimental set up used to demonstrate that, indeed, the cooling effect of blood flow adversely affects the ability of a temperature sensing catheter to obtain an accurate reading;

FIGURE 4 illustrates how, by occluding the flow of a liquid around a temperature sensor, a more accurate reading may be obtained;

FIGURE 5A is a perspective view drawing of an expandable braid catheter design and elastic sleeve covering with a separate occlusion balloon constructed in accordance with this invention;

FIGURE 5B illustrates how the positions of the temperature-sensing structure and occluding feature may be reversed as compared to Figure 5A;

FIGURE 6A is a close-up view of the alternative embodiment of the invention showing an occluding balloon and temperature-sensing structure that may be moved independently of one another;

FIGURE 6B shows how it may be more advantageous to utilize an inner tube to permit the use of a guidewire central to the entire catheter assembly;

FIGURE 7A through 7I illustrate the way in which apparatus according to this invention may be used to sense particular point on a vessel wall prior to, and following, occlusion of blood flow;

FIGURE 8A is a drawing which shows one way in which a separate occluding balloon may be positioned distally as opposed to proximally of an expandable/collapsible temperature-sensing structure; and

FIGURE 8B shows how a tube may be extended to the distal end of a device such as that shown in Figure 8A, facilitating the use of a central guidewire.

DETAILED DESCRIPTION OF THE INVENTION

[0027] This invention resides in a thermal sensing catheter (TSC) operative to perform localized temperature measurements with respect to a human or animal arterial or other vessel wall. The embodiments find particular utility in predicting whether a section of a body lumen undergoing stenting as a treatment for stenosis will likely be subject to restenosis. If such is the case, alternative approaches to the stenting procedure (i.e., length/diameter, coated/medicated) may be elected as appropriate. The instrument and methods are also valuable to other diagnoses, including plaque assessment, including plaque stability, not available with current technology.

[0028] In terms of apparatus, in the preferred embodiments, miniaturized temperature sensors in the form of microthermistors are embedded into or supported relative to a plurality of expandable presentation elements disposed at the distal end of a catheter. The sensors may then be deployed to measure the surface temperature of the inner wall of coronary arteries at multiple sites to identify sites conducive to restenosis or exhibiting an elevated temperature indicative of unstable plaque.

[0029] In the preferred embodiment, the presentation elements are disposed relative to an expandable braided structure that is actively caused to collapse and expand. A control mechanism located at the proximal end of the catheter outside the body is used to expand and collapse the structure as further described below. In one disclosed example, a dedicated guide wire coupled to the control mechanism is used to pull on the distal-most end of the braid elements, causing it to shorten along its length and to expand out radially. When the guide wire is pushed,

the ends of the structure are pulled apart, causing the braid to collapse.

[0030] The control mechanism preferably forms part of a battery-powered, hand-held data box including a port to which the catheter assembly connects, thereby making electrical contact for ground and the signal lines of each of the individual sensors. The connections from each sensing element are preferably separate and dedicated; however, in an alternative configuration, multiplexing may be used to reduce the number of signal wires.

[0031] The data box includes a display to present the calibrated readings from the sensors, as well as memory capabilities to store data for later download through a port incorporated in the housing. The output of the data box may be provided to a computer, to permit full-screen display of the thermal data. In either mode, a full recording of a procedure may be saved for later analysis.

[0032] The braid structure can be made from any of a variety of biocompatible materials, including polymers and metallic compositions, such as stainless steel or nitinol. The strands used to make the braid may have a round cross section, like a wire, or they could be square, rectangular or some other geometric shape so long as they serve the purposes of the expansion and contraction.

[0033] As an option to the placement of the temperature sensors on the braid structure, they may be made an integral part of the braid itself, as shown in Figure 1. This may be accomplished by weaving the sensors into the braid, in which case the electrical lead wires associated with the sensing elements may replace some of the regular strands in the braid. Alternately, the lead wires may be attached to strands before they are woven into the braid construction. As a further alternative, as discussed below, if an elastic sleeve covering is used over the structure, the sensors may be disposed on or in the covering. In all cases, the sensors move with the braid. That is, when the structure is dilated and makes contact with the wall, the sensors will also make contact with, or at least become immediately proximate to, the vessel wall. Conversely, when the braid collapses to a low profile state, the sensors are also positioned away from the inner wall of the body lumen.

[0034] Figure 2 shows a thermal sensing catheter according to the invention incorporating an expandable braid and transient occlusion sleeve. The device includes an outer catheter 202, having dimensions on the order of 0.027 inch I.D./0.035 inch O.D., and an inner catheter 204 having dimensions of 0.016 inch I.D./0.024 inch O.D. The braid, depicted generally at 206, is expandable to a diameter on the order of 6 mm, or thereabouts, with a length on the order of 25 mm, or thereabouts, to transiently occlude blood flow. The lower portion of the diagram in Figure 2 illustrates certain details associated with the distal tip. A plurality of thermistors 210, with lead wires form an integral part of the transient occlusion sleeve. The braided structure is rigidly fixed to both catheters at 212, preferably through the use of a crimped ferrule. The sleeve is then bonded at 214 to both catheters to seal off the structure and prevent blood flow from entering the space.

[0035] In other respects the catheter may be generally similar to other diagnostic or interventional catheters. Its length, construction, flexibility, and size (diameter) would all be appropriate for the application. For example, if the invention were to be used for a cardiac catheterization, it might be 130-150cm long, constructed of flexible polymers, contain a central guide wire lumen, and be about 8F (2.7mm diameter) or smaller in order to pass through a guide catheter. The catheter would also preferably include a y-connector with standard luer fittings on the proximal end to interface with other devices. If the braid structure is not otherwise radiopaque, a radiopaque marker may be included so the sensing element may be located with fluoroscopy.

[0036] In use, the braided end of the catheter is in a collapsed state while it is inserted and positioned in a vessel. Once properly positioned, the braid can be expanded so that the thermal sensing elements make contact with the vessel wall. The braid can be designed so that it makes a gentle atraumatic contact. This is important to prevent, or minimize, damage to the vessel.

[0037] There are several advantages to this approach. First, the device provides an efficient means for expanding a structure in a vessel and making contact with the wall. The braid will make gentle contact with the wall and cause little or no damage. While it is expanded, it will allow for blood flow and not occlude the vessel. It will conform to the topography of the vessel and maintain contact if the catheter is moved. Moreover, with the use of an elastic sleeve, a more uniform arrangement of the sensors is maintained around the circumference of the artery or other vessel. As perhaps best seen in Figure 7E, the use of a braid and sleeve facilitates intimate contact around the entire circumference of the inside of the vessel, even if it is non-round in shape.

[0038] As discussed in the Background of the Invention, it has recently been demonstrated that the "cooling effects" due to blood flow may adversely affect the ability of a temperature-sensing catheter to conduct accurate *in vivo* estimates of temperature. To investigate this hypothesis, an experiment was undertaken to determine the extent to which a flowing liquid inhibits the ability to conduct accurate measurements of vessel wall temperatures. The experimental set up, shown in Figure 3, broadly uses a pair of canulated tubes, which engage with each other at a point of contact in cris-crossing fashion. A first tube 402 carries unheated water. A metal (brass) tube 404 touching the water-carrying tube in a localized area 418 carries heated water. This second tube 404 in turn creates a small localized spot 418 on the wall of the first tube 402 which is higher in temperature than the rest of the tube 402 or the unheated water passing through it.

[0039] Three miniature temperature sensors were used, including a first temperature sensor 412 used to

measure the temperature of the flowing unheated water (Tw), a second sensor 414 used to measure the wall temperature inside of the tube 402 (Tt), and a third temperature sensor 420 within the unheated water carrying tube to measure the point of contact with the brass tube carrying the heated water (Tc).

[0040] The results of these experiments are shown in Figure 4. Note that Tw and Tc generally track one another until a point X, wherein the curves depart from one another. It is at this point that the flow through the non-heated water carrying tube is occluded. When this occurs, it will be seen that the difference between Tc and Tt transitions from being relatively large to much smaller, as the curve representative of Tc begins to approach Tt beginning at the point X. This confirms the fact that while non-occluding temperature sensing catheters may be useful in some cases, a more accurate reading of elevated vessel wall temperature may be obtained by occluding blood flow. Note also that, even with flow occlusion, several seconds are required before the temperature(s) detected by the sensors have stabilized to the point of acceptable accuracy. Indeed, at least using one type of available thermistor, ten to twenty seconds or more may be required before and/or after occlusion before accurate measurements are obtained.

[0041] Figure 5A is a perspective view a blood-flow-occluding embodiment, which broadly includes a temperature-sensing structure 502 and an occluding component 504. Although a basket structure may be used as described in U.S. Patent No. 6,712,771, an expandable braid design is preferred in the temperature sensing structure as it resists the tendency to twist under tortional movements and provides the other benefits outlined herein. An optional elastic cover is also preferably used over the expandable structure to provide a sealed, gas-filled backing for the sensors to further improve the accuracy of ΔT measurements by providing increased thermal insulation from the temperature of flowing blood.

[0042] According to this invention, temperature sensing catheters with blood-occluding structures may be designed different ways. As shown in Figure 5A, for example, the temperature-sensing structure 502 and occluding feature 504 may be preset at a predetermined distance from one another, such that they move in unison during repositioning. Although this limits flexibility somewhat by requiring that the occluding feature be deflated in order to reposition the temperature-sensing structure, it does simplify overall construction. Distal end 506 may either represent a connection to a central expansion control wire or a tube facilitating the use of a guidewire 508 central to the entire catheter assembly. As shown in Figure 5B, the positions of the temperature-sensing structure 502' and occluding feature 504' may essentially be reversed.

[0043] As an alternative to fixed-distance arrangements, the temperature-sensing feature may be movable relative to the occluding feature, thereby enabling independent positioning and repositioning of the two structures. Such independent movements may also be implemented in different ways, including entirely separate occluding balloons and temperature-sensing tips, insertable and positionable side-by-side within a vessel or, alternatively, concentric structures may be used facilitating independent movement of a temperature-sensing tip relative to a proximal occluding feature (Figure 6), or a temperature-sensing structure which is itself proximal to a more distal expandable/collapsible balloon used to occlude blood flow (Figure 8). It will further be appreciated that a more complex structure may be implemented with proximal and distal blood-occluding balloons, all independently readjustable through appropriate combination of Figures 6 and 8.

[0044] Figure 6A is a close-up view of a system having an occluding balloon 604 located proximally to a distal temperature-sensing structure 602, shown in an expanded state. The occlusion feature 604 is preferably in the form of a highly compliant balloon such that when it is inflated it conforms to the contour of the inside wall of the artery. A separate lumen 608 is provided to the balloon 604 for expansion and contraction utilizing air, CO_2 or a liquid such as saline. It is envisioned that the balloon will be inflated to a pressure just sufficient enough to occlude flow, which would be significantly less than the pressure typically used for an angioplasty. The balloon tipped portion of the catheter is tracked over a guide wire 706 which can pass through the inside lumen 606 of the balloon-tipped portion. It will be appreciated that in this and other designs according to the invention, at least one separate temperature-sensing element may be used to measure a non-wall temperature with the sensor portion in an expanded state.

[0045] The temperature sensing structure 602 includes an expandable braid 702 covered with an elastic sleeve 704 which incorporates a plurality of sensors such as 710 which communicate through wires to the proximal end of the device and data unit (not shown) located outside the patient. The elastic sleeve keeps the sensors uniformly dispersed around the circumference of the braid as it expands. It is also sealed at points 720 and 723 to keep blood from entering the space created by the expanding braid. This space will be filled with a gas, either air or some other specifically chosen gas such as CO_2, which will help insulate the sensor from blood temperature, allowing the sensor to yield a more accurate measurement of the artery wall temperature guide wire 706. Indeed, the temperature-sensing structure may be intentionally designed not to track over the guide wire, allowing it to be made with a smaller profile. In this design, the expandable braid portion is attached to a cable, or wire, on one end, and a tube 722 on its other end. The design may be further refined to incorporate a "fixed floppy-tip guide wire" extending from the tip of the control cable 730. This fixed guide wire would help the cardiologist navigate the temperature measuring portion of the catheter. As shown in Figure 6B, it may be more advantageous to utilize an inner tube 731 as opposed to the

control cable 730 to permit the use of a guidewire 707 central to the entire catheter assembly.

[0046] As will now be explained in detail, a unique and important advantage of this invention is that it allows the temperature of the vessel wall at a particular point to serve as its own temperature baseline reference. This is particularly advantageous, since it is now being understood that lesions exhibiting even slightly elevated temperatures may be representative of pathophysiology indicative of a potential adverse clinical event. According to this invention, however, by virtue of an independently controllable temperature sensing structure and occlusion feature, the temperature of a target point on a vessel wall may first be measured with blood at least partially flowing then, with the temperature sensing structure continuing to be in an expanded position, blood flow may be partially or fully occluded with the occlusion feature to obtain a more accurate reading of ΔT, defined as $\Delta T = T_{occluded} - T_{flowing}$.

[0047] This procedure is illustrated in the diagrams of Figure 7. In Figure 7A, a guide wire is inserted into an artery past an area containing plaque. In Figure 7B, a structure of the type shown in Figure 6 is journaled onto the guide wire, with the temperature sensing structure positioned relative to the plaque deposit. Note that in this embodiment and others, at least one radiopaque marker is provided on or in the expandable temperature-sensing structure, preferably in a central location to aid with fluoroscopic positioning.

[0048] In Figure 7C, the temperature-sensing structure is expanded by pulling back on the central control. As shown in Figure 7D, although the expandable temperature-sensing structure may include an elastic covering effective in occluding blood flow by itself, preferably at least a slight amount of blood is permitted to flow past the temperature-sensing elements in the expanded condition. This may either be carried out with an expandable basket or braid structure without an elastic covering, or with an elastic covering designed so as to not fully occlude the vessel, at least in the areas proximate to the sensors themselves. This is shown in Figures 7D and 7E, with the latter being in cross-section.

[0049] In Figure 7F, with the temperature-sensing structure still expanded and having taken a temperature reading in a non-occluded or semi-occluded state, the occlusion feature is now expanded to fully occlude blood flow. With this arrangement, a second temperature reading is taken, enabling ΔT to be calculated as the difference between the occluded and non-occluded states.

[0050] Figure 7G is a drawing that shows a collapsed occlusion balloon, and blood now flowing around the sensing basket or braid structure, along with a plotting ΔT versus time. Figure 7H shows the sensing structure collapsed, and Figure 7I shows the sensing structure further collapsed for movement or repositioning.

[0051] Having taken both readings, the occluding feature is now collapsed, establishing at least low level of blood flow, after which the temperature-sensing structure is collapsed, enabling the assembly to be removed from the body or repositioned to a different location. It will be appreciated that the procedure just described may be carried out with any of the blood-occluding embodiments disclosed herein, whether the sensors and occluding balloon are fixed at a predetermined distance or movable to one another.

[0052] Figure 8 illustrates an alternative embodiment of the invention, wherein the occluding feature 802 is located distally with respect to the temperature-sensing structure 810 having sensors 812. In this case, three elongated cannula are used, including a central tube 804 to inflate and deflate the balloon 802, the tube 820 sealed distally to the temperature-sensing structure 810 and tube 830 sealed to the proximal end of the temperature-sensing structure 810. Through the use of concentric tube 820 and 830 configured concentrically with one in the other, the temperature-sensing structure 810 may be expanded by pulling on tube 820 with 830 fixed; pushing on tube 830 with 820 fixed; or simultaneously pulling on tube 820 with pushing on tube 830. The temperature-sensing structure 810 may be collapsed by pushing on tube 820 with 830 fixed; pulling on tube 830 with 820 fixed, or simultaneously pushing 820 while pulling on tube 830. As shown in Figure 8B, tube 804 may be extended to the distal end of the device as 804', facilitating the use of a central guidewire 806. Tube 804' would need to be a multi-lumen tube to provide a path for inflating/deflating balloon 805.

Claims

1. Apparatus for sensing the temperature of the inner wall of a blood vessel, comprising:

an elongated catheter having a distal end with a temperature sensing structure and a proximal end including a manually operated expansion control;

the temperature sensing structure including a plurality of presentation elements in the form of a basket or braided structure (702) having at least one temperature sensor (710) supported thereon, each sensor being operative to generate an electrical signal indicative of temperature;

the presentation elements being physically coupled to the manually operated expansion control such that operation of the control causes the basket or braided structure to move between a collapsed state, enabling the temperature sensing structure to be positioned in a section of the vessel to be measured, and an expanded state, wherein the at least one temperature sensor is in contact with, or immediately proximate to, the vessel wall;

a component to occlude blood flow (604) while the basket or braided structure is expanded to

perform a temperature reading; and
further including an elastic sleeve (704) covering the expandable basket or braid structure.

2. The apparatus of claim 1, wherein the component to occlude blood flow (604) is an inflatable balloon disposed near the expandable basket or braid structure.

3. The apparatus of claim 1, wherein each temperature sensor is a thermistor.

4. The apparatus of claim 1, further including at least one thermal sensor to measure a non-wall temperature.

5. The apparatus of claim 1, further including a data unit operative to receive signals from each temperature sensor and display information indicative of the sensed vessel wall temperature.

6. The apparatus of claim 5, wherein each temperature sensor is hardwired to the data unit.

7. The apparatus of claim 5, wherein each temperature sensor is multiplexed to the data unit.

8. The apparatus of claim 1, wherein the catheter is disposable.

9. The apparatus of claim 1, wherein the component to occlude blood flow (604) includes an inflatable balloon surrounding the end of a tube through which a temperature-sensing tip extends.

10. The apparatus of claim 9, further including a primary guide wire (706) onto which the tube may be journaled.

11. A catheter assembly for sensing the temperature of a blood vessel wall, comprising:

an outer tube (202) having a proximal end intended to remain outside a patient and a distal end terminating in an inflatable balloon (604) to occlude blood flow;
an inner tube (204) disposed co-extensively within the outer tube, the inner tube extending to a distal tip beyond the distal end of the outer tube;
an expandable basket or braid structure (702) having a first end attached to the distal tip of the inner tube and a second end attached to a central elongate member slidingly disposed within the inner tube to an expansion control at the proximal end;
the expandable basket or braid structure including one or more temperature sensors (710) supported thereon, each sensor being operative to generate an electrical signal indicative of temperature, such that operation of the control causes the structure to move between a collapsed state, enabling at least one of the sensors to be positioned in a section of the vessel to be measured, and an expanded state, wherein at least one of the sensors is in contact with, or immediately proximate to, the vessel wall before and after blood flow is occluded; and
further including an elastic sleeve (704) covering the expandable basket or braid structure.

12. The catheter assembly of claim 11, wherein each temperature sensor is a thermistor.

13. The catheter assembly of claim 11, further including at least one sensor for measuring a non-wall temperature.

14. The catheter assembly of claim 11, further including a data unit operative to receive signals from each temperature sensor and display information indicative of vessel wall temperature.

15. The catheter assembly of claim 14, wherein each temperature sensor is individually hardwired to the data unit.

16. The catheter assembly of claim 14, wherein each temperature sensor is multiplexed to the data unit.

17. The catheter assembly of claim 11, wherein the catheter is disposable.

18. The catheter assembly of claim 11, wherein the central elongate member is an expansion control wire.

19. The catheter assembly of claim 11, wherein the central elongate member is a tube to receive a guidewire (706).

Patentansprüche

1. Vorrichtung zum Erfassen der Temperatur einer Innenwand eines Blutgefäßes, umfassend:

einen länglichen Katheter, der ein distales Ende mit einer Anordnung zur Temperaturerfassung und ein proximales Ende mit einer manuell zu bedienenden Expansionssteuerung hat;
wobei die Anordnung zur Temperaturerfassung eine Mehrzahl von Präsentationselementen in der Form einer Korb- oder geflochtenen Struktur (702) beinhaltet, auf denen zumindest ein Temperatursensor (710) angebracht ist, wobei jeder Sensor funktionsfähig ist, ein der Temperatur entsprechendes elektrisches Signal zu erzeu-

gen;
wobei die Präsentationselemente physisch an die manuell zu bedienende Expansionssteuerung gekoppelt sind, sodass die Betätigung der Steuerung dazu führt, dass sich die Korb- oder geflochtene Struktur zwischen einem zusammengeklappten Zustand, der das Positionieren der Anordnung zur Temperaturerfassung in einem Abschnitt des zu messenden Gefäßes ermöglicht, und einem expandierten Zustand,in dem der zumindest eine Temperatursensor in Kontakt mit der oder in unmittelbarer Nähe zur Gefäßwand ist, bewegt;
eine Komponente zum Unterbrechen des Blutflusses (604), während die Korb- oder geflochtene Struktur expandiert ist, um eine Temperaturmessung durchzuführen; und
des Weiteren eine elastischen Hülle (704) beinhaltend, welche die expandierbare Korb- oder geflochtene Struktur umschließt.

2. Vorrichtung nach Anspruch 1, wobei die Komponente zum Unterbrechen des Blutflusses (604) ein aufblasbarer Ballon ist, der nahe der expandierbaren Korb- oder geflochtenen Struktur positioniert ist.

3. Vorrichtung nach Anspruch 1, wobei jeder Temperatursensor ein Thermistor ist.

4. Vorrichtung nach Anspruch 1, die des Weiteren zumindest einen thermischen Sensor zum Messen einer Temperatur nicht an einer Gefäßwand enthält.

5. Vorrichtung nach Anspruch 1, die des Weiteren eine Dateneinheit enthält, die betätigbar ist, um Signale von jedem Temperatursensor zu erhalten und Informationen, welche die erkannte Temperatur der Gefäßwand anzeigen, darzustellen.

6. Vorrichtung nach Anspruch 5, wobei jeder Temperatursensor mit der Dateneinheit fest verdrahtet ist.

7. Vorrichtung nach Anspruch 5, wobei jeder Temperatursensor zur Dateneinheit gemultiplext ist.

8. Vorrichtung nach Anspruch 1, wobei der Katheter wegwerfbar ist.

9. Vorrichtung nach Anspruch 1, wobei die Komponente zum Unterbrechen des Blutflusses (604) einen aufblasbaren Ballon enthält, der das Ende eines Schlauchs umgibt, durch den sich eine Spitze zum Erfassen der Temperatur erstreckt.

10. Vorrichtung nach Anspruch 9, des Weiteren umfassend einen primären Führungsdraht (706), auf dem der Schlauch gelagert werden kann.

11. Katheteranordnung für das Erfassen der Temperatur einer Wand eines Blutgefäßes, umfassend:

einen äußeren Schlauch (202), der ein proximales Ende, das außerhalb eines Patienten bleiben soll, und ein distales Ende aufweist, das in einem aufblasbaren Ballon (604) zum Unterbrechen des Blutflusses endet;
einen inneren Schlauch (204), der koextensiv im äußeren Schlauch positioniert ist, wobei sich der innere Schlauch zu einer distalen Spitze jenseits des distalen Endes des äußeren Schlauchs erstreckt;
eine expandierbare Korb- oder geflochtene Struktur (702), deren erstes Ende an der distalen Spitze des inneren Schlauches befestigt ist und deren zweites Ende an einem zentralen länglichen Bauteil angebracht ist, der gleitend im inneren Schlauch an einer Expansionssteuerung am proximalen Ende positioniert ist;
wobei die expandierbare Korb- oder geflochtene Struktur einen oder mehrere Temperatursensoren (710), die darauf angebracht sind, beinhaltet, wobei jeder Sensor betätigbar ist, ein elektrisches Signal, das die Temperatur anzeigt, zu erzeugen, sodass die Betätigung der Steuerung dazu führt, dass sich die Struktur zwischen einem zusammengeklappten Zustand, der das Positionieren von zumindest einem der Sensoren in einem Abschnitt des zu messenden Gefäßes ermöglicht, und einem expandierten Zustand bewegt, wobei der zumindest eine Sensor in Kontakt mit der oder in unmittelbarer Nähe zur Gefäßwand ist, vor und nach dem Unterbrechen des Blutflusses; und
des Weiteren eine elastische Hülle (704) beinhaltend, welche die expandierbare Korb- oder geflochtene Struktur umschließt.

12. Katheteranordnung nach Anspruch 11, wobei jeder Temperatursensor ein Thermistor ist.

13. Katheteranordnung nach Anspruch 11, die des Weiteren zumindest einen Sensor zum Messen einer Temperatur nicht an einer Gefäßwand enthält.

14. Katheteranordnung nach Anspruch 11, die des Weiteren eine Dateneinheit enthält, die betätigbar ist, um Signale von jedem Temperatursensor zu erhalten und Informationen, welche die Temperatur der Gefäßwand anzeigen, darzustellen.

15. Katheteranordnung nach Anspruch 14, wobei jeder Temperatursensor einzeln mit der Dateneinheit fest verdrahtet ist.

16. Katheteranordnung nach Anspruch 14, wobei jeder Temperatursensor zur Dateneinheit gemultiplext ist.

17. Katheteranordnung nach Anspruch 11, wobei der Katheter wegwerfbar ist.

18. Katheteranordnung nach Anspruch 11, wobei der zentrale längliche Bauteil ein Draht der Expansionssteuerung ist.

19. Katheteranordnung nach Anspruch 11, wobei der zentrale längliche Bauteil ein Schlauch zum Aufnehmen eines Führungsdrahtes (706) ist.

Revendications

1. Appareil pour détecter la température de la paroi interne d'un vaisseau sanguin, comprenant :

un cathéter de forme allongée ayant une extrémité distale dotée d'une structure de détection de la température et une extrémité proximale qui comprend une commande d'expansion à actionnement manuel ;
la structure de détection de la température comprenant une pluralité d'éléments de présentation sous forme de panier ou de structure tressée (702) portant au moins un capteur de température (710), chaque capteur fonctionnant de manière à générer un signal électrique indiquant la température ;
les éléments de présentation étant physiquement raccordés à la commande d'expansion à actionnement manuel, de sorte que le fonctionnement de la commande amène le panier ou la structure tressée à passer d'un état replié, permettant à la structure de détection de la température de se positionner dans une section du vaisseau dont on souhaite prendre la mesure, et un état dilaté, dans lequel le au moins un capteur de température est en contact avec la paroi du vaisseau, ou à proximité immédiate de cette dernière ;
un composant pour bloquer le flux sanguin (604) alors que le panier ou la structure tressée est dilaté afin de réaliser une lecture de la température ; et
comprenant en outre un manchon élastique (704) recouvrant le panier ou la structure tressée expansible.

2. Appareil de la revendication 1, dans lequel le composant destiné à bloquer le flux sanguin (604) est un ballon gonflable disposé à proximité du panier ou de la structure tressée expansible.

3. Appareil de la revendication 1, dans lequel chaque capteur de température est une thermistance.

4. Appareil de la revendication 1, comprenant en outre au moins un capteur thermique destiné à mesurer une température autre que celle de la paroi.

5. Appareil de la revendication 1, comprenant en outre une unité de données destinée à recevoir les signaux provenant de chacun des capteurs de température et à afficher les informations qui indiquent la température de la paroi vasculaire.

6. Appareil de la revendication 5, dans lequel chaque capteur de température est raccordé par câble à l'unité de données.

7. Appareil de la revendication 5, dans lequel chaque capteur de température est multiplexé à l'unité de données.

8. Appareil de la revendication 1, dans lequel le cathéter est à usage unique.

9. Appareil de la revendication 1, dans lequel le composant destiné à bloquer le flux sanguin (604) comprend un ballon gonflable entourant l'extrémité d'un tube au travers duquel s'étend une tête de détection de la température.

10. Appareil de la revendication 9, comprenant en outre un fil guide principal (706) sur lequel le tube peut être tourillonné.

11. Ensemble Cathéter pour détecter la température de la paroi d'un vaisseau sanguin, comprenant :

un tube externe (202) ayant une extrémité proximale destinée à demeurer à l'extérieur d'un patient et une extrémité distale se terminant en un ballon gonflable (604) destiné à bloquer le flux sanguin ;
un tube interne (204) disposé en co-extension à l'intérieur du tube externe, le tube interne s'étendant jusqu'à une tête distale au-delà de l'extrémité distale du tube externe ;
un panier ou structure tressée expansible (702) ayant une première extrémité fixée à la tête distale du tube interne et une seconde extrémité fixée à un élément central de forme allongée disposé de manière à coulisser dans le tube interne jusqu'à une commande d'expansion au niveau de l'extrémité proximale ;
le panier ou structure tressée expansible comprenant un ou plusieurs capteurs de température (710) supportés sur ce dernier, chaque capteur fonctionnant de manière à générer un signal électrique indiquant la température, de sorte que le fonctionnement de la commande amène la structure à passer d'un état replié, permettant à au moins un des capteurs de se positionner dans une section du vaisseau dont on souhaite

prendre la mesure, et un état dilaté, dans lequel au moins un des capteurs est en contact avec la paroi du vaisseau, ou à proximité immédiate de cette dernière, avant et après le blocage du flux sanguin ; et
comprenant en outre un manchon élastique (704) recouvrant le panier ou la structure tressée expansible.

12. Ensemble cathéter de la revendication 11, dans lequel chaque capteur de température est une thermistance.

13. Ensemble cathéter de la revendication 11, comprenant en outre au moins un capteur destiné à mesurer une température autre que celle de la paroi.

14. Ensemble cathéter de la revendication 11, comprenant en outre une unité de données destinée à recevoir les signaux provenant de chacun des capteurs de température et à afficher les informations qui indiquent la température de la paroi vasculaire.

15. Ensemble cathéter de la revendication 14, dans lequel chaque capteur de température est individuellement raccordé par câble à l'unité de données.

16. Ensemble cathéter de la revendication 14, dans lequel chaque capteur de température est multiplexé à l'unité de données.

17. Ensemble cathéter de la revendication 11, dans lequel le cathéter est à usage unique.

18. Ensemble cathéter de la revendication 11, dans lequel l'élément central de forme allongée est un câble de commande de l'expansion.

19. Ensemble cathéter de la revendication 11, dans lequel l'élément central de forme allongée est un tube destiné à recevoir un fil guide (706).

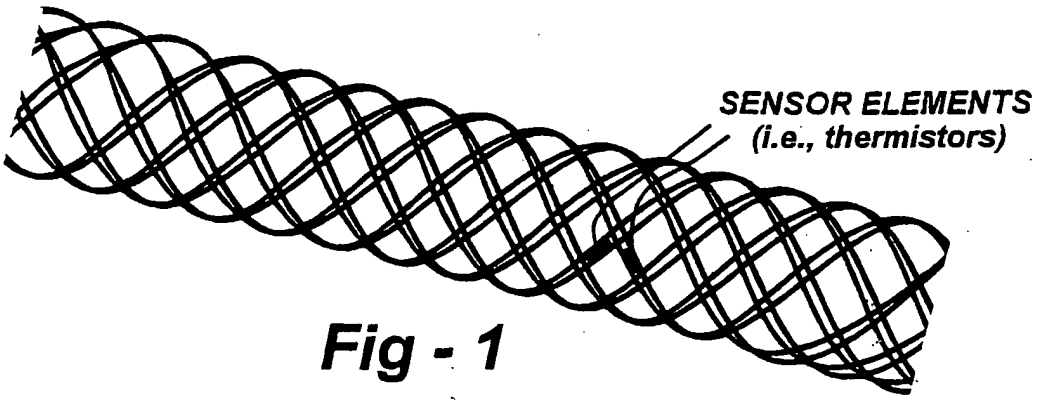

Fig - 1

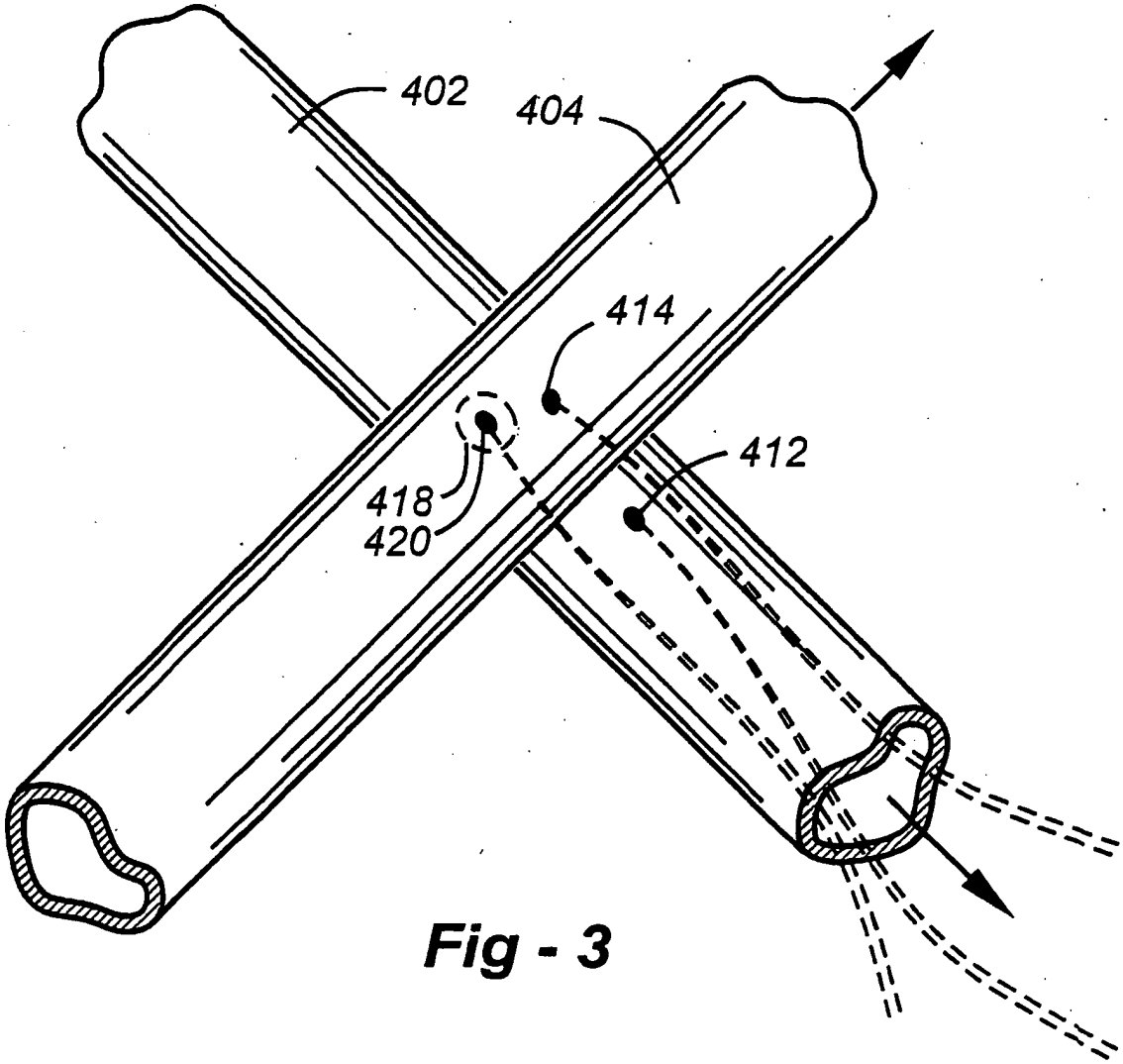

Fig - 3

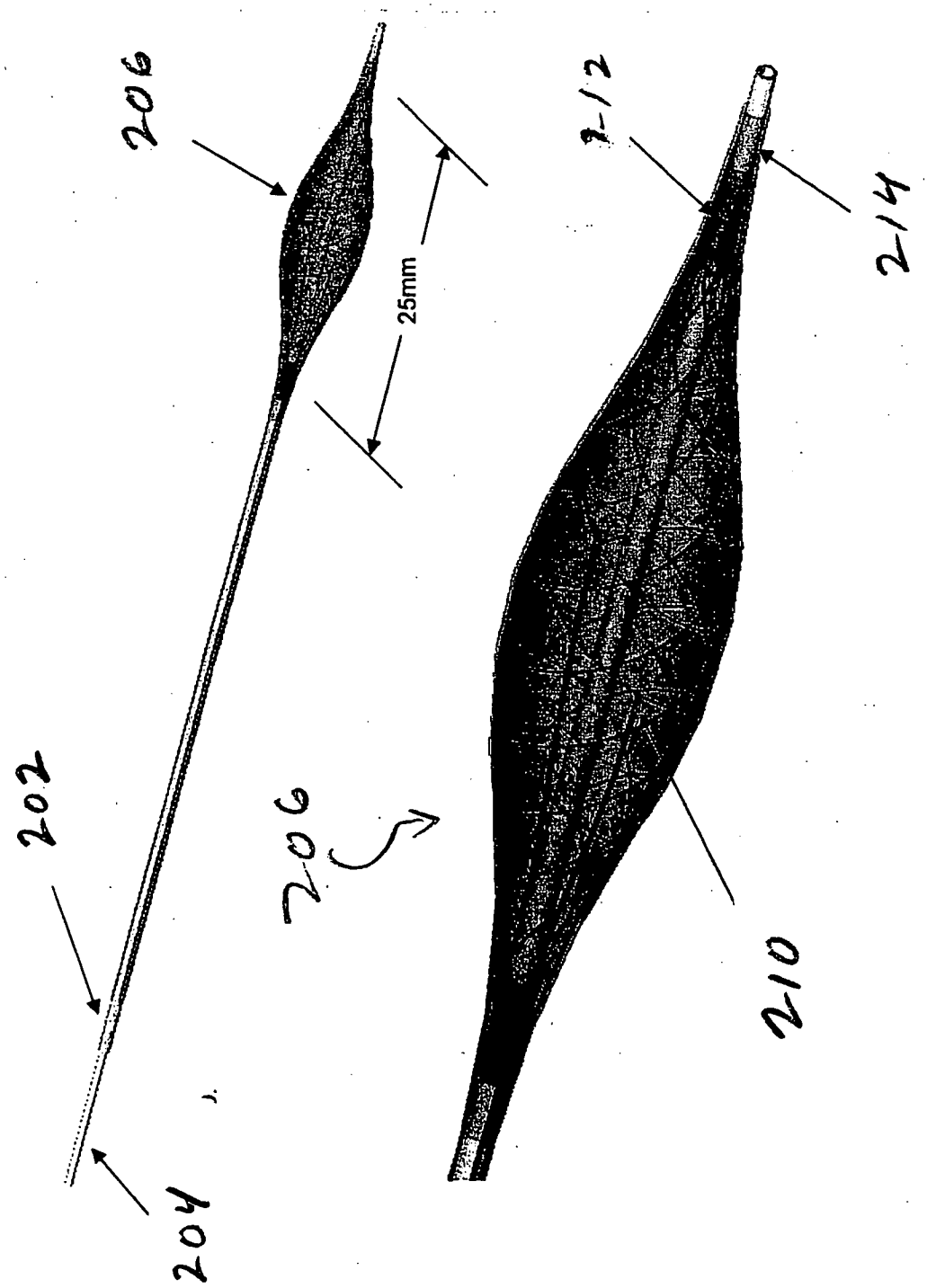

Fig. 2

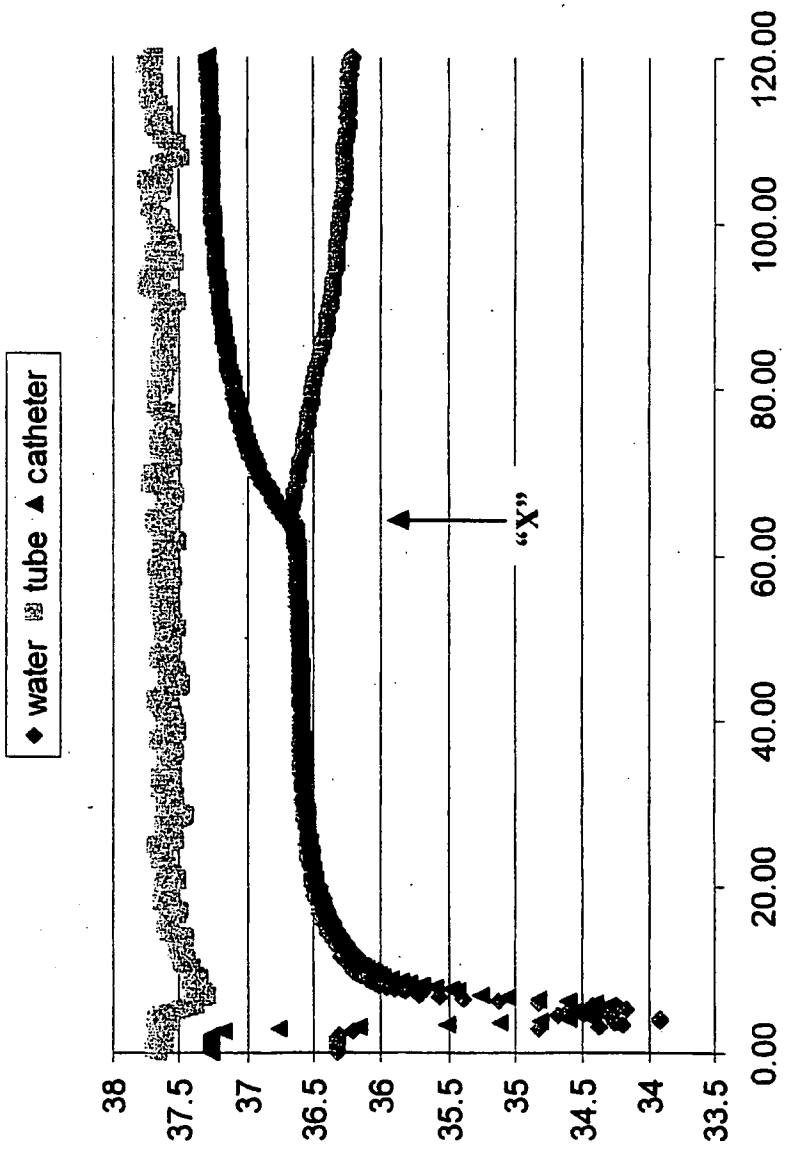
◆ water ▩ tube ▲ catheter
38
37.5
37
36.5
36
35.5
35
34.5
34
33.5
0.00
20.00
40.00
60.00
80.00
100.00
120.00
time (sec)
"X"

Fig. 4

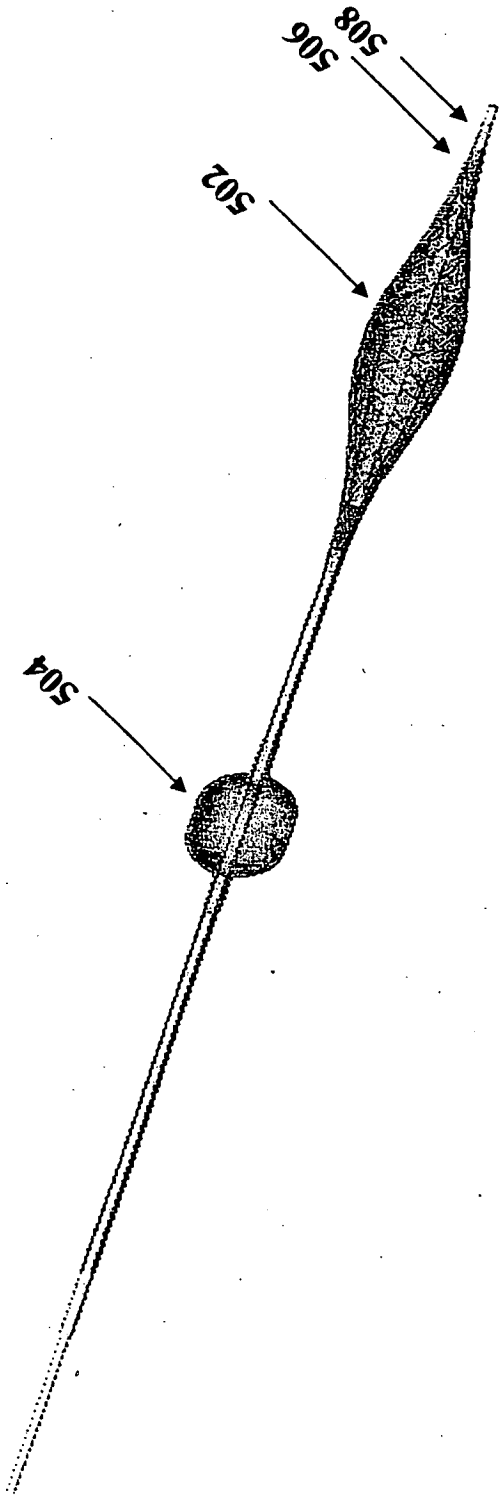

Fig. 5A

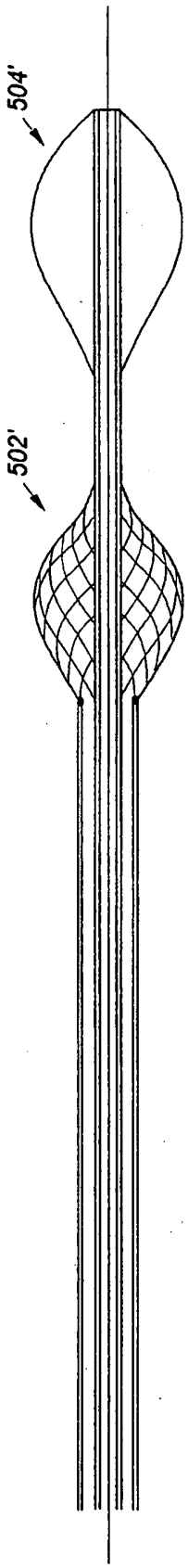

Fig - 5B

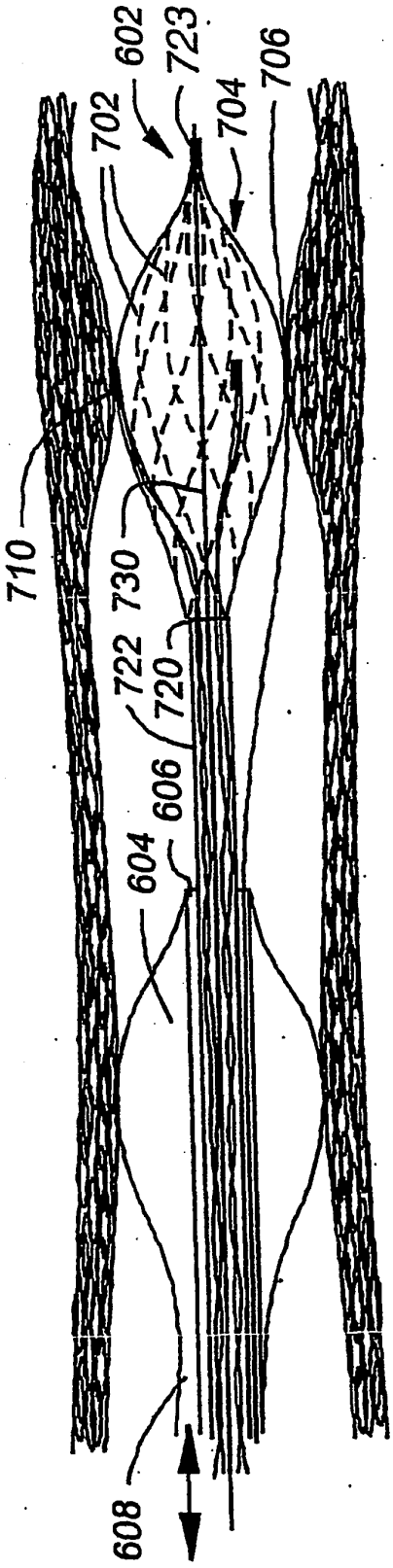

Fig - 6A

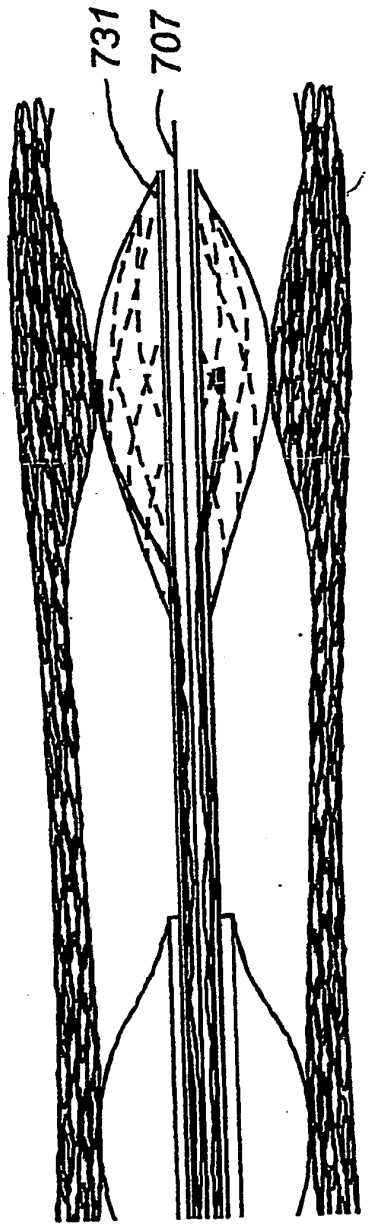

Fig - 6B

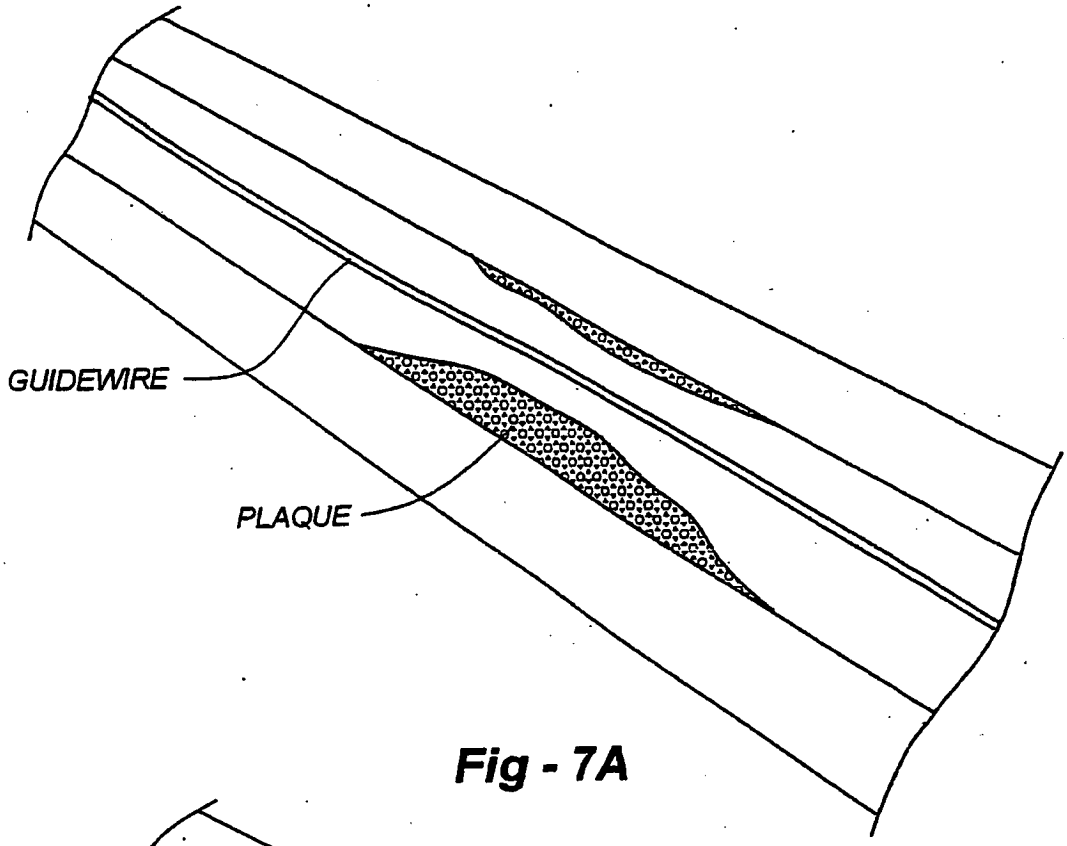

Fig - 7A

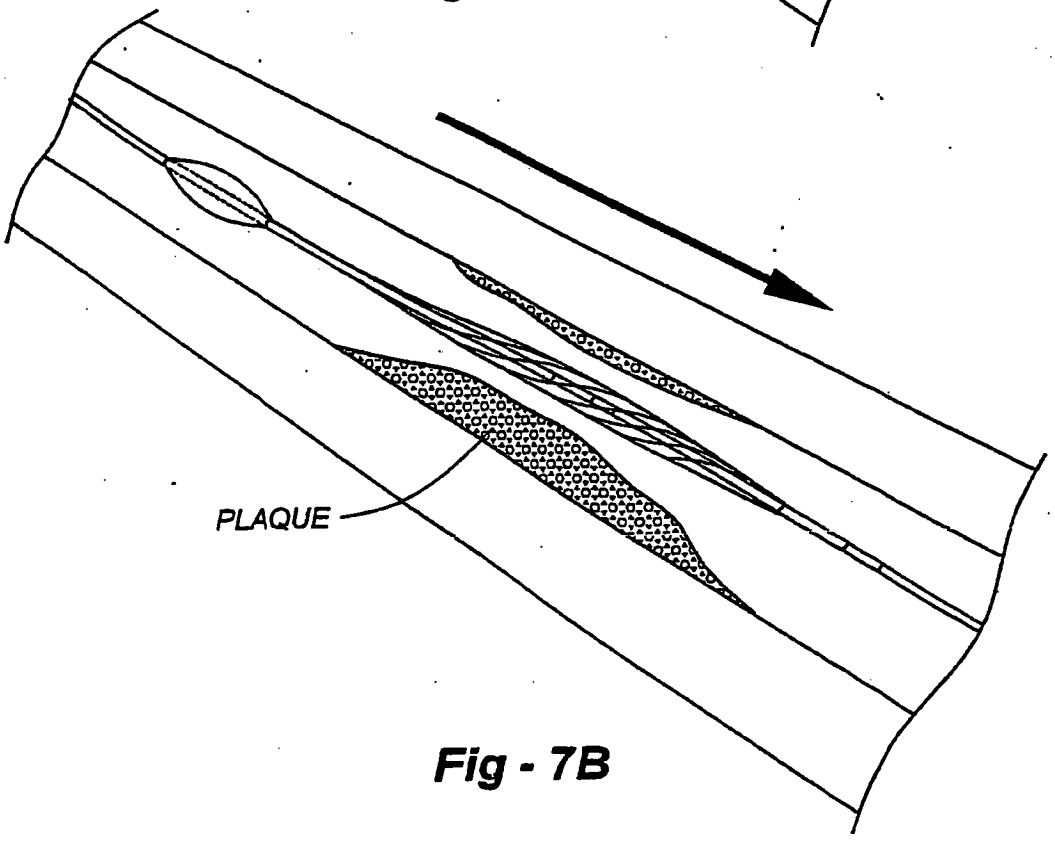

Fig - 7B

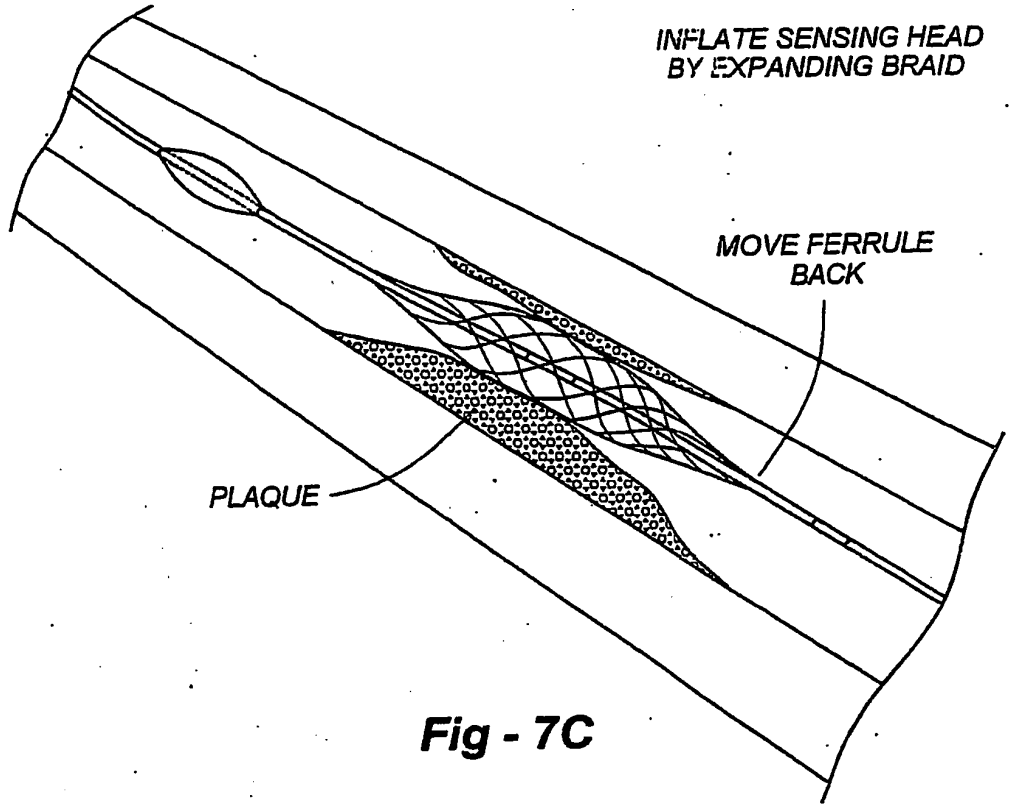
INFLATE SENSING HEAD
BY EXPANDING BRAID
MOVE FERRULE
BACK
PLAQUE

Fig - 7C

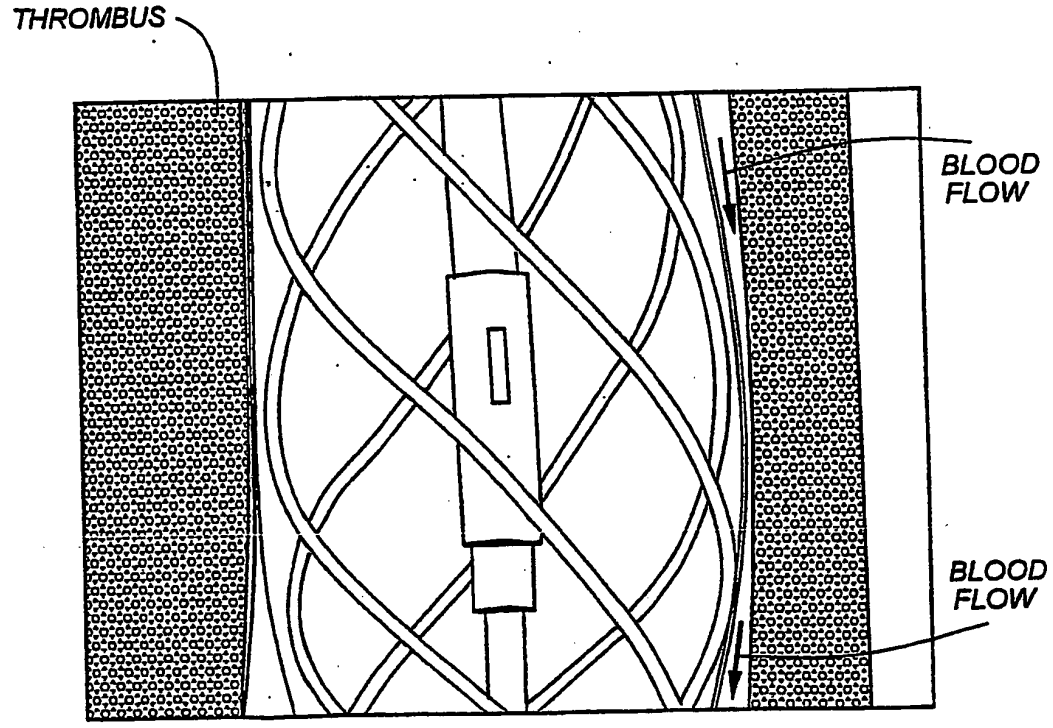
THROMBUS
BLOOD
FLOW
BLOOD
FLOW

Fig - 7D

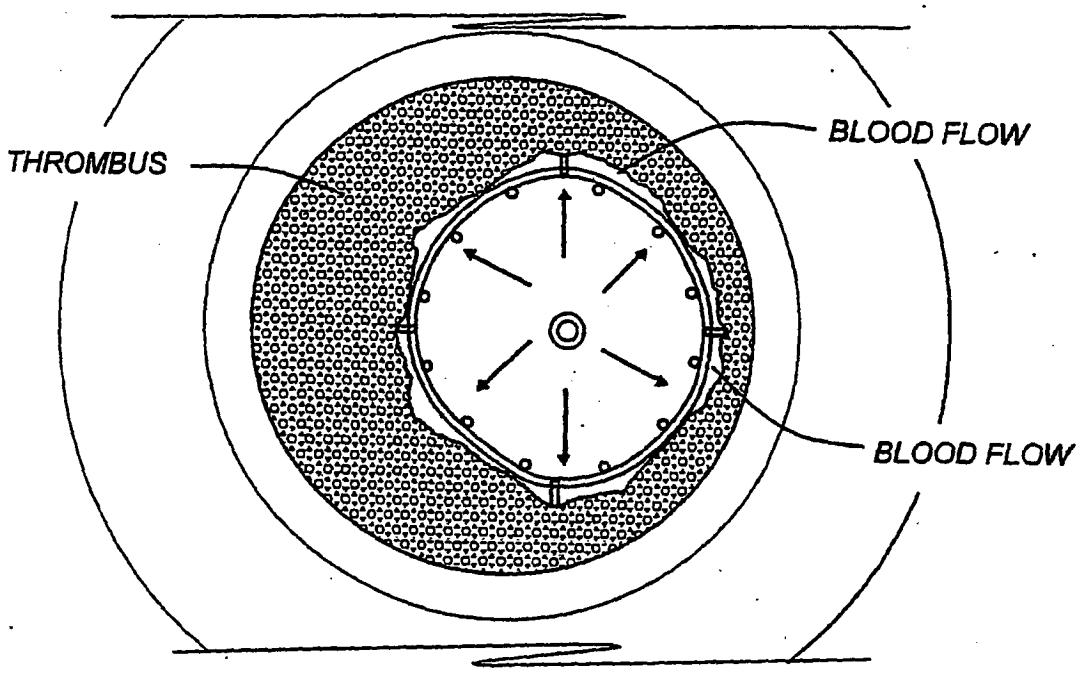
THROMBUS
BLOOD FLOW
BLOOD FLOW

Fig - 7E

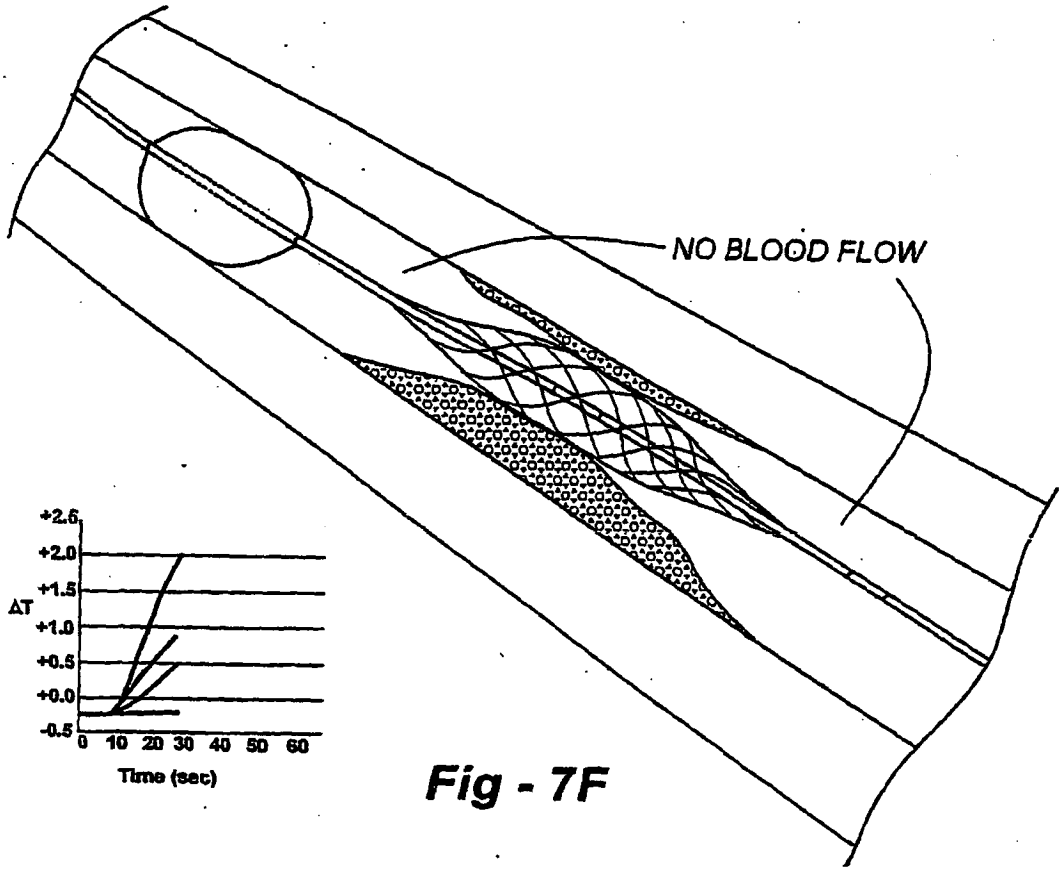
NO BLOOD FLOW
+2.5
+2.0
+1.5
+1.0
+0.5
+0.0
-0.5
ΔT
0 10 20 30 40 50 60
Time (sec)

Fig - 7F

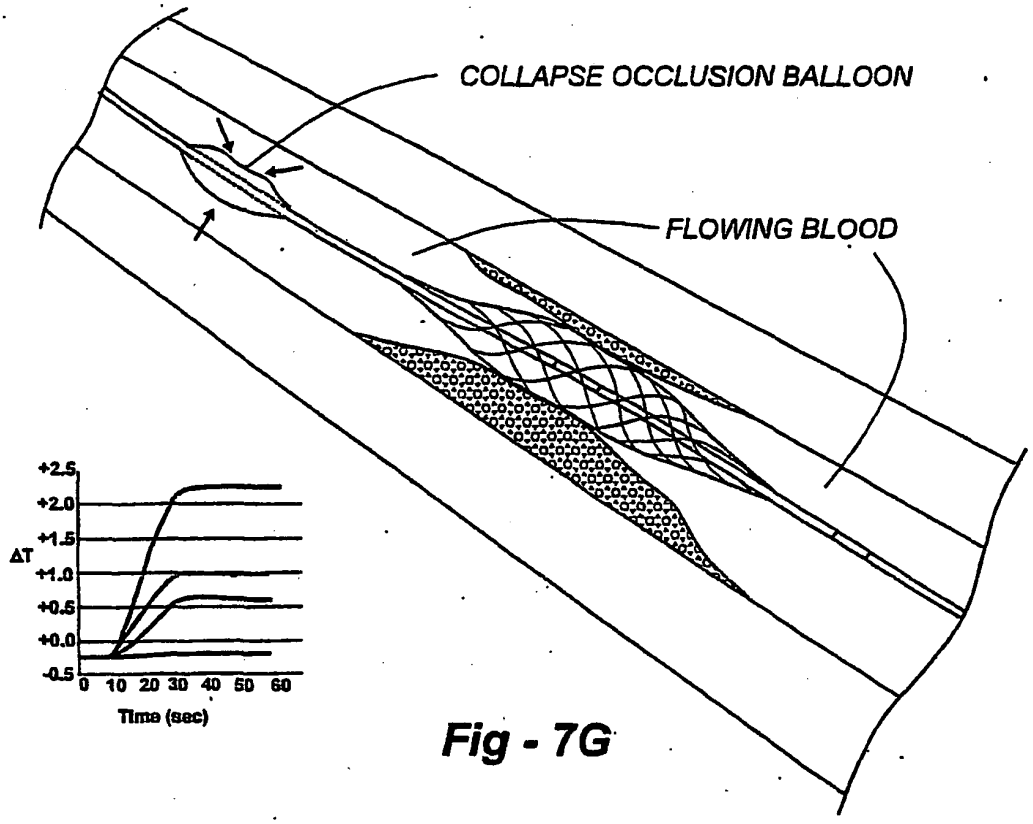
COLLAPSE OCCLUSION BALLOON
FLOWING BLOOD
+2.5
+2.0
+1.5
ΔT
+1.0
+0.5
+0.0
-0.5
0 10 20 30 40 50 60
Time (sec)

Fig - 7G

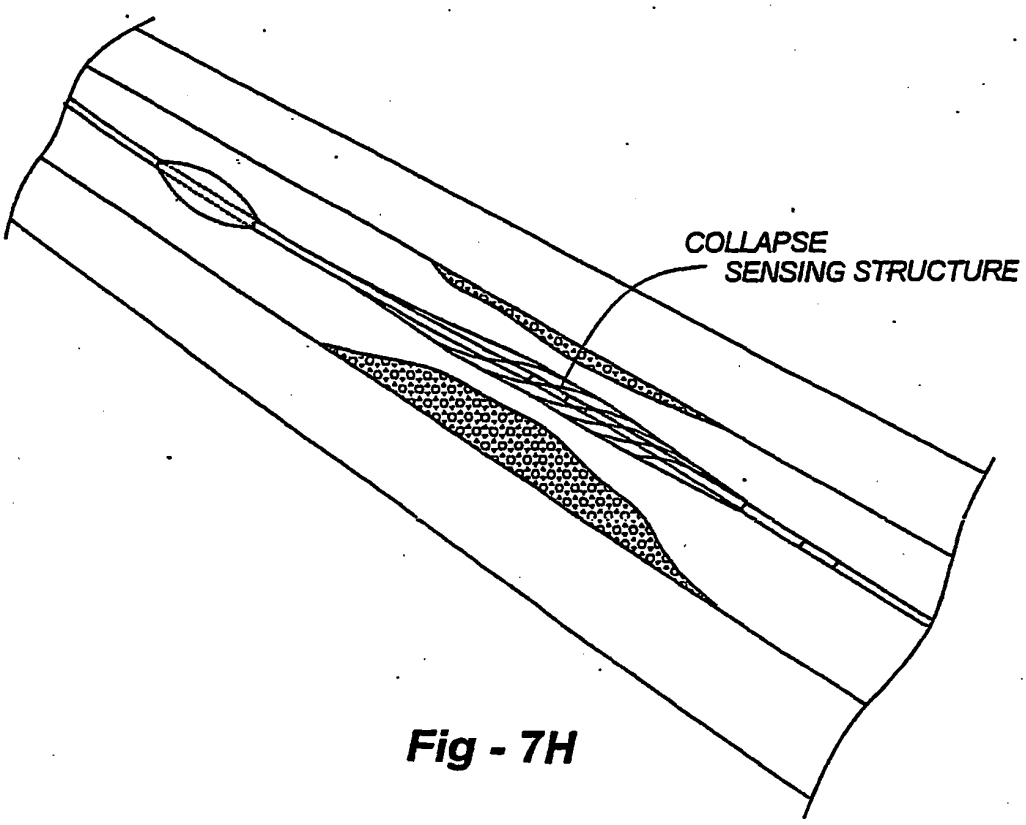
COLLAPSE
SENSING STRUCTURE

Fig - 7H

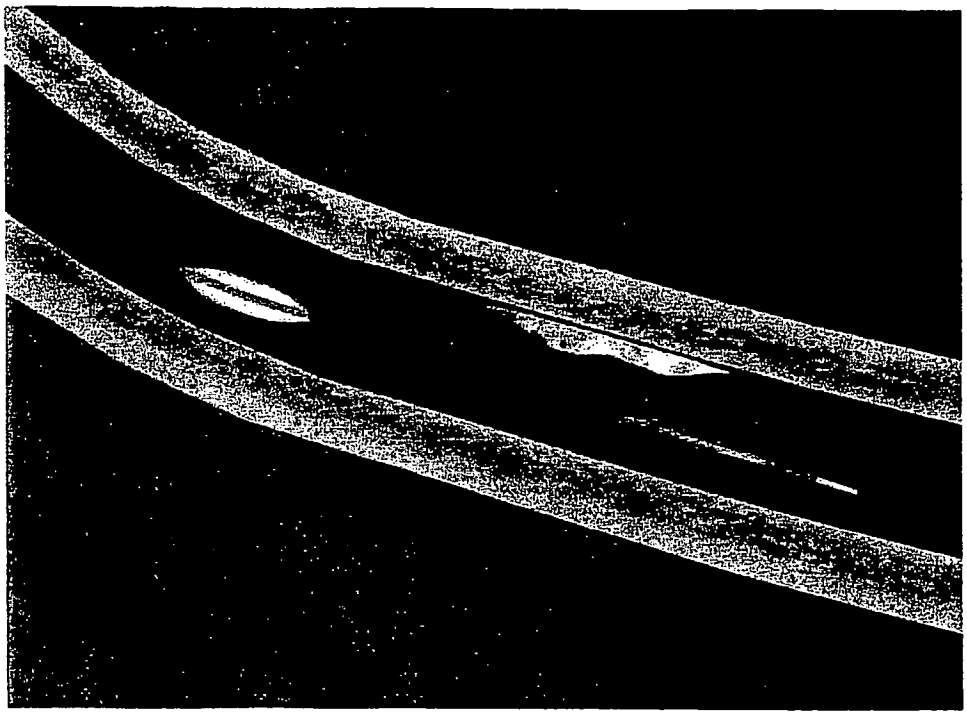

Fig – 7I

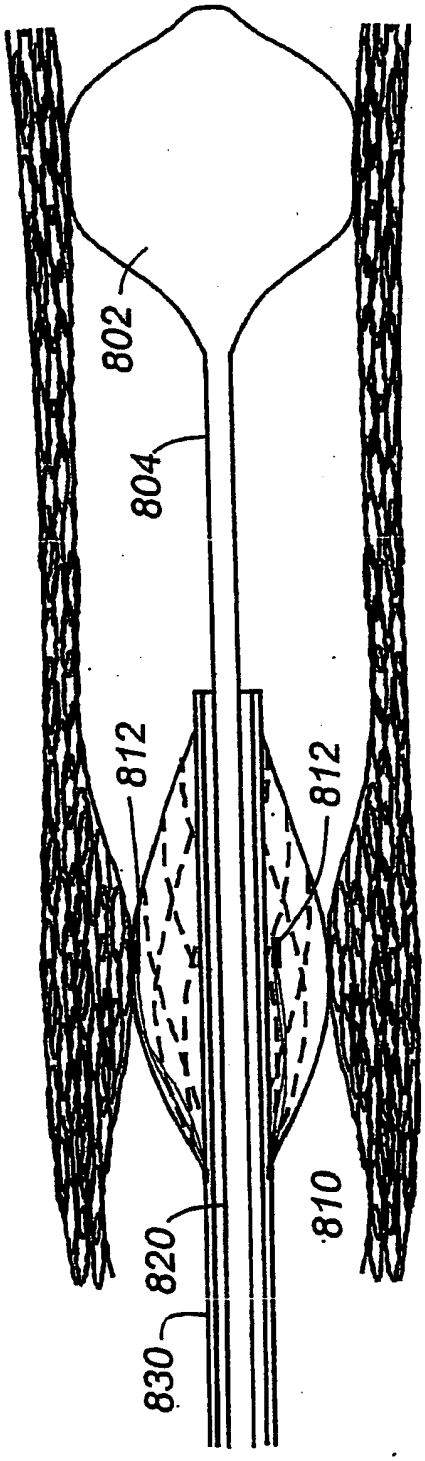

Fig - 8A

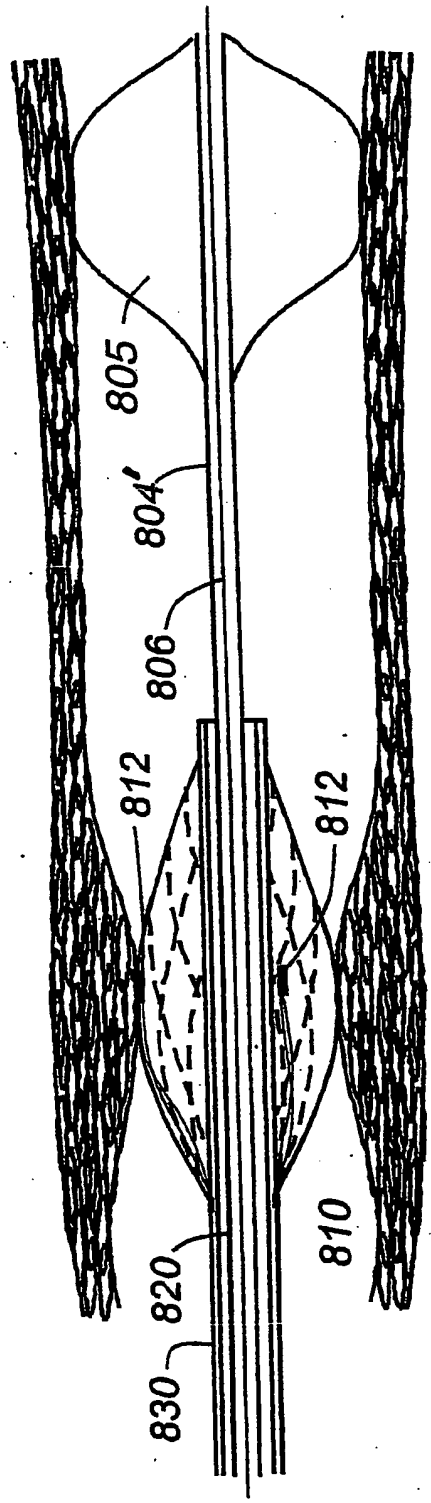

Fig - 8B

REFERENCES CITED IN THE DESCRIPTION

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- US 5924997 A **[0005]**
- US 5935075 A **[0005]**
- US 20030028114 A **[0016]**
- US 6712771 B **[0041]**

专利名称(译)	血流闭塞，温度感应导管和使用方法		
公开(公告)号	EP1608263A4	公开(公告)日	2008-03-12
申请号	EP2004749488	申请日	2004-03-29
[标]申请(专利权)人(译)	ACCUMED SYST		
申请(专利权)人(译)	ACCUMED系统		
当前申请(专利权)人(译)	ACCUMED系统		
[标]发明人	KOROTKO JOSEPH R		
发明人	KOROTKO, JOSEPH, R.		
IPC分类号	A61B5/00 A61B5/01 A61F		
CPC分类号	A61B5/01 A61B5/02007 A61B5/6853 A61B5/6858 A61B5/6859 A61B5/6885 A61B2562/0271 A61B2562/028 A61B2562/043		
代理机构(译)	谢谢你，迈克尔诺曼		
优先权	10/401927 2003-03-28 US 10/639347 2003-08-12 US		
其他公开文献	EP1608263B1 EP1608263B8 EP1608263A2		
外部链接	Espacenet		

摘要(译)

用于感测动脉壁或其他体腔温度的导管组件包括血流阻塞特征，以增加温度测量的准确性。 除了流动阻塞特征之外，导管还包括具有温度感测结构的远端和包括手动操作的膨胀控制器的近端。 温度感测结构包括篮或编织结构形式的一个或多个呈现元件，其上支撑有至少一个温度传感器，每个传感器可操作以产生指示温度的电信号。 在优选实施例中，阻塞血流的特征是设置在可扩张的篮或编织物结构附近的可充气的气球。 温度传感器优选地是热敏电阻，并且还优选地提供覆盖可膨胀的篮或编织物结构的弹性套筒，以使温度传感器与血流的冷却作用进一步隔离。

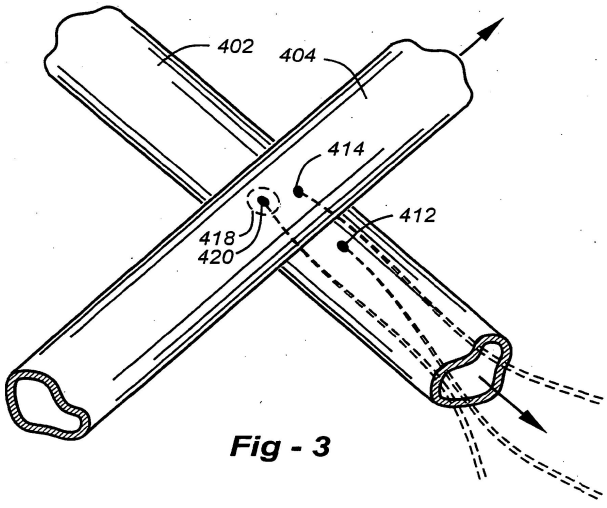

Fig - 3