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(54) **METHOD FOR SENSING TEMPERATURE PROFILE OF A HOLLOW BODY ORGAN**

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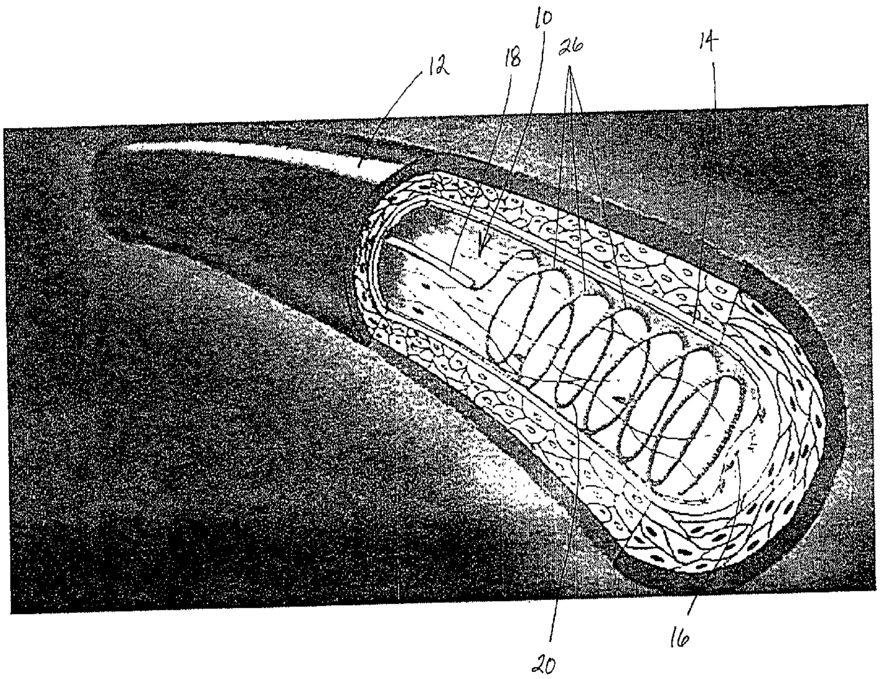
(57) **ABSTRACT**

A method for sensing the temperature profile of a hollow body organ utilizes a catheter and a hollow guidewire. The guidewire is configured as a plurality of helical loops of greater diameter than the catheter when unconstrained. When constrained within the catheter, the guidewire can be advanced to a region of interest in hollow body organ. The catheter can be withdrawn, leaving the guidewire in place in an expanded configuration wherein the helical loops contact the inner wall of the hollow body organ. A temperature sensor is moveable within the guidewire to sense the temperature at multiple locations.



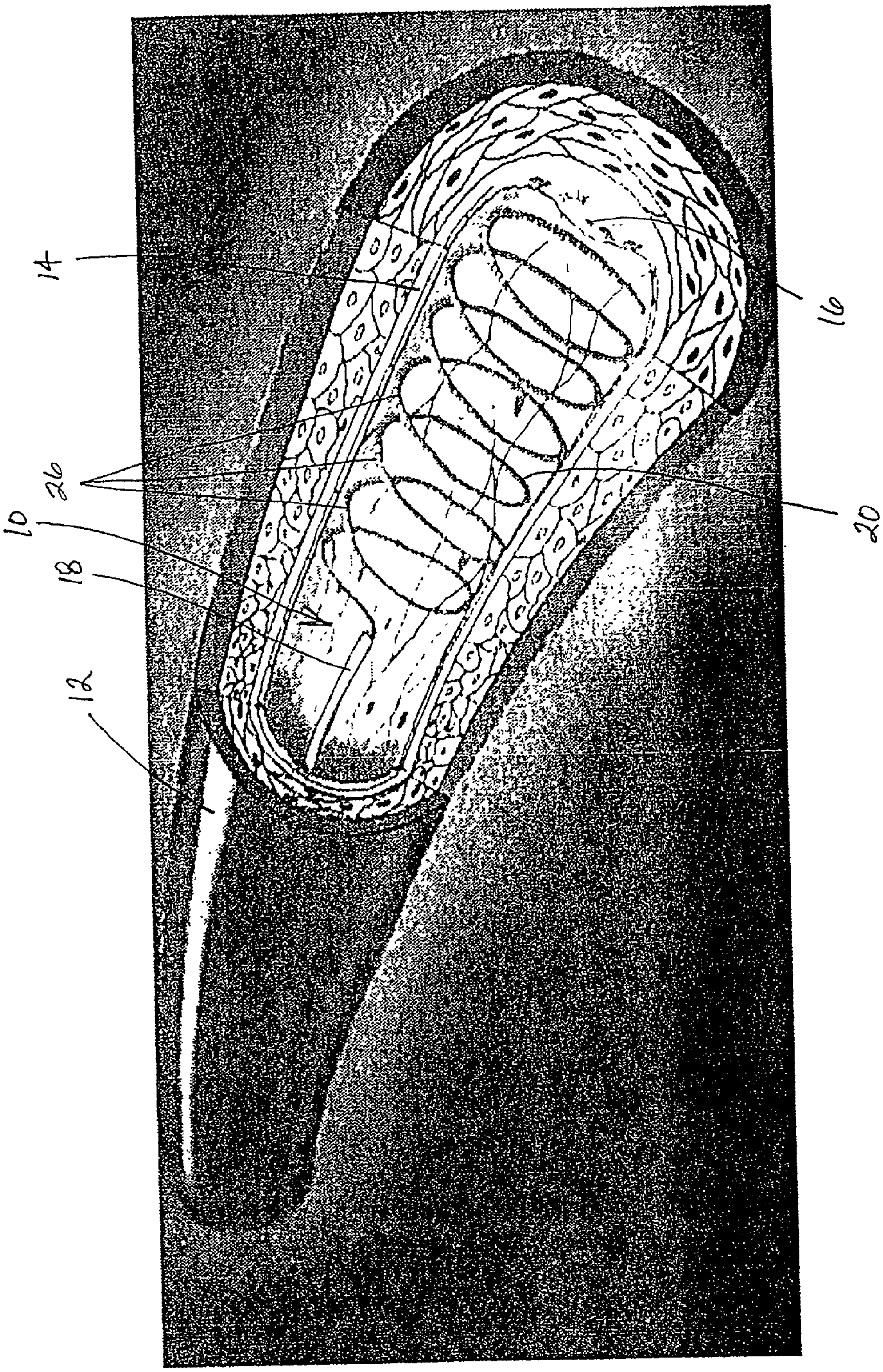


FIG. 1

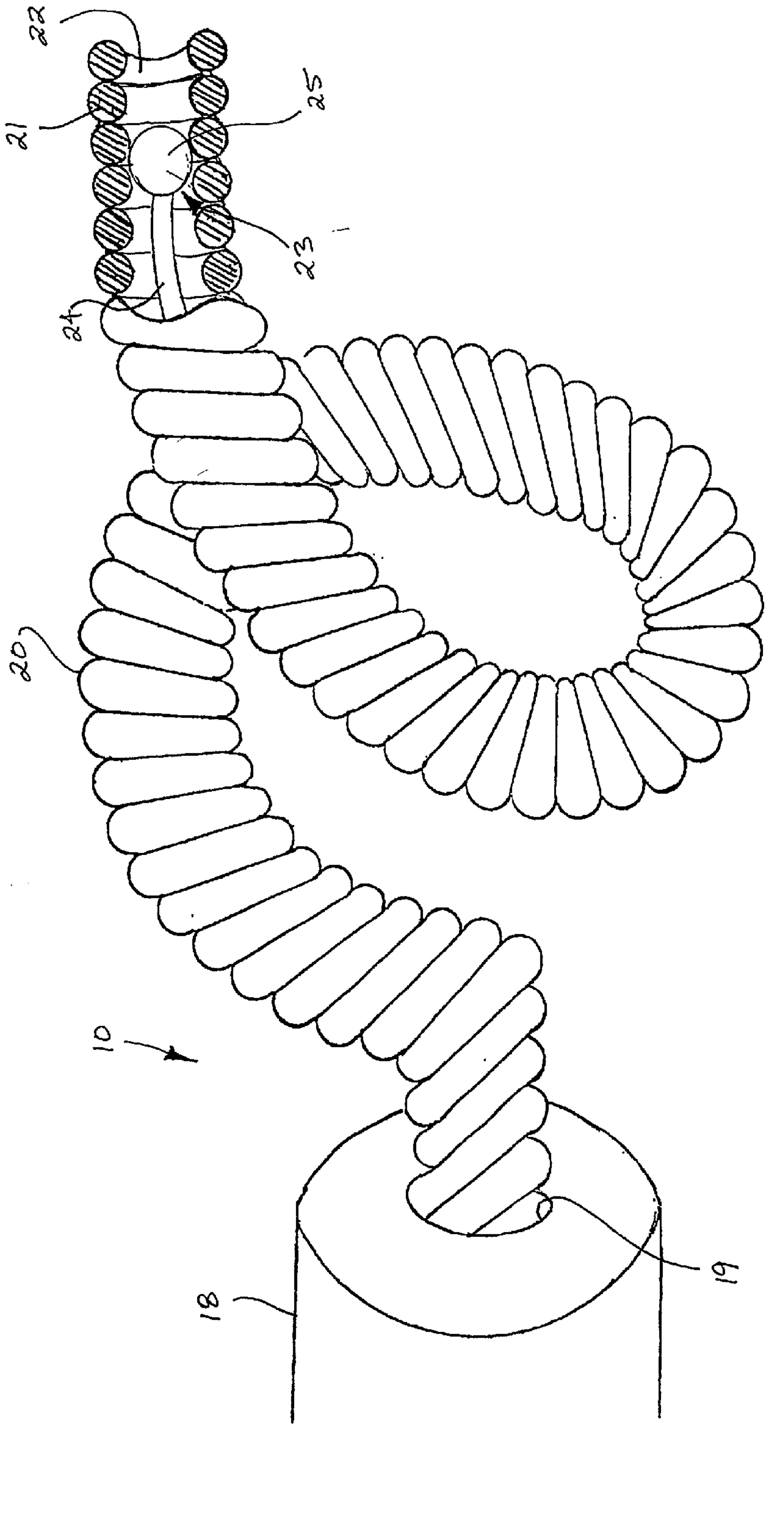


FIG. 2

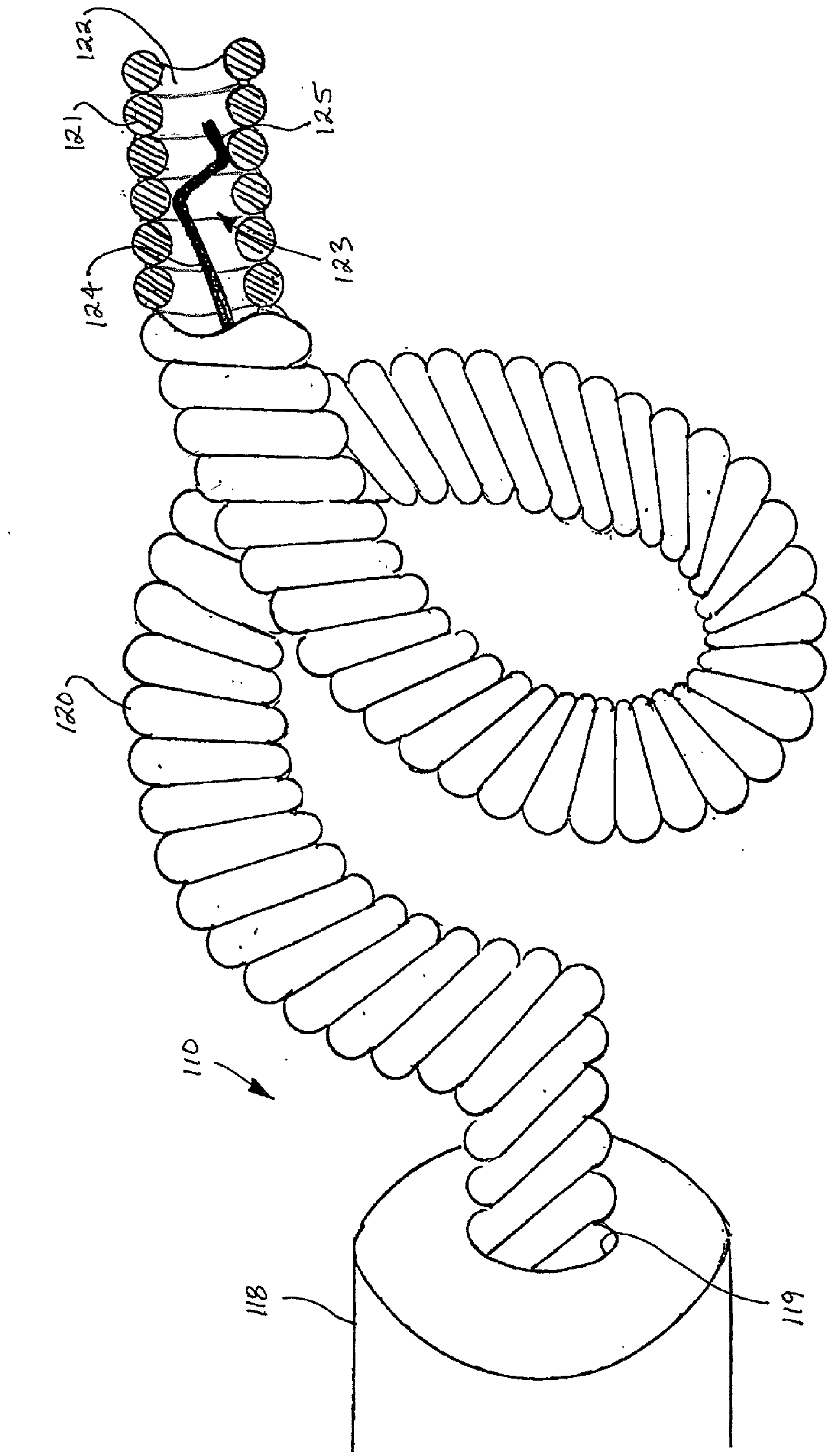


FIG. 3

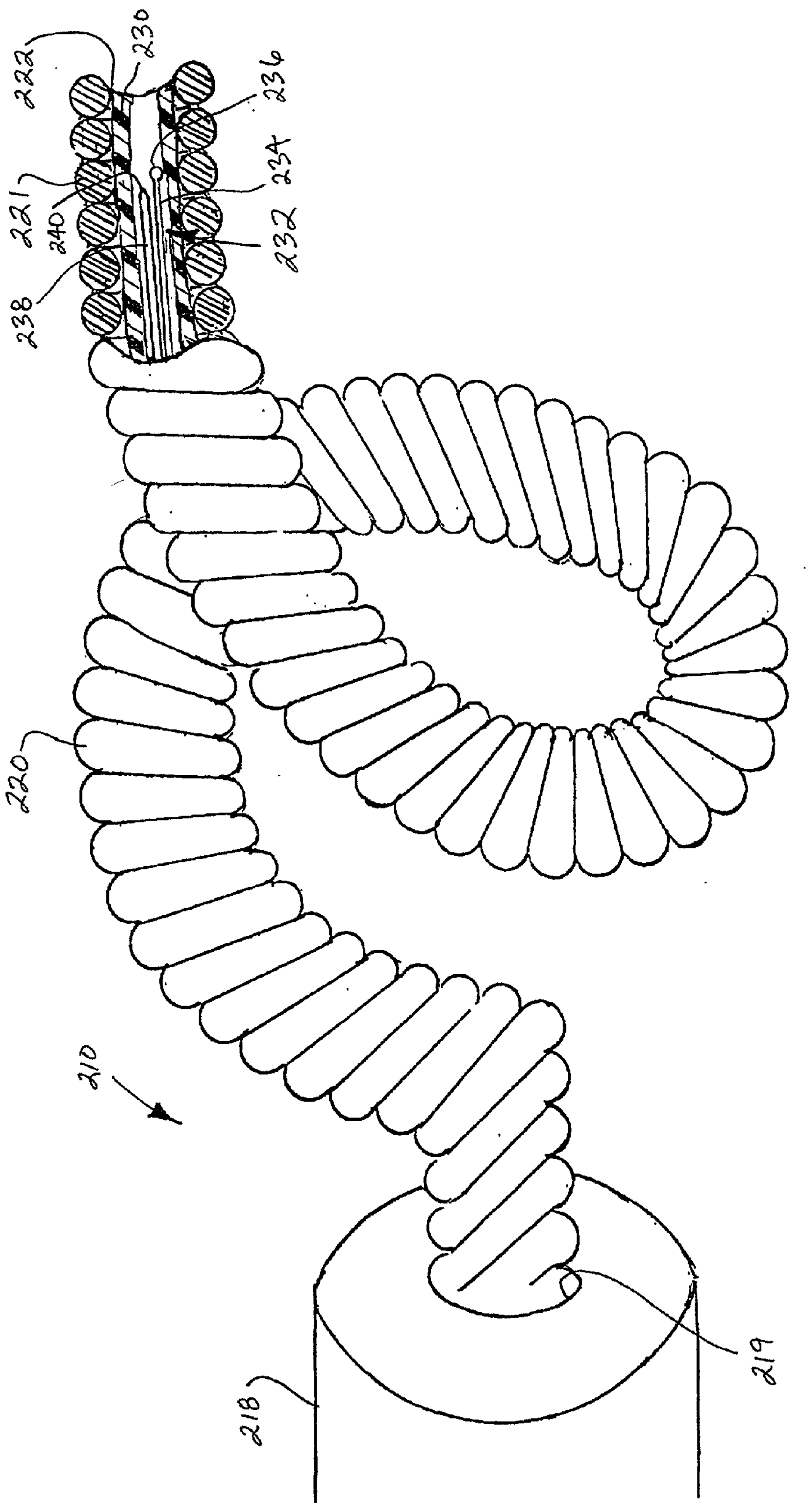


FIG. 4

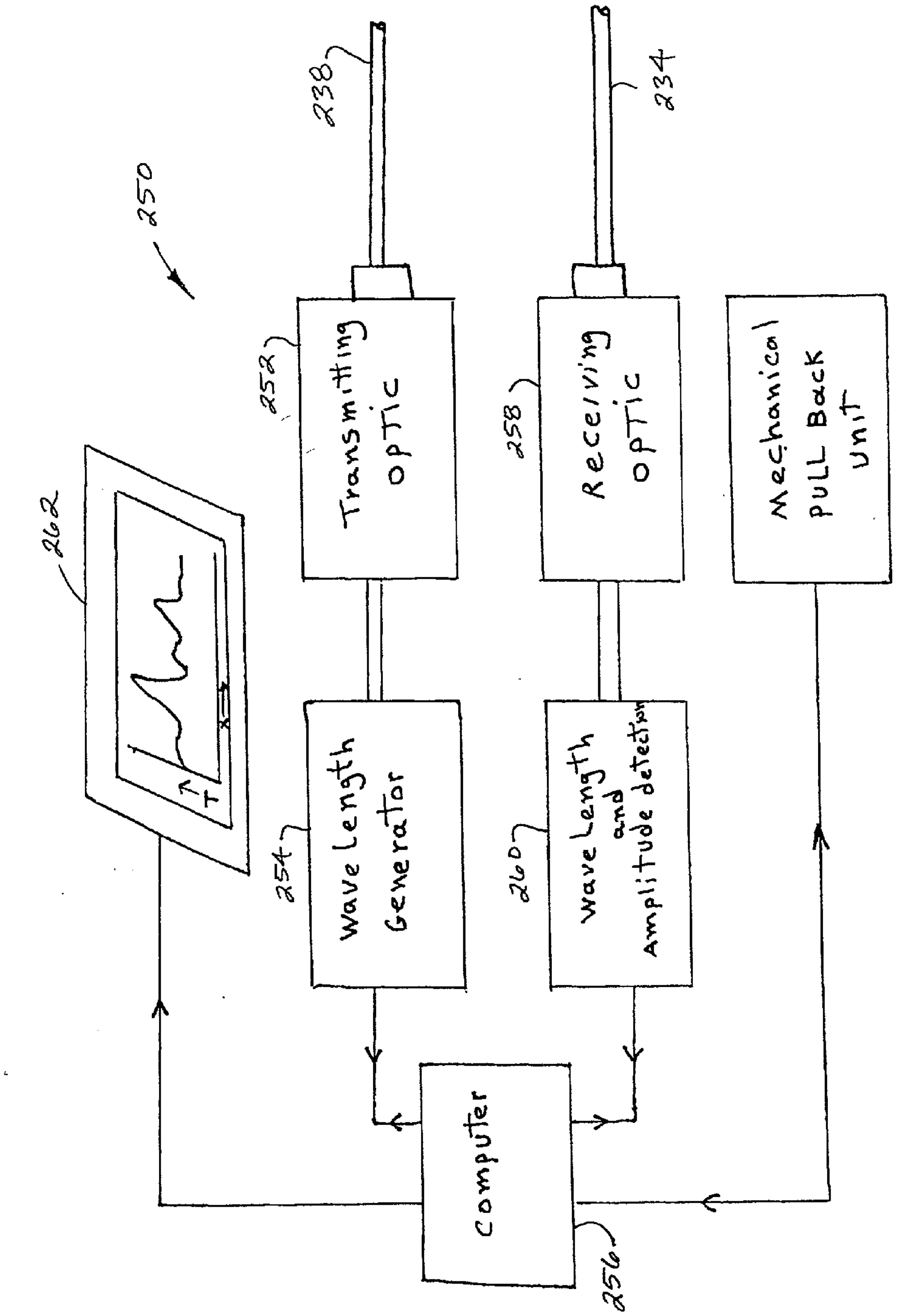

238
234
250
252
Transmitting
OPTIC
258
Receiving
OPTIC
Mechanical
PULL Back
Unit
262
254
Wave Length
Generator
260
Wave Length
and
Amplitude detection
Computer
256

FIG. 5

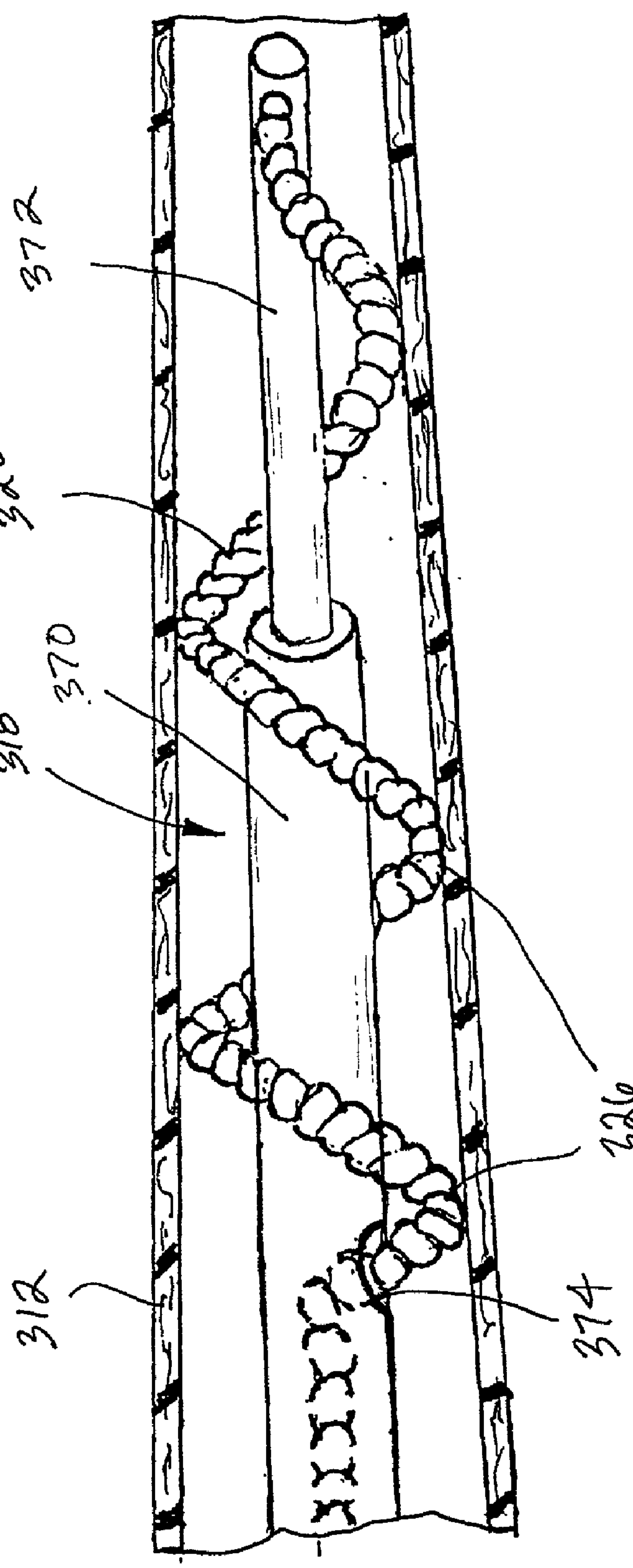


FIG. 6

METHOD FOR SENSING TEMPERATURE PROFILE OF A HOLLOW BODY ORGAN

TECHNICAL FIELD OF THE INVENTION

[0001] This invention relates generally to invasive medical devices and more particularly to methods using such devices for sensing the temperature of the interior wall of a hollow body organ such as a blood vessel.

BACKGROUND OF THE INVENTION

[0002] Acute ischemic syndromes involving arterial blood vessels, such as myocardial infarction, or heart attack, and stroke, frequently occur when atherosclerotic plaque ruptures, triggering the formation of blood clots, or thrombosis. Plaque that is inflamed is particularly unstable and vulnerable to disruption, with potentially devastating consequences. Therefore, there is a strong need to detect and locate this type of plaque so that treatment can be initiated before the plaque undergoes disruption and induces subsequent life-threatening clotting.

[0003] Various procedures are known for detecting and locating plaque in a blood vessel. Angiography is one such procedure in which X-ray images of blood vessels are generated after a radiopaque dye is injected into the blood stream. This procedure is capable of locating plaque in an artery, but is not capable of revealing whether the plaque is the inflamed, unstable type.

[0004] Researchers, acting on the theory that inflammation is a factor in the development of atherosclerosis, have discovered that local variations of temperature along arterial walls can indicate the presence of inflamed plaque. The temperature at the site of inflamation, i.e., the unstable plaque, is elevated relative to adjacent plaque-free arterial walls.

[0005] Using a tiny thermal sensor at the end of a catheter, the temperature at multiple locations along an arterial wall were measured in people with and without atherosclerotic arteries. In people free of heart disease, the temperature was substantially homogeneous wherever measured: an average of 0.65 degrees F. above the oral temperature. In people with stable angina, the temperature of their plaques averaged 0.19 degrees F. above the temperature of their unaffected artery walls. The average temperature increase in people with unstable angina was 1.23 degrees F. The increase was 2.65 degrees F. in people who had just suffered a heart attack. Furthermore, temperature variation at different points at the plaque site itself was found to be greatest in people who had just had a heart attack. There was progressively less variation in people with unstable angina and stable angina.

[0006] The temperature heterogeneity discussed above can be exploited to detect and locate inflamed, unstable plaque through the use of cavity wall profiling apparatus. Typically, cavity wall profiling apparatus are comprised of temperature indicating probes such as thermocouples, thermistors, fluorescence lifetime measurement systems, resistance thermal devices and infrared measurement devices.

[0007] One problem with conventional cavity wall profiling apparatus is that they usually exert an undue amount of force on the region of interest. If the region of interest cannot withstand these forces, it may be damaged. The inside walls of a healthy human artery are vulnerable to such damage. Furthermore, if inflamed, unstable plaque is present it may be ruptured by such forces.

[0008] Another problem with conventional cavity wall profiling apparatus is that they can only measure the temperature at one specific location. In order to generate a map of the cavity temperature variation, one would need to move the temperature indicating probe from location to location. This can be very tedious, can increase the risk of damaging the vessel wall or rupturing vulnerable plaque, and may not resolve temporal characteristics of the profile with sufficient resolution. An array of probes could be employed but that could be very big and heavy.

SUMMARY OF THE INVENTION

[0009] According to one aspect of the invention, a device is provided for sensing the temperature profile of a hollow body organ. The device includes a catheter, a hollow guidewire, and a temperature sensor longitudinally moveable within the guidewire. The guidewire has an expanded configuration externally of the catheter including a plurality of helical loops of greater diameter than the catheter. The guidewire also has a contracted configuration internally of the catheter and is of a lesser diameter than the catheter.

[0010] According to another aspect of the invention, the device is used by contracting the guidewire elastically and constraining the guidewire within the catheter. The catheter and guidewire are advanced to a region of interest in a hollow body organ. The catheter is withdrawn while securing the guidewire against substantial longitudinal movement relative to the hollow body organ, resulting in the guidewire self-expanding into helical loops in contact with the hollow body organ. As the temperature probe is advanced to a region of interest, the hollow guidewire and the probe remain within the catheter. The temperature sensing is done while the hollow guidewire is deployed out of the catheter and the temperature probe is retracted within the hollow guidewire. The temperature probe is moved through the guidewire to sense the temperature of the hollow body organ at multiple locations.

[0011] Further aspects and advantages of the present invention are apparent from the following description of a preferred embodiment referring to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] In the drawings,

[0013] **FIG. 1** is a perspective, partially cut-away view of an arterial hollow body organ in which a preferred embodiment of the present invention is deployed;

[0014] **FIG. 2** is an enlarged perspective view of the embodiment of **FIG. 1**;

[0015] **FIG. 3** is an enlarged perspective view of another preferred embodiment of the present invention;

[0016] **FIG. 4** is an enlarged perspective view of a further preferred embodiment of the present invention;

[0017] **FIG. 5** is a block diagram of a controller useful in connection with the embodiment of **FIG. 4**; and

[0018] **FIG. 6** is a perspective view, partially is section, of yet another preferred embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0019] **FIGS. 1 and 2** show an expandable device **10** for profiling the wall of a hollow body organ. Device **10** is shown deployed in a hollow body organ comprising an arterial blood vessel **12** having an endothelium **14** forming the inner wall thereof. A plaque **16** is disposed in endothelium **14**.

[0020] Device **10** includes a lumened catheter **18** having a central lumen **19**, a hollow guidewire **20** comprising a tubular helix formed of metal wire **21** or the like in the shape of a coil defining a central lumen **22**, and a temperature probe **23** disposed within the lumen **22** of guidewire **20**. The temperature probe **23** comprises a flexible elongate member **24** of sufficient stiffness to permit insertion into and withdrawal from lumen **22** of guidewire **20**, following the curves thereof, without bending or kinking. A thermal sensor **25** is disposed at the distal end of the temperature probe **23**, and conventional conductors or other signal carrying structures (not shown) are provided to convey signals from the thermal sensor along the guidewire **20** and out of the proximal end of guidewire **20** for connection to appropriate signal processing apparatus that converts the signals to a temperature indication. Thermal sensor **25** can be a thermocouple or a thermistor, for example.

[0021] The temperature probe can be made of metal wire, or a suitable plastic material, or a combination of both such as a metal wire coated with lubricous polymer material such as polytetrafluoroethylene (PTFE or Teflon®), polyethylene or other lubricous polymer material as known in the art. The coils of guidewire **20** may also be coated with a lubricous polymer such as PTFE to aid the insertion and withdrawal of the temperature probe within the lumen of guidewire **20**. Such a coating also helps to thermally isolate the adjacent coils from one another and make the thermal mapping more precise. In other words, it will reduce the spread of heat from a hot zone to a normothermic zone.

[0022] Guidewire **20** is made of thin wire **21** wound, for example around a mandrel, into small helical coils of desired diameter that lie tightly adjacent one another to form a hollow tube having a central passageway or lumen **22** therethrough. Guidewire **20** has an outer diameter somewhat less than the inner diameter of catheter **18** to permit guidewire **20** to slide freely within the lumen **19** of catheter **18**. In addition, guidewire **20**, in its relaxed configuration, is shaped as large, loosely spaced helical loops **26**. Guidewire **20** can be deformed from this relaxed configuration under force, and when the force is removed guidewire **20** returns to the relaxed, looped configuration.

[0023] Temperature probe **23** has a stiffness substantially less than that of the guidewire **20** and has flexibility while having excellent pushability. Flexibility permits temperature probe **23** to follow the curves of helical loops **26** of guidewire **20** without forcing guidewire **20** to become straight.

[0024] The self-looping characteristic of guidewire **20** can be accomplished in several ways. One way is to construct guidewire **20** of spring steel that can be deformed into a relatively straight configuration when withdrawn into catheter **18**, but which springs back to its looped configuration when extruded from catheter **18** and released from constraint. Another way is to construct guidewire **20** of superelastic nitinol and take advantage of the martensitic transformation properties of nitinol. Guidewire **20** can be inserted into catheter **18** in its straight form and kept cool within the catheter by the injection of cold saline through catheter **18** and over guidewire **20**. Upon release of guidewire **20** into the bloodstream, it will warm up and change to its austenite memory shape based on the well-known martensitic transformation by application of heat and putting the material through its transformation temperature.

[0025] Guidewire **20** can also be made out of a composite such as a nitinol tube within the guidewire structure. In this fashion, the martensitic or superelastic properties of nitinol can be combined with the spring steel characteristics of the spring and lead to a desirable composition. Other suitable materials for guidewire **20** include copper, constantan, chromel or alumel.

[0026] In use, the procedure is to first advance the catheter, separately, or together with the hollow guidewire and the temperature probe therewithin, to the region of interest. Thereafter the hollow guidewire and the temperature probe are deployed beyond the distal end of the catheter. At this time the temperature probe can be positioned to a desired longitudinal location within the guidewire, preferably so that the tip of the probe is at the distal end of the deployed guidewire. Preferably, the temperature probe is inserted into the lumen **22** of guidewire **20** from the proximal end until the tip with the thermal sensor **25** is disposed at the distal end of guidewire **20**. Guidewire **20** is inserted into the lumen **19** of catheter **18** from the proximal end, thereby constraining guidewire **20** into a substantially straight configuration. Using conventional percutaneous insertion techniques, access to the blood vessel **12** is obtained surgically and device **10** is advanced through the blood vessel **12** to the region of interest.

[0027] To deploy the probe, guidewire **20** is secured against movement relative to the patient, catheter **18** is slowly withdrawn such that guidewire **20** emerges from the distal end of catheter **20** and reverts to its looped configuration within the blood vessel **12**. Guidewire **20** remains substantially fixed in the axial direction relative to the blood vessel **12** as catheter **18** is withdrawn, with the reformed loops **26** springing radially outwardly into contact with the vessel wall **14**. The relative lack of movement between guidewire **20** and vessel wall **14** alleviates the risk of damage to vessel wall **14** and the risk of rupturing unstable plaque.

[0028] With guidewire **20** exposed and lying in helical contact with the wall **14** of blood vessel **12**, the temperature probe **23** is able to sense the localized temperature of the vessel wall **14** through the guidewire **20** at the region where the thermal sensor **25** is located. By slowly withdrawing the temperature probe **23** from guidewire **20**, the thermal sensor **25** traverses a helical path around the wall **14** of the blood vessel **12**, permitting temperature measurements to be taken at intervals of different regions of the vessel wall **14**. By withdrawing the temperature probe **23** at a constant rate, the location of the thermal sensor **25** relative to the distal end of the guidewire **20** can be determined as a function of time, so that a temperature profile of the blood vessel **12** can be mapped.

[0029] Once the mapping is completed, the catheter **18** can be pushed forward again while securing guidewire **20** against longitudinal movement. Catheter **18** will thereby re-sheath guidewire **20** and constrain it in a substantially straight configuration for withdrawal from the blood vessel **12** so that the temperature probe will be able to advance to the forward position.

[0030] **FIG. 3** shows a second preferred embodiment of an expandable device **110** for profiling the wall of a hollow body organ. Device **110** can be deployed in a hollow body organ in a manner similar to that shown in **FIG. 1** and described above with respect to the first embodiment of expandable device **10**. Components of device **110** that are similar in structure and function to corresponding components of device **10** of **FIG. 1** are designated by like reference numerals in the **100** series but having the same last two digits. The description of device **10** above applies also to device **110** unless described otherwise below.

[0031] Device **110** includes a lumened catheter **118**, a hollow guidewire **120**, and a temperature probe **123** disposed within the lumen **122** of guidewire **120**. The temperature probe **123** comprises a flexible elongate member **124** of sufficient stiffness to permit insertion into and withdrawal from lumen **122** of guidewire **120**, following the curves thereof, without bending or kinking. A thermal sensor **125** is disposed at the distal end of the temperature probe **123**, sensor **125** comprising a dog-leg bend at the distal end of elongate member **124** of sufficient length and angular orientation to remain in contact with the interior surface of lumen **122** of guidewire **120** as temperature probe **123** is moved axially within guidewire **120**.

[0032] Guidewire **120** and thermal sensor **125** are composed of dissimilar metals such that contact therebetween forms a thermocouple junction that generates an electrical voltage proportional to the temperature of the thermocouple junction. Elongate member **124** of temperature probe **123** comprises one conductor and guidewire **120** comprises another conductor of the resulting thermocouple for conveying signals from the thermal sensor **125** to the proximal end of guidewire **120** for connection to appropriate signal processing apparatus that converts the signals to a temperature indication. Suitable materials for guidewire **120** and thermal sensor **125** to create a thermocouple include copper, constantan, chromel, alumel, and the like, the lead serving as the thermal sensor **125** being suitably insulated except at the tip thereof.

[0033] Device **110** of **FIG. 3** can be used in a manner substantially similar to the manner of use described above with respect to device **10** of **FIG. 1**.

[0034] **FIG. 4** shows yet another preferred embodiment of an expandable device **210** for profiling the wall temperature of a hollow body organ. Device **210** can be deployed in a hollow body organ in the manner shown in **FIG. 1** and described above with respect to the first embodiment of expandable device **10**. Components of device **210** that are similar in structure and function to corresponding components of device **10** of **FIG. 1** are designated by like reference numerals in the **200** series but having the same last two digits. The description of device **10** above applies also to device **210** unless described otherwise below.

[0035] Device **210** includes a lumened catheter **118** and a hollow guidewire **120**. The inner surface of lumen **222** of guidewire **220** is lined with a thermochromic material **230** that is sensitive to a change of temperature of the guidewire **220**. The color of the thermochromic material **230** varies as a function of temperature.

[0036] Disposed within lumen **222** of guidewire **220**, inwardly of thermochromic material **230**, is an optical probe **232** including an illuminating optical fiber **234** having a radially emitting diffuser **236** at the distal end thereof, and a sensing optical fiber **238** having a conically beveled distal end **240** for collecting light. Optical fibers **234** and **238** are moveable in unison within lumen **222** in a manner similar to that of temperature probes **23** and **123** described above with reference to FIGS. **1-3**. An illuminating electromagnetic radiation source is connected to the proximal end of illuminating optical fiber **234** provides illuminating radiation that is guided by optical fiber **234** to the region of interest within the hollow body organ, and diffused radially by diffuser **236** to illuminate the interior of lumen **222**, particularly thermochromic material **230**. The illuminating radiation can be in the visible, infrared or ultraviolet portions of the spectrum. Radiation from diffuser **236** is differentially absorbed and reflected by thermochromic material **230**, according to the color of material **230** which is indicative of the temperature of guidewire **220** in contact with the wall of the hollow body organ in the region of interest.

[0037] The light reflected from thermochromic material **230**, having wavelengths indicative of the color thereof, is collected by distal end **240** and directed toward the proximal end of sensing optical fiber **238**. An appropriate optical reflectance spectrometry device connected to the proximal end of sensing optical fiber **238** generates an electrical signal indicative of the color, and therefore temperature, of thermochromic material **230**.

[0038] **FIG. 5** shows a block diagram of a control device **250** suitable for use with device **210** of **FIG. 4**. An optical transmitter **252** generates light for transmission through optical fiber **238** as discussed above. Transmitter **252** is operably connected to a wavelength generator **254** that generates signals indicative of the wavelength of the light transmitted by transmitter **252**, which signal is conveyed as an input to a computer **256**. An optical receiver **258** receives light reflected from thermochromic material **230** (**FIG. 4**) through optical fiber **234** as discussed above. Receiver **258** is operably connected to a wavelength and amplitude detector **260** that generates signals indicative of the wavelength and amplitude of the light received by receiver **258**, which signals are conveyed as an input to a computer **256**. A processed output signal from computer **256** generates a graphical display **262** of detected color, i.e., temperature, as a function of linear displacement of optical probe **232** relative to catheter **218**. A mechanical pull-back device **264** is mechanically connected to optical probe **232** and is controlled by and sends feedback signals to computer **256**, which signals contribute to the generation of the display **262**.

[0039] Device **210** of **FIG. 4** can be used in a manner substantially similar to the manner of use described above with respect to device **10** of **FIG. 1**.

[0040] **FIG. 6** shows still another preferred embodiment of the present invention that can incorporate any of the various temperature sensing technologies described above with respect to the first, second and third embodiments. Catheter **318** includes a first portion **370** and a second portion **372** that is telescopically received within first portion **320** and axially moveable relative thereto. Hollow guidewire **320** is fixed at the distal end thereof to second portion **372**, and is received within the lumen of first portion **370** via an aperture **374**. A movable, temperature sensing transducer as described hereinabove is situated within guidewire **320**. By extending and retracting second portion **372** relative to first portion **370**, the pitch and outer diameter of loops **326** of guidewire **320** can be adjusted for optimal contact with the inner wall of hollow body organ **312**.

[**0041**] Although the present invention has been described in detail in terms of preferred embodiments, no limitation on the scope of the invention is intended. The scope of the subject matter in which an exclusive right is claimed is defined in the appended claims.

I claim:

1. A method for sensing the temperature profile of a hollow body organ, comprising the steps of:

providing a catheter;

providing a hollow, self-expanding guidewire that expands when unconstrained into a configuration including a plurality of helical loops of greater diameter than the catheter;

providing a temperature sensor disposable within the lumen of the guidewire and moveable longitudinally therein;

contracting the guidewire elastically and constraining the guidewire within the lumen of the catheter;

advancing the catheter and guidewire to a region of interest in a hollow body organ;

withdrawing the catheter while securing the guidewire against substantial longitudinal movement relative to the hollow body organ, whereby the guidewire self-expands into loops in contact with the hollow body organ;

moving the temperature probe through the lumen of the guidewire; and

sensing the temperature of the hollow body organ at multiple locations.

2. The method of claim 1 wherein the temperature probe is advanced together with the catheter and guidewire to the region of interest.

3. The method of claim 1, wherein the guidewire comprises a tubular helix.

4. The method of claim 1, wherein the guidewire comprises a material having martensitic transformation properties.

5. The method of claim 4, wherein the guidewire comprises nitinol.

6. The method of claim 1, wherein the guidewire comprises an elastic material.

7. The method of claim 6, wherein the guidewire comprises spring steel.

8. The method of claim 1, wherein the temperature sensor comprises a thermocouple.

9. The method of claim 8, wherein the temperature sensor comprises one leg of the thermocouple and the guidewire comprises another leg of the thermocouple.

10. The method of claim 1, wherein the temperature sensor comprises a thermistor.

11. The method of claim 1, wherein the temperature sensor comprises a thermochromic material.

12. The method of claim 11, wherein the thermochromic material is in thermal contact with the lumen of the guidewire.

13. The method of claim 12, wherein the temperature sensor further includes an optical probe for sensing the color of the thermochromic material.

14. The method of claim 13, wherein the optical probe includes an illumination device for illuminating a region of interest of the guidewire.

15. The method of claim 14, wherein the optical probe includes a sensing device for sensing reflected radiation from the thermochromic material.

16. The method of claim 15, wherein the reflected radiation is in the visible spectrum.

17. The method of claim 15, wherein the reflected radiation is in the infrared spectrum.

18. The method of claim 15, wherein the reflected radiation is in the ultraviolet spectrum.

* * * * *

专利名称(译)	用于感测中空身体器官的温度分布的方法		
公开(公告)号	US20030013985A1	公开(公告)日	2003-01-16
申请号	US09/904080	申请日	2001-07-12
[标]申请(专利权)人(译)	萨达特瓦希德		
申请(专利权)人(译)	萨达特瓦希德		
当前申请(专利权)人(译)	萨达特瓦希德		
[标]发明人	SAADAT VAHID		
发明人	SAADAT, VAHID		
IPC分类号	A61B5/00 A61B5/01 A61M25/00 A61B5/103 A61B5/117		
CPC分类号	A61B5/01 A61B5/6857 A61B5/6885		
外部链接	Espacenet USPTO		

摘要(译)

用于感测中空身体器官的温度分布的方法利用导管和中空导丝。当不受约束时，导丝被配置为直径大于导管的多个螺旋环。当被约束在导管内时，导丝可以前进到中空身体器官中的感兴趣区域。可以取出导管，将导丝留在扩张构型中，其中螺旋环接触中空身体器官的内壁。温度传感器可在导丝内移动，以感测多个位置的温度。