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

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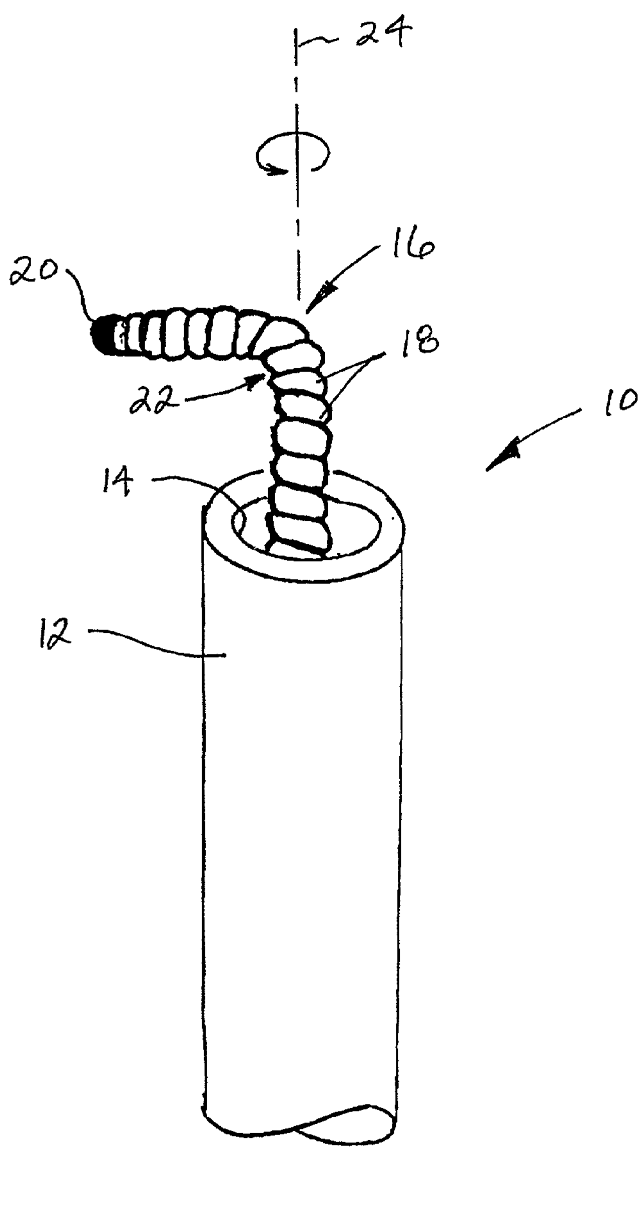
(57) **ABSTRACT**

A device for sensing the temperature profile of a hollow body organ includes a catheter and hollow a guidewire carrying a thermal sensor. The hollow guidewire is configured to displace the thermal sensor radially relative to the catheter when unconstrained and can be rotated about the longitudinal axis of the catheter. 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 The catheter can be withdrawn, leaving the guidewire in place in an expanded configuration wherein the thermal sensor contacts the inner wall of the hollow body organ. The guidewire is moveable to sense the temperature at multiple locations. The thermal sensor can be replaced with an electrode for sensing the impedance profile of the hollow body organ.



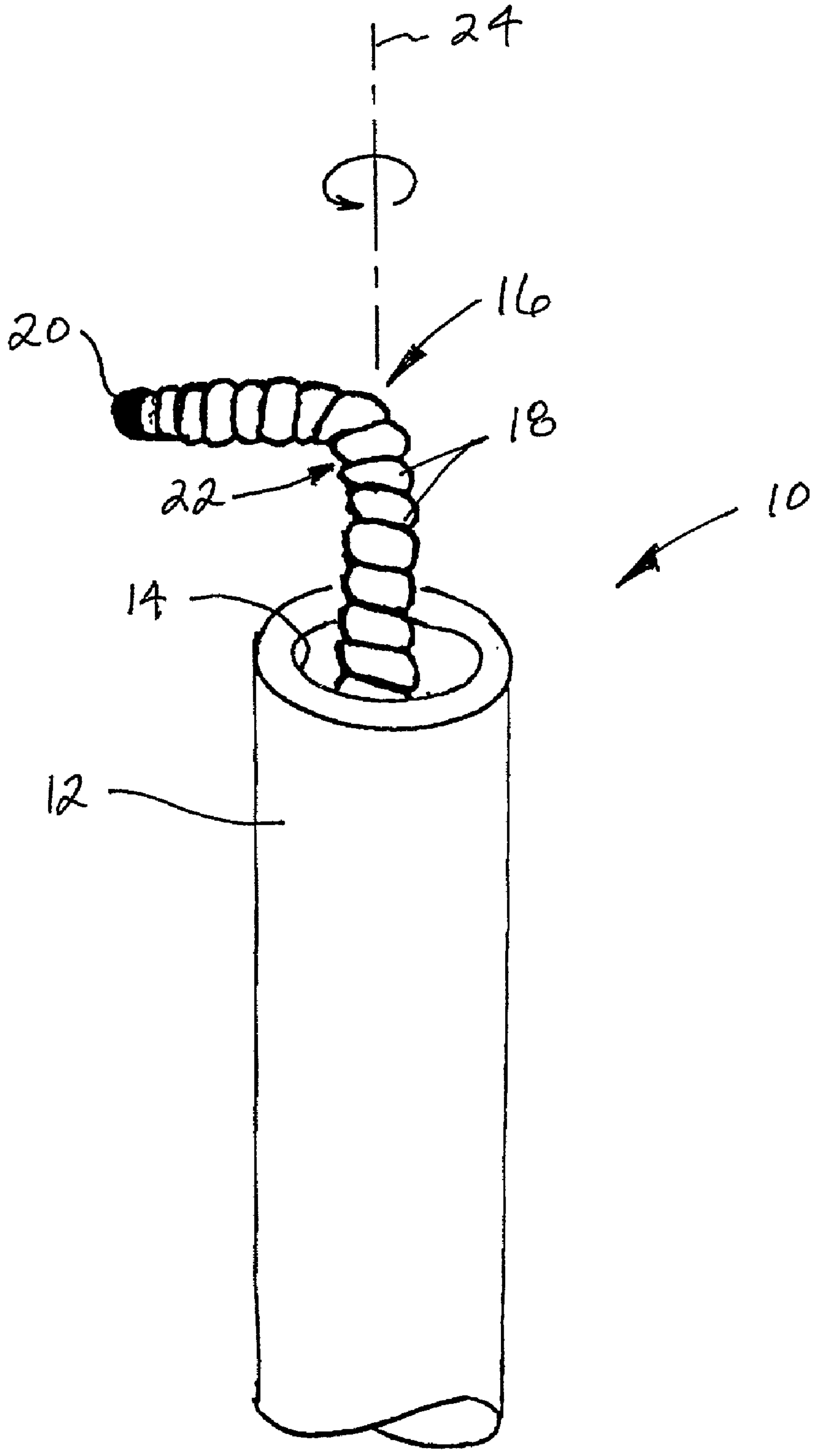


FIG. 1

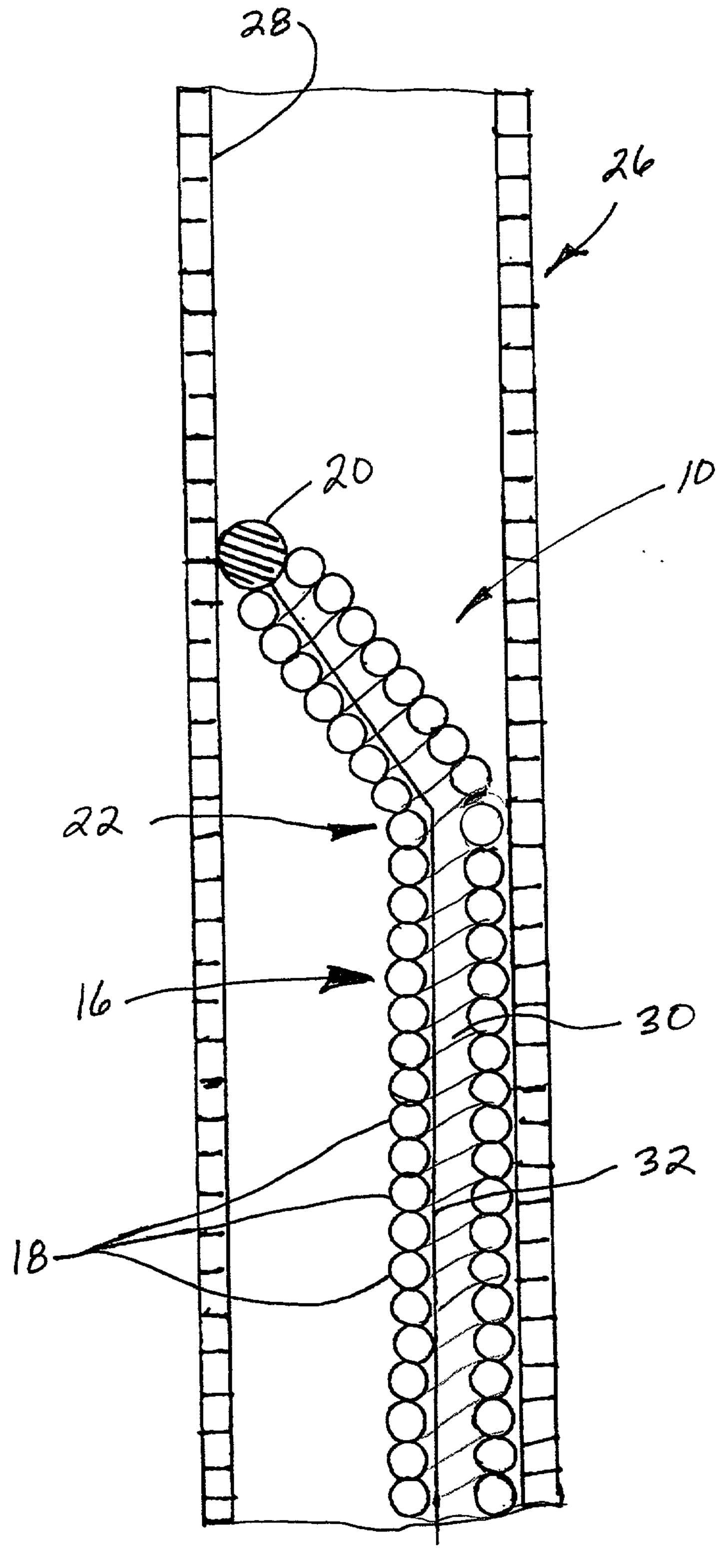


FIG. 2

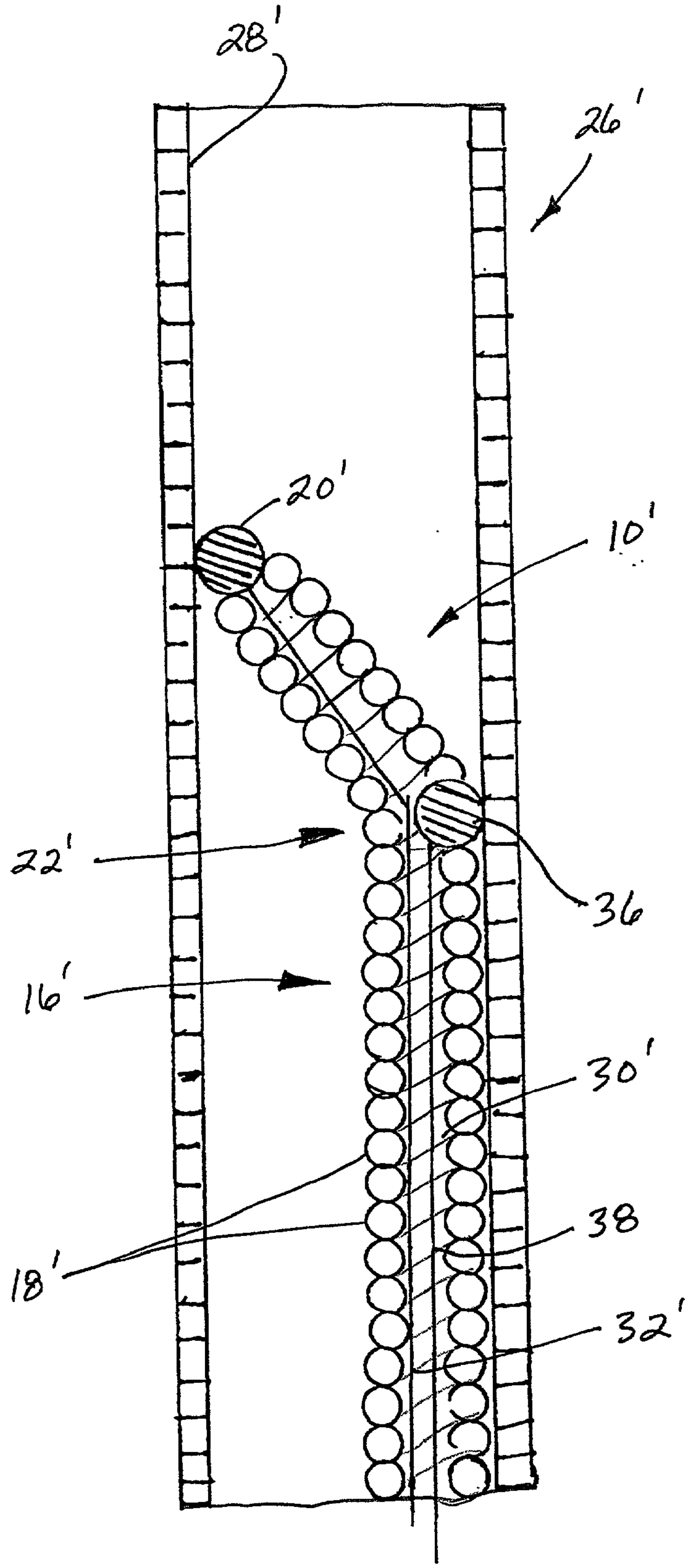


FIG. 3

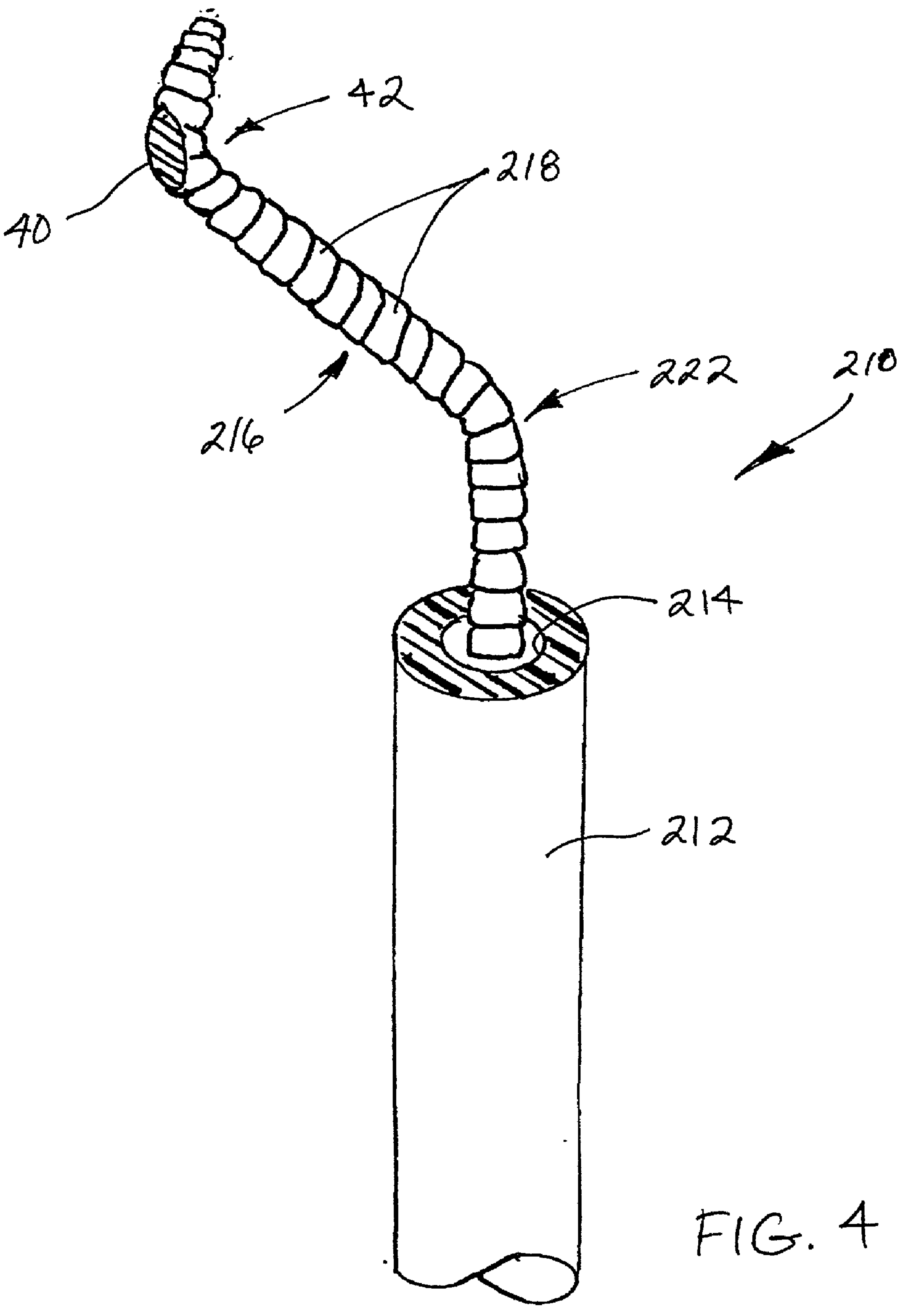


FIG. 4

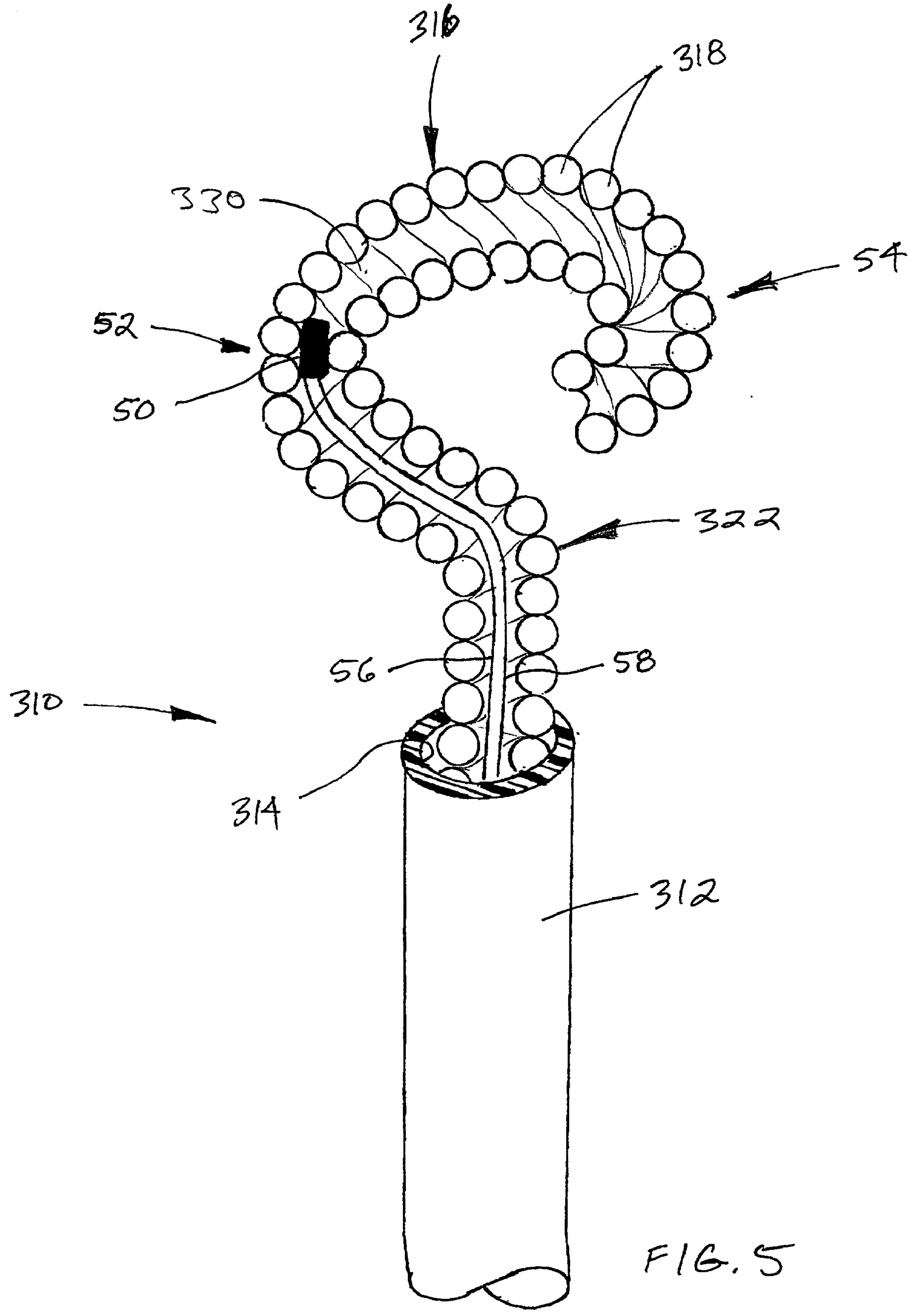


FIG. 5

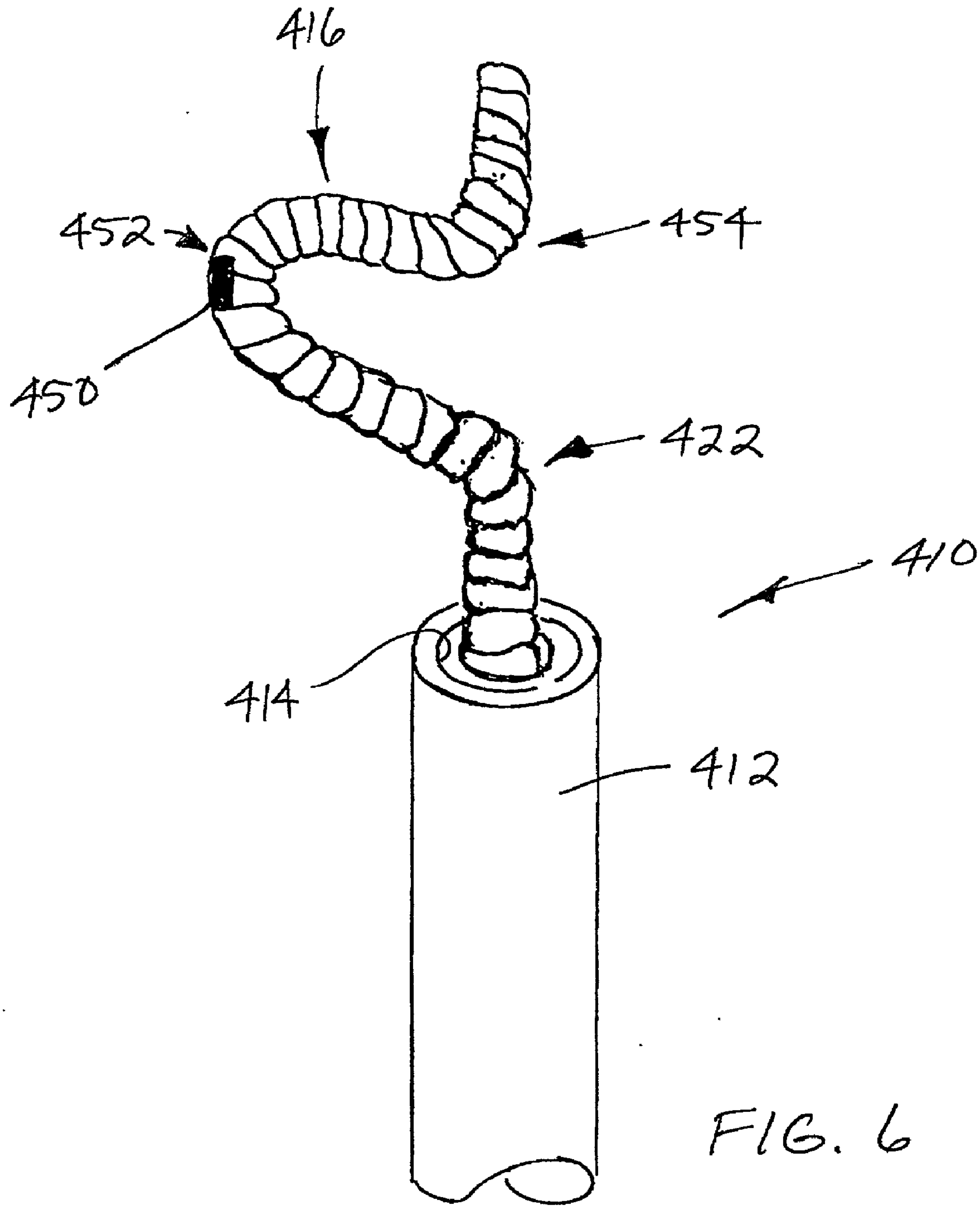


FIG. 6

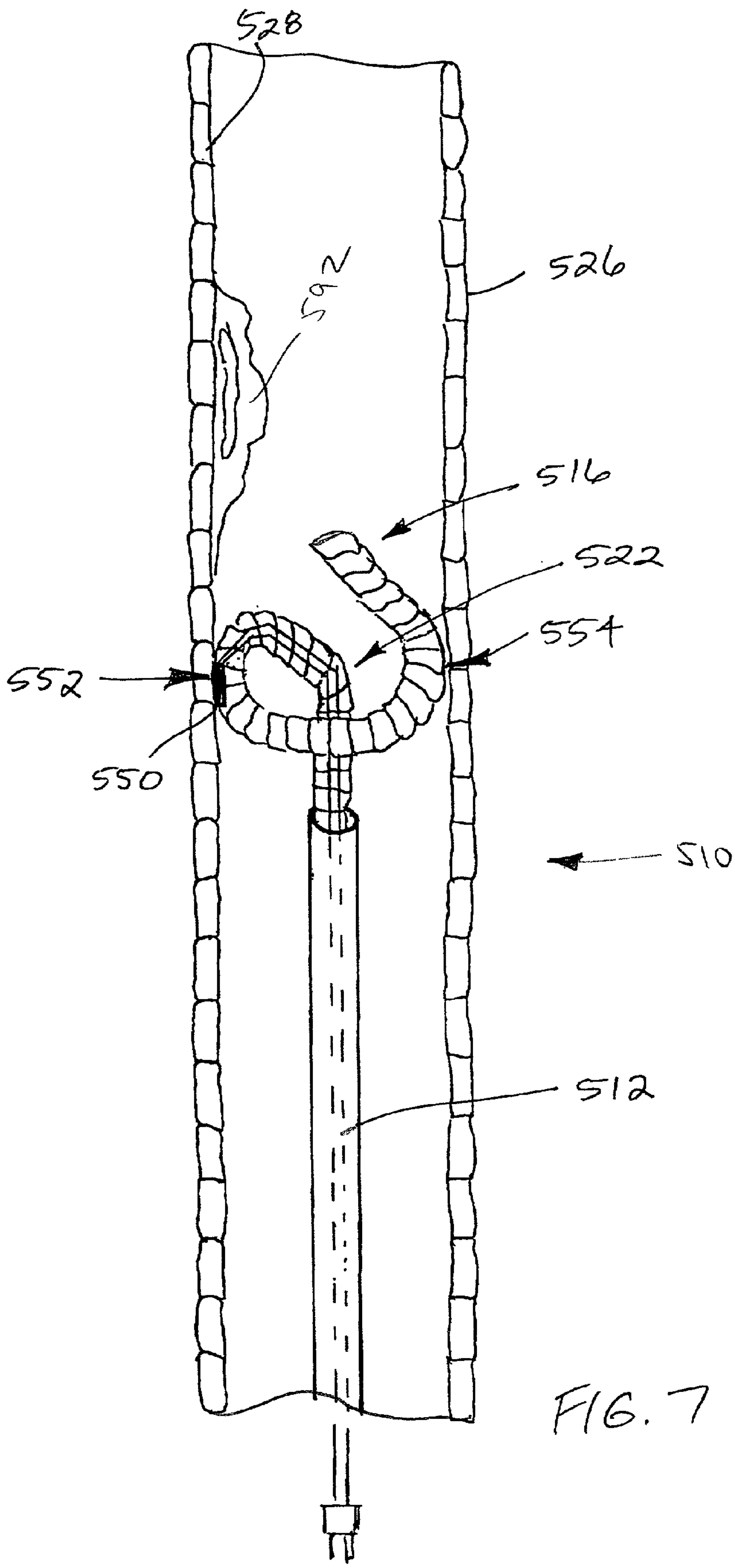


FIG. 7

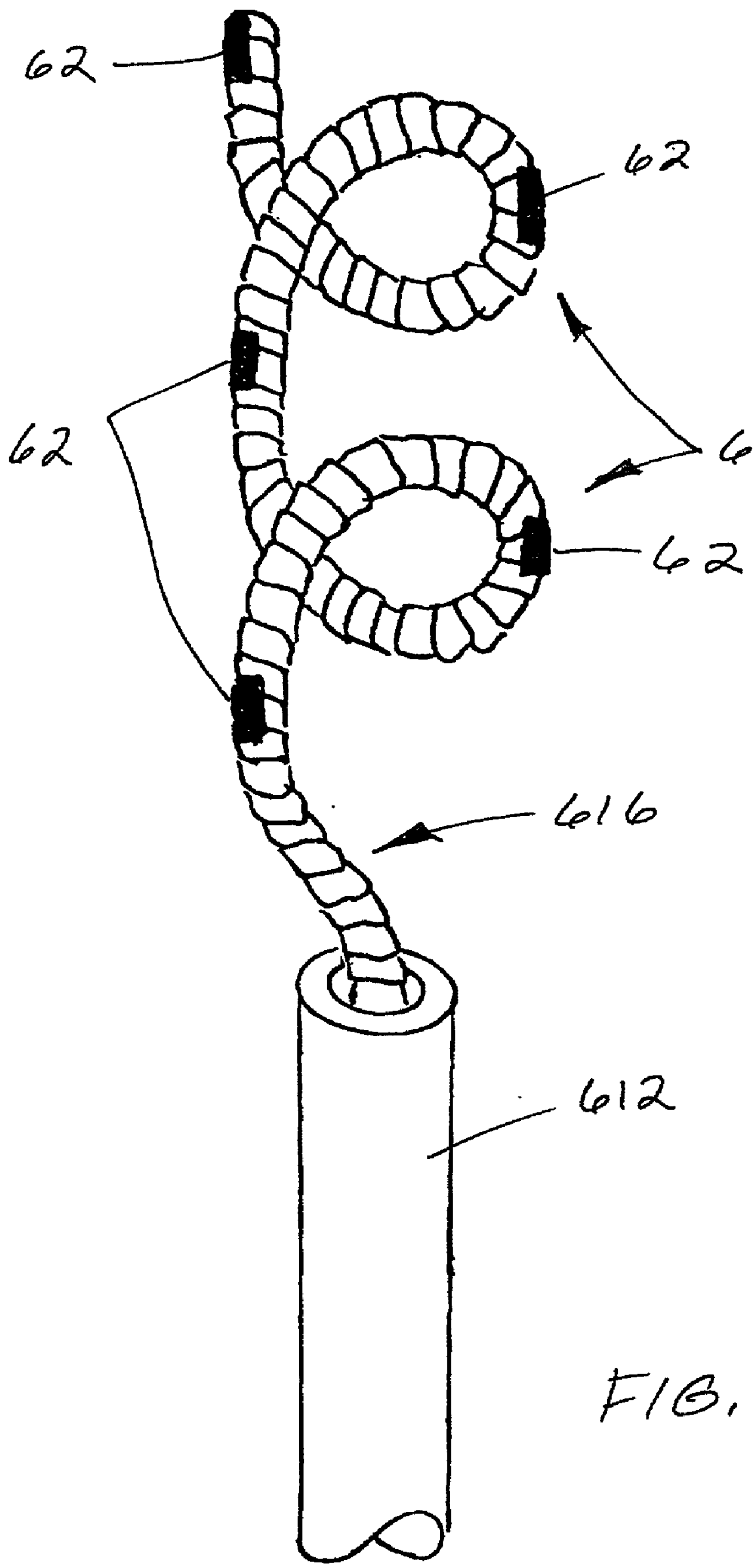


FIG. 8

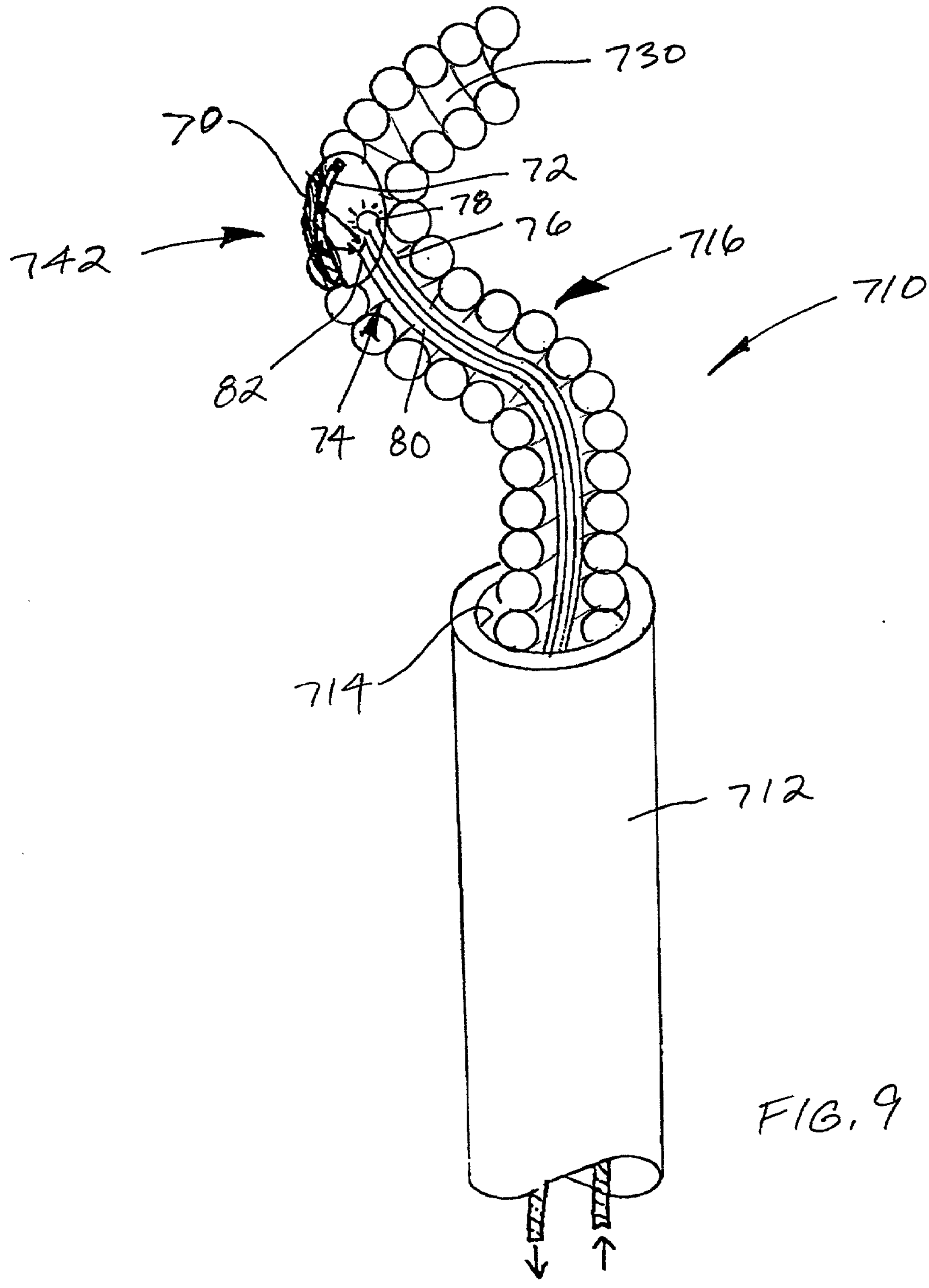


FIG. 9

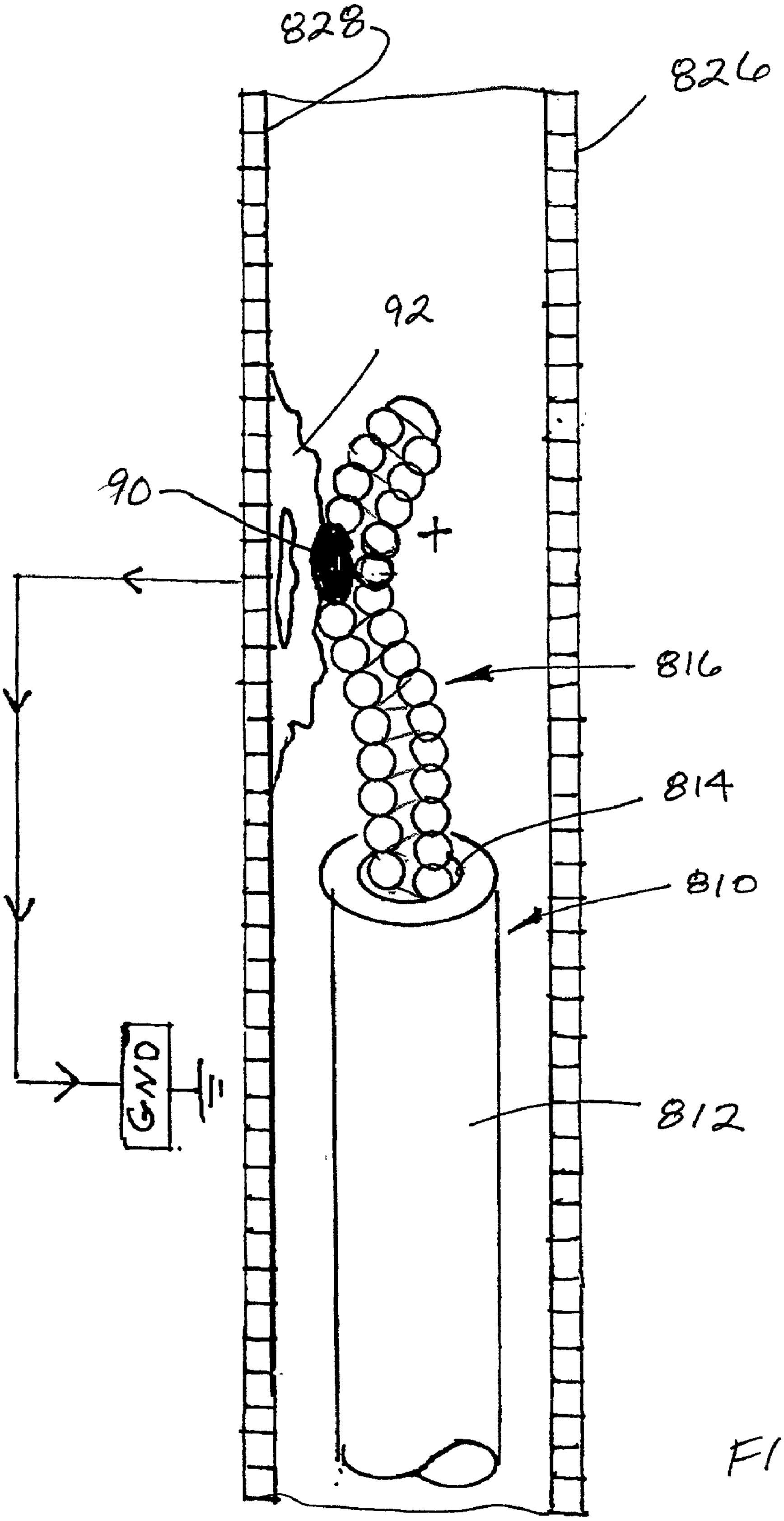


FIG. 10

DEVICE 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 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 disposed on or within the guidewire. The guidewire has a relaxed configuration externally of the catheter that is formed to provide contact with the wall of the hollow body organ. 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 to expose the distal portion of the guidewire in a relaxed configuration in contact with the hollow body organ. The guidewire is moved longitudinally and rotated, continuously or continually, 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 view of a preferred embodiment of the present invention;

[0014] **FIG. 2** is a longitudinal sectional view of an arterial hollow body organ in which the embodiment of **FIG. 1**, also shown in longitudinal section, is deployed;

[0015] **FIG. 3** is a longitudinal sectional view of an arterial hollow body organ in which another preferred embodiment of the present invention, also shown in longitudinal section, is deployed;

[0016] **FIG. 4** is a perspective view of yet another preferred embodiment of the present invention;

[0017] **FIG. 5** is a perspective view, partially in section, of a further preferred embodiment of the present invention;

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

[0019] **FIG. 7** is a longitudinal sectional view of an arterial hollow body organ in which another preferred embodiment of the present invention, shown in perspective, is deployed;

[0020] **FIG. 8** is a perspective view of a further preferred embodiment of the present invention;

[0021] **FIG. 9** is a perspective view of another preferred embodiment of the present invention; and

[0022] **FIG. 10** is a longitudinal sectional view of an arterial hollow body organ in which yet another preferred embodiment of the present invention, shown in perspective, is deployed.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0023] **FIG. 1** shows a device **10** for profiling the wall of a hollow body organ. Device **10** includes a lumened catheter **12** having a central lumen **14**, a hollow guidewire **16** that defines a conduit comprising a tubular helix formed of metal wire **18** or the like in the shape of a coil defining a central lumen (not shown), and a thermal sensor **20** disposed at the terminal end of the distal portion of guidewire **16**. Conventional conductors or other signal carrying structures (not shown) are provided to convey signals from the thermal sensor **20** along guidewire **16** and out of the proximal portion of guidewire **16** for connection to appropriate signal processing apparatus that converts the signals to a temperature indication. Thermal sensor **20** can be a thermocouple, a thermistor, or an infrared radiation sensor, for example, and is secured by appropriate mechanical or adhesive means to the terminal end of guidewire **16**.

[0024] Hollow guidewire **16** is made of thin wire **18** 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 therethrough. Guidewire **16** has an outer diameter somewhat less than the inner diameter of catheter **12** to permit guidewire **16** to slide freely within the lumen **14** of catheter **12**. In addition, guidewire **16**, in its relaxed configuration, is shaped in the form of a bend **22** at the distal portion thereof, the bend **22** being spaced from the terminal end of guidewire **16** at which thermal sensor **20** is disposed. Consequently, thermal sensor **20** is displaced radially from the longitudinal axis **24** of guidewire **16** and catheter **12** when guidewire **16** is in the relaxed, bent configuration. Through external manipulation, guidewire **16** in the relaxed, bent configuration can be made to rotate about axis **24**, continuously or continually, depending on the response time for the sensor, thereby causing thermal sensor **20** to traverse a circumferential or helical path about axis **24** while providing temperature information. Guidewire **16** can be deformed elastically into a substantially straight configuration, i.e., without bend **22**, under force. When the force is removed, guidewire **16** returns to the relaxed, bent configuration.

[0025] Guidewire **16** can be constructed of spring steel that can be deformed into a relatively straight configuration when withdrawn into catheter **12**, but which springs back to its bent configuration when extruded from catheter **12** and released from constraint. Another way is to construct guidewire **16** of superelastic nitinol and take advantage of the martensitic transformation properties of nitinol. Guidewire **16** can be inserted into catheter **12** in its straight form and kept cool within the catheter by the injection of cold saline through catheter **12** and over guidewire **16**. Upon release of guidewire **16** 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.

[0026] Guidewire **16** 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 **16** include copper, constantin, chromel or alumel.

[0027] **FIG. 2** shows device **10** deployed in a hollow body organ comprising an arterial blood vessel **26** having an endothelium **28** forming the inner wall thereof. Only the distal portion of guidewire **16** that extends beyond catheter **12** is shown. Electrical conductor **32** extends through lumen **30** of guidewire **16**. Conductor **32** is electrically insulated from the coils **18** of guidewire **16** so that guidewire **16** comprises one conductor and conductor **32** comprises another conductor or lead of the thermal sensor **20** which can be a thermocouple or thermistor. The conductors convey signals from the thermal sensor **20** to the proximal end of guidewire **16** for connection to appropriate signal processing apparatus that converts the received signals to a temperature indication.

[0028] In use, the guidewire **16** and thermal sensor **20** of the preferred embodiment of device **10**, as shown in **FIGS. 1 and 2**, are inserted into the lumen **14** of catheter **12** from the proximal end, thereby constraining guidewire **16** in a substantially straight configuration with the thermal sensor **20** near the distal end of catheter **12**. Using conventional percutaneous insertion techniques, access to the blood vessel **26** is obtained surgically. Catheter **12**, with guidewire **16** and thermal sensor **20** disposed within, is advanced through the blood vessel **26** to the region of interest.

[0029] Catheter **12** is slowly withdrawn while guidewire **16** is secured against movement relative to the patent such that guidewire **16** emerges from the distal end of catheter **12** and reverts to the relaxed, bent configuration within the blood vessel **26**. Guidewire **16** remains substantially fixed in the axial direction relative to the blood vessel **26** as catheter **12** is withdrawn, with the re-formed bent distal portion of guidewire **16** springing gently radially outwardly into contact with the vessel wall **28**.

[0030] With guidewire **16** exposed and thermal sensor **20** lying in contact with the wall **28** of blood vessel **26**, the thermal sensor **20** senses the localized temperature of the vessel wall **26** at the region where the thermal sensor **20** is situated. By slowly withdrawing guidewire **16** into catheter **12** while simultaneously rotating guidewire **16** about its longitudinal axis, thermal sensor **25** can be made to traverse a helical path around the inner wall **28** of the blood vessel **26**, permitting temperature measurements to be taken at intervals of different regions of the vessel wall **28**. Depending upon the response time of thermal sensor **20**, rotation can be intermittent or continuous, as needed. By withdrawing and rotating the guidewire **16** at constant rates, the location of the thermal sensor **20** relative to the distal end of the catheter **12** can be determined as a function of time, so that a temperature profile of the blood vessel **26** can be mapped, provided the response time of the thermal sensor is relatively short.

[0031] Once the mapping is completed, the guidewire **16** is withdrawn fully into catheter **12**, re-sheathed and constrained in a substantially straight configuration. Catheter **12** can then either be withdrawn from the blood vessel **26** or repositioned to another region of interest within the hollow body organ for further mapping of the temperature profile at that region.

[0032] **FIG. 3** shows a second preferred embodiment of a device **10'** for profiling the wall of a hollow body organ. Device **10'** can be deployed in a hollow body organ in a manner similar to the embodiment of device **10** shown in **FIGS. 1 and 2** and described above with respect to structure and use. Components of device **10'** that are similar in structure and function to corresponding components of device **10** of **FIGS. 1 and 2** are designated by like primed numerals. The description of device **10** above applies also to device **10'** unless described otherwise below.

[0033] Device **10'** includes a second thermal sensor **36** disposed at the outside of bend **22'** and exposed for contact with the inner wall **28'** of vessel **26'**. A second electrical conductor **38** is electrically insulated the conductor **32'** and from the wire **18'** of guidewire **16'** so that guidewire **16'** comprises one conductor and conductor **38** comprises another conductor of the thermocouple or thermistor of thermal sensor **36** for conveying signals from the thermal sensor **36** to the proximal end of guidewire **16** for connection to appropriate signal processing apparatus that converts the signals to a temperature indication. Wire **18'** of guidewire **16'** is a conductor common to thermal sensors **20'** and **36**.

[0034] Device **10'** of **FIG. 3** can be used in a manner substantially similar to the manner of use described above with respect to device **10** of **FIGS. 1 and 2**, except that thermistors **20'** and **38** simultaneously traverse intertwined helical paths in contact with the inner wall **28'** of hollow body organ **26'**. Consequently, the temperature profile of the inner wall **28'** can be mapped more quickly because data can be gathered from different locations simultaneously.

[0035] **FIG. 4** shows yet another preferred embodiment of a 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 described above with respect to the embodiments of devices **10** and **10'** shown in **FIGS. 1, 2** and **3** and described above. Components of device **210** that are similar in structure and function to corresponding components of device **10** of **FIGS. 1 and 2** 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.

[0036] Device **210** of **FIG. 4** includes one thermal sensor **40** disposed at the outside of a dogleg bend **42** that is spaced distally from bend **222** and from the terminal end of guidewire **216**. Thermal sensor **40** is exposed for contact with the inner wall **228** of vessel **226**. An electrical conductor (not shown) is electrically insulated from the wire **218** of guidewire **216** so that guidewire **216** comprises one conductor and the electrical conductor comprises another conductor of the thermocouple or thermistor of thermal sensor **40** for conveying signals from the thermal sensor **40** to the proximal end of guidewire **216** for connection to appropriate signal processing apparatus that converts the signals to a temperature indication. Unlike the embodiments of devices **10** and **10'** of **FIGS. 1, 2** and **3**, device **210** includes only a thermistor at dog-leg bend **42** and no thermistor at the terminal end of guidewire **216** or at bend **222**.

[0037] 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 **FIGS. 1 and 2**.

[0038] **FIG. 5** shows a further preferred embodiment of a device **310** for profiling the wall temperature of a hollow body organ. Device **310** can be deployed in a hollow body organ in the manner described above with respect to the embodiments of device **10** shown in **FIGS. 1 and 2** and described above. Components of device **310** that are similar in structure and function to corresponding components of device **10** of **FIGS. 1 and 2** are designated by like reference numerals in the 300 series but having the same last two digits. The description of device **10** above applies also to device **310** unless described otherwise below.

[0039] Device **310** of **FIG. 5**, rather than having externally exposed thermal sensors as in the embodiments of **FIGS. 1 through 4** above, includes a thermal sensor **50** disposed within the lumen **330** of hollow guidewire **316** and in thermal contact with the coiled wire **318** that comprises guidewire **316**. Thermal sensor **50** is located at a dogleg bend **52** that is spaced between bend **322** and the distal end of guidewire **316**. Guidewire **316** also includes bend **54** between bend **52** and the distal end of guidewire **316**. Bends **322, 52** and **54** together cause the distal portion of guidewire **316** to assume the shape of a question mark when in a relaxed configuration. In such a configuration, bend **52** and bend **54** contact opposite sides of the inner wall of the hollow body organ. The spring nature of guidewire **316** urges bend **52** in contact with the hollow body organ. Insulated electrical conductors **56** and **58** are operatively connected to the thermocouple or thermistor of thermal sensor **50** for conveying signals from the thermal sensor **50** to the proximal end of guidewire **316** for connection to appropriate signal processing apparatus that converts the signals to a temperature indication.

[0040] Device **310** of **FIG. 5** can be used in a manner substantially similar to the manner of use described above with respect to device **10** of **FIGS. 1 and 2**.

[0041] **FIG. 6** shows another embodiment of a device **410** for profiling the wall temperature of a hollow body organ. Device **410** is an alternative configuration of the device **310** of **FIG. 5**, in which bend **454** extends in a direction opposite to that of bend **54**, such that the terminal end portion of guidewire **416** extends axially away from catheter **412**. Bend **454** serves a purpose similar to that of bend **54** of device **310** of **FIG. 5**, i.e., to assure that bend **452**, at which thermal sensor **450** is located, remains in contact with the inner wall of the hollow body organ when deployed therein.

[0042] **FIG. 7** shows yet another embodiment of the present invention. Temperature sensing device **510** is carried by hollow guidewire **516** which extends outwardly from the distal end of catheter **512** and includes thermal sensor **550**, e.g., a thermistor at a dogleg bend **552** spaced from bend **522** which is situated between the sensor-carrying bend **552** and the distal end portion of catheter **512**. The distal end portion of guide wire **516** terminates in a generally crescent-shaped loop and is rotatable, continuously or continually, as desired, to sense the temperature of the endothelium **528** lining the wall of blood vessel **526** in the vicinity of plaque deposit **592**.

[0043] **FIG. 8** shows a further embodiment of a device **610** for profiling the wall temperature of a hollow body organ. Device **610** comprises another alternative configuration of the device **310** of **FIG. 5**, in which guidewire **616** is shaped as a plurality of loops **60** with a plurality of thermal sensors **62** located within guidewire **616** at each location along the loops **60** that would contact the wall of the hollow body organ when disposed therein.

[**0044**] **FIG. 9** shows yet another embodiment of a device **710** for profiling the wall temperature of a hollow body organ. Device **710** includes a lumened catheter **712** and a hollow guidewire **716**. The inner surface of lumen **730** of guidewire **716**, at a bend **742** similar to bend **42** of device **210** of **FIG. 4**, is lined with a layer of black paint **70** which is in turn lined with a thermochromic material **72** that is sensitive to a change of temperature of the guidewire **716**. The color of the thermochromic material **716** varies as a function of temperature.

[**0045**] Disposed within lumen **730** of guidewire **716**, inwardly of thermochromic material **72**, is an optical probe **74** including an illuminating optical fiber **76** having a radially emitting diffuser **78** at the distal end thereof, and a sensing optical fiber **80** having a conically beveled distal end **82** for collecting light. An illuminating electromagnetic radiation source connected to the proximal end of illuminating optical fiber **76** provides illuminating radiation that is guided by optical fiber **76** to the region of interest within the hollow body organ, and diffused radially by diffuser **78** to illuminate the interior of lumen **730**, particularly thermochromic material **72**. The illuminating radiation can be in the visible, infrared or ultraviolet portions of the spectrum. Radiation from diffuser **78** is differentially absorbed and reflected by thermochromic material **72**, according to the color of material **72** which is indicative of the temperature of guidewire **716** in contact with the wall of the hollow body organ in the region of interest.

[**0046**] The light reflected from thermochromic material **72**, having wavelengths indicative of the color thereof, is collected by distal end **82** and directed toward the proximal end of sensing optical fiber **80**. An appropriate optical reflectance spectrometry device connected to the proximal end of sensing optical fiber **80** generates an electrical signal indicative of the color, and therefore temperature, of thermochromic material **72**.

[**0047**] **FIG. 10** shows yet another embodiment of a device **810** suitable for profiling the impedance of the wall of a hollow body organ. Device **810** includes a catheter **812** within which is disposed a guidewire **816** having a dog-leg bend in the distal portion thereof. Device **810** is similar in configuration to the embodiment of device **210** of **FIG. 4**, and like components are indicated by like reference numerals in the 800 series but having the same last two digits. Unlike device **210** of **FIG. 4**, device **810** does not employ thermal sensing, but rather employs impedance sensing for profiling the wall of a hollow body organ. An electrode **90** at the outside of the dog-leg bend of guidewire **816** is in electrical contact with guidewire **816** and in electrical contact with the inner wall **828** of the hollow body organ **826**. Guidewire **816** comprises a conductor operatively connected to an external impedance measuring device that has a ground terminal electrically connected to the body in which the hollow body organ is located. A small electrical current is applied via guidewire **816** and electrode **90** to the inner wall **828** at the region of contact therebetween. The impedance of the electrical path through the body, including through the region of interest in the hollow body organ **826**, can be measured and recorded. By moving guidewire **816** relative to the hollow body organ **826** as described above with respect to other embodiments, the impedance of the wall of the vessel **826** can be mapped. Any change of impedance along the wall **828** indicates the presence of an anomaly in the wall, such as a plaque **92**.

[**0048**] 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 device for sensing the temperature profile of a hollow body organ, comprising:

a catheter having a longitudinal axis;

a hollow guidewire being disposable in a relaxed configuration externally of the catheter, and in a contracted configuration internally of the catheter; a temperature sensor connected to the guidewire and moveable therewith, the temperature sensor being displaced laterally relative to the longitudinal axis of the catheter when the guidewire is in the relaxed configuration.

2. The device of claim 1, wherein the hollow guidewire comprises a tubular helix.

3. The device of claim 1, wherein the hollow guidewire comprises a material having martensitic transformation properties.

4. The device of claim 3, wherein the hollow guidewire comprises nitinol.

5. The device of claim 1, wherein the hollow guidewire comprises an elastic material.

6. The device of claim 5, wherein the hollow guidewire comprises spring steel.

7. The device of claim 1, wherein the temperature sensor is a thermocouple.

8. The device of claim 7, wherein the temperature sensor comprises one leg of the thermocouple and the guidewire comprises another leg of the thermocouple.

9. The device of claim 1, wherein the temperature sensor is a thermistor.

10. The device of claim 1, wherein the temperature sensor comprises a thermochromic material.

11. The device of claim 10, wherein the thermochromic material is in thermal contact with the lumen of the hollow guidewire.

12. The device of claim 11, wherein the temperature sensor further includes an optical probe for sensing the color of the thermochromic material.

13. The device of claim 12, wherein the optical probe includes an illumination device for illuminating a region of interest of the hollow guidewire.

14. The device of claim 13, wherein the optical probe includes a sensing device for sensing reflected radiation from the thermochromic material.

15. The device of claim 14, wherein the reflected radiation is in the visible spectrum.

16. The device of claim 14, wherein the reflected radiation is in the infrared spectrum.

17. The device of claim 14, wherein the reflected radiation is in the ultraviolet spectrum.

18. The device of claim 1 wherein the temperature sensor is adapted for rotational displacement about the longitudinal axis of the catheter while in contact with the hollow body organ.

19. A device for sensing the impedance profile of a hollow body organ, comprising:

a catheter having a longitudinal axis;

a hollow guidewire being disposable in a relaxed configuration externally of the catheter, and in a contracted configuration internally of the catheter; an electrode connected to the guidewire and moveable therewith, the electrode being displaced laterally relative to the longitudinal axis when the guidewire is in the relaxed configuration.

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