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Published:
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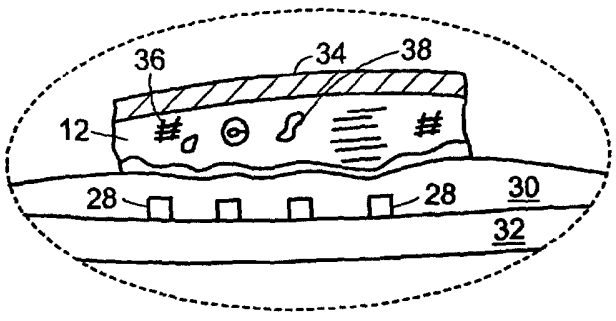
(54) Title: CATHETER WITH PIEZO ELEMENTS FOR LESION DIAGNOSTICS



(57) Abstract: Catheter lesion diagnostics are disclosed. In some embodiment, a diagnostic apparatus (2) includes an expandable catheter, comprising a catheter body (4) having an expandable portion (6), the expandable portion (6) including a plurality of spaced piozoelectric elements (28), and a controller (26) that controllably produces and receives a signal from elelments (28) of said plurality.

WO 03/030752 A1

CATHETER WITH PIEZO ELEMENTS FOR LESION DIAGNOSTICS

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority from U.S. provisional patent application serial no. 60/329,193, filed on October 12, 2001, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

This invention relates to catheter lesion diagnostics.

BACKGROUND

In an angioplasty procedure, a catheter carrying an inflatable balloon is threaded through a body lumen. The balloon is positioned at the location of a lesion which is occluding the lumen and inhibiting flow of body fluid. The balloon is inflated to apply a radial force about the lesion to force the lumen open. The balloon is then deflated and the catheter withdrawn from the body. A stent may be positioned at the location of the lesion, either simultaneously with the dilation or at a later time, to reduce the likelihood of reocclusion of the vessel.

SUMMARY

In one aspect, the invention features an expandable catheter including a catheter body having an expandable portion. The expandable portion has a plurality of spaced piezoelectric elements. A controller controllably produces and receives the signals from select elements of said plurality.

In another aspect, the invention features a balloon catheter. The balloon catheter includes a catheter body having an expandable polymeric balloon. The expandable balloon includes a first layer and a second layer, and the first layer has embedded therein a plurality of piezoelectric transducers.

In a further aspect, the invention features a method that includes providing a catheter having an expandable member thereon. The expandable member has a plurality of spaced piezoelectric elements. The method also includes locating the balloon in a vessel near a region of interest, and inflating the balloon. The invention

further includes launching an acoustic signal into the region of interest using a first piezoelectric element, and detecting the acoustic signal using a second piezoelectric element.

In another aspect, the invention features a medical having a piezoelectric element which is located in a lumen to position the piezoelectric element near a region of interest. Using the piezoelectric element, an acoustic signal is launched and/or received from the region of interest using the piezoelectric element. An acoustic signal from the region of interest is detected.

In another aspect, the invention features a member for delivery into a lumen including a piezoelectric member, and a controller for launching and/or receiving an acoustic signal into and/or from the lumen using the piezoelectric element. The controller analyzes acoustic signal from the region of interest to indicate a mechanical or morphological property below the surface of the region.

In aspects, the invention includes one or more of the following. The expandable member can be an inflatable balloon. The balloon can be substantially nondistendable. The balloon can include a generally cylindrical expandable portion, and the expandable portion can include the piezoelectric elements. The piezoelectric elements can be in a regular array. The piezoelectric elements can be disk shaped members. The piezoelectric elements can be embedded in a polymer layer. The polymer layer can have a thickness of about 0.005 inch or less. The balloon can include a first layer of non-distendable polymer selected from, for example, PET and/or nylon. The piezoelectric elements can be embedded in a second layer of a different polymer than the first layer. The second polymer layer can be an outer layer. The second layer can be more compliant than the first layer. The controller can produce an acoustic signal from a first piezoelectric element and receives the signal in another piezoelectric element. The signal can be received by multiple other piezoelectric elements. The catheter can include a stent positioned over the expandable member.

The signal is analyzed to indicate a mechanical or morphological property of tissue of the region, particularly below the surface of the region. Mechanical properties include density, impedance, or viscoelastic properties. The signal may be indicative of soft lipid or brittle plaque. A radial map of the property and/or an axial map of the property is provided. The medical device is an elongate flexible device. The device is delivered into the vascular system. The device includes an inflatable balloon. The

piezoelectric element is embedded in a polymer. The medical device includes a plurality of piezoelectric elements. The signal is detected after dilation of the region and/or during dilation of the region. A stent in the region includes a drug.

In additional aspects, the invention features embodiments including a wire and/or a catheter having piezoelectric elements controlled as described herein.

Further aspects involve combinations of embodiments.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

We first briefly describe the drawings.

FIGs. 1A and 1B are schematics of a diagnostic catheter in a body lumen, while FIG. 1C is an expanded cross-sectional view of the region C, in FIG. 1B;

FIG. 2A is a schematic of an array of piezoelectric elements in proximity to a lesion feature, while FIG. 2B is a graph illustrating acoustic signal generation and sensing from FIG. 2A; and

FIGs. 3A-3D illustrate construction of a diagnostic catheter.

DETAILED DESCRIPTION

Referring to FIGs. 1A and 1B, a diagnostic catheter system 2 includes a catheter body 4 carrying near its distal end an expandable member 6, in this case an expandable balloon. The catheter can be delivered into a vessel 7 by sliding it over a guidewire 8 to locate the expandable member 6 near a lesion 12 which is partially occluding the vessel lumen. Referring particularly to FIG. 2B, the expandable member is expanded to position the outer surface of the expandable member in close proximity, e.g., into contact with, the outer surface of the lesion. As illustrated, the proximal end of the catheter includes fitting 14 with a port 16 that accesses an internal catheter lumen which directs inflation fluid between an inflator 18 to the interior of the expandable member. A port 20 communicates with an internal catheter lumen opening at the catheter distal end to facilitate delivery over the guidewire 8. A port 22 includes a

communication conduit 24 which is connected between a controller 26 and piezoelectric diagnostic apparatus associated with the expandable member.

Referring particularly to FIG. 1C, the diagnostic apparatus includes an array of piezoelectric elements 28 carried by the expandable member 6. The elements 28 are spaced at regular intervals and, in this embodiment, are embedded within an outer layer 30 of the wall structure of the balloon, which also includes an inner layer 32. The inner layer 32 may be, for example, a relatively noncompliant material, such as polyethylene terephthelate, so that the relative position of the elements 28 in the array region remain substantially constant as a function of inflation pressure. The outer layer 30 may be a more compliant material, such as Hytrel, selected to generally conform to the outer surface of the lesion and/or have a desired acoustic impedance. The piezoelectric elements are operated to diagnose the nature of the lesion 12.

As illustrated, the lesion 12 is a deposit on the vessel wall 34. The lesion is generally not homogenous. For example, it may include heavily calcified, brittle regions 36 intermixed as a function of depth and axial positions with more compliant lipid pools 38. The presence, amount, and location of such regions can affect the angioplasty procedure. The success of the angioplasty procedure and the likelihood of reocclusion can be dependent upon the nature of the lesion. For example, in blood vessels, the lesion is typically in the form of plaque, which can be made of disparate components such as hard, calcified deposits and/or softer lipid deposits. Some lesions are not safely dilated because they may rupture and release particles into the blood stream. For example, a concentration of brittle calcified material can crack and break off upon compression.

Referring as well to FIG. 2A, the piezoelectric elements work in coordination to diagnose such features. A portion of the array, elements A and S1-S5, is illustrated about a region 40, which may be, for example, a lipid pool located within a more brittle plaque matrix. The element A is operated to launch an acoustic signal into the plaque, while elements S1-S5 are operated to receive the signal. Referring as well to FIG. 2B, the signal A, having a desired signal shape is launched at a time t_1. The elements S1-S5 detect this signal after it propagates through the lesion. The timing and shape of the signal varies as a function of the location of each element and acoustic impedance of the structures encountered by the acoustic pulse due to reflection and refraction of the signal. As a result, by analyzing the wave shape and timing of multiple pulses from

multiple elements, an axial and radial spatial map of the acoustic features and hence the composition of the lesion can be determined. The map can, for example, be compared with standard lesion brittleness patterns to determine the desired conditions for angioplasty, whether a stent should be inserted, or whether angioplasty is not suitable.

Acoustic diagnostics can be used to interrogate the mechanical material properties. The diagnostics can be passive or active. Active diagnostics involve launching a controlled signal into the material and determining the mechanical properties from reflections and from refractions of the signal deep within the material as the wave encounters structures having different acoustic impedances. Passive diagnostics involves detecting acoustic waves as the material responds to normal stress. One system utilized for diagnostics of composite construction materials is the Stanford Multi-Actuator Receiver Transduction (SMART) layer. The SMART layer is a dielectric film carrying a distributed network of piezoelectric elements that serve as both sensors and actuators. The layer is integrated with a composite structure. In active mode, some of the disks are operated in an actuator mode to launch acoustic wave signals into the material, while other disks are utilized as sensors to detect the signals. In the passive mode, multiple disks act as sensors to detect stress response. The piezoelectric elements 28 are preferably small ceramic units, e.g., of PZT. A suitable unit is used in the SMART layer system, which has an array of disk shaped PZT elements having a diameter of desired size (e.g., about 0.25 inch, less than about 0.25 inch, less than about 0.125 inch). The disks may be embedded in a polymer film having a thickness of about 0.002 inches. Such films may be bonded directly to the interior or exterior of a medical balloon. Alternatively, the array is incorporated into the balloon during balloon manufacture.

The construction and control of a piezoelectric array for diagnosing and monitoring material properties is further discussed in F.K. Chang, Materials Today, Vol. 2, Issue 2, June 1999; F.K. Chang, "Manufacturing and Design of Built-In Diagnostics for Composite Structures," Progress Report to the U.S. Army Research Office P00001, 1997; M. Lin and F.K. Chang, "Development of SMART Layers for Built-in Diagnostics for Composite Structures," The 13th Annual ASC Technical, 1998; M. Tracy, "Impact, Load Identification for Composite Plates Using Distributed Piezoelectric Sensors," Ph.D. dissertation, Department of Aeronautics, Stanford University, 1996; M. Tracy and F.K. Chang, "Identifying Impact Load in Composite

Plates Based on Distributed Piezo-sensors," The Proceeding of SPIE Smart, CA 1996; Y.S. Rah, "Built-In diagnostics for Identifying an Anomaly in Plates using Wave Scattering," Ph.D. Dissertation, Department of Aeronautics, Stanford University; M. Lin, "Manufacturing of composite Structures with a Built-In Network of Pizeoceramics," Ph.D. Dissertation, Department of Mechanical Engineering, Stanford University, the entire contents of each of which is incorporated herein by reference. The piezoelectric members typically induce a signal in the ultrasonic range, e.g. in the 100-300 kHz range. Operation and data analysis is further described, for example, in "Damage Detection and Diagnosis of Composites Using Built-In Piezoceramics," C.H. Keilers and F.-K. Chang, Proceedings S.P.I.E. The International Society for Optical Engineering, Issue 1917, pp. 1009-1019 (1993), the entire contents of which is hereby incorporated by reference.

Referring to FIGS. 3A-3D, a balloon may be formed by extruding a tube 50 of a desired balloon polymer or polymers. The tube is then patterned with an array of piezoelectric elements 52. The pattern is located on the portion of the tube that will become the expandable portion of the balloon. The elements may be fixed to the tube using an adhesive, friction fit, or surface melting. A series of communication conduits 53, e.g., metal or conductive polymer wires are connected to the elements.

Referring particularly to FIG. 3B, the tube 50 carrying the array is next coated with an outer polymer layer 54. The coating may be done by dipping. Alternatively, the outer layer 54 is provided by extruding the polymer over the tube 50. The extrusion is carried out using a die having an annular opening through which the polymer is extruded and a central opening within the annulus, through which the tube 50 is drawn. The ends of the communication conduits 53 extend beyond the tube.

Referring particularly to FIG. 3C, the multilayer tube is blown into a balloon by free blowing or mold forming. In the case of a balloon including biaxially oriented layers, the tube is heated while the ends of the tube are drawn axially (arrows 56) and the interior is pressurized to radial expand (arrows 58) the central portion of the tube including the element array. Multilayer coextrusion of medical balloons is described in USSN 09/798,749, filed March 2, 2001, the entire contents of which is incorporated herein by reference. Balloon-forming is discussed in USSN 09/950,195, filed September 10, 2001, the entire contents of which is incorporated herein by reference.

Referring as well to FIG. 3D, the balloon is attached to the catheter body by bonding balloon sleeves using, e.g., an adhesive or melt bonding. The communication conduit is directed through the catheter sidewall into a lumen 60. The lumen opening is covered by epoxy 62.

As discussed above, the balloon may be a noncompliant balloon including a layer of non-distandable polymer, such as PET or the like. Alternatively, the balloon may be a compliant balloon that stretches upon expansion. In this case, the balloon can closely conform to larger irregular lesion or vessel features to position a large number of the elements close to the feature. The balloon is preferably a multilayer balloon. The multilayer balloon may include more than the two layers above. For example, the balloon may include an outer layer in which the piezoelectric elements are embedded, a middle layer that provides high tensile strength and low distentibility an inner layer that provides a desired acoustic function, such as absorption or reflection of acoustic energy emitted by the element that is directed back toward the catheter. The middle and the inner layer may be formed by coextruding the initial tube. In embodiments, multiple layers may be provided over the piezoelectric elements to, e.g., provide desirable acoustic properties. For example, a hydrophilic layer (e.g., a hydrogel) may be provided to enhance transmission through blood or water. The balloon and catheter can be sized for the target vessel. For example, for blood vessels, the balloon has a length of about 3 to 10 cm and an inflated diameter of about 3 to 15 mm.

The analysis of the acoustic signals can be carried out in various ways to interrogate the mechanical properties. For example, the refraction and reflection of signals can yield a density or acoustic impedance map of the lesion structures. Alternatively, an average density, compliance measure, or acoustic impedance can be determined and compared to standard values based on historical angioplasty data. The devices to may be operated as multiple transducers that can be used to measure certain properties (e.g., viscoelastic properties) of a lesion in a body lumen. The balloon is typically expanded to place the elements in close proximity to or in contact with the lesion. But the balloon can be expanded to pressurize the lesions and diagnosis may be carried out as a function of pressure. Dilation of the vessel can be carried out by the diagnostic balloon catheter by inflating to dilation pressures. Diagnosis can be conducted before and after dilation. In addition, pressure can be monitored across the array during dilation by operating the elements in a passive mode. In addition, a stent

or stent graft can be positioned over the balloon and placed by the catheter. The transducer can be operated in a receiving mode to monitor the force on the ends of the stent compared to the center or the stent. The system can be useful in drug delivery. For example, the insertion of drugs into the lesion can be monitored by monitoring acoustic impedance changes in the lesion. Drug delivery can be accomplished with a drug coated balloon or a drug coated stent. Drug delivery is described in Sahatjian et al., U.S. Patent No. 5,954,706, the entire contents of which is incorporated herein by reference. In addition, the piezoelectric elements can be arranged in an asymmetric pattern.

While certain embodiments of balloons are described above, the piezoelectric elements can be applied to other medical devices that can be used in body lumens (e.g., blood vessels) to evaluate the lumens (e.g., by measuring one or more characteristics of an aspect of the lumen, such as the viscoelastic properties of a lesion). As an example, piezoelectric elements can be used in conjunction with (e.g., by integrally forming with) a wire. In certain embodiments, such a wire can be used with a relatively narrow vessel, such as one in which the wire can be adjacent to (e.g., in direct contact with) a lumen lesion.

As another example, piezoelectric elements can be used in conjunction with (e.g., by integrally forming with) a nonexpendable catheter. In certain embodiments, such a catheter can be used with a relatively narrow vessel, such as one in which the catheter can be adjacent to (e.g., in direct contact with) a lumen lesion.

Moreover, the devices disclosed can be used, for example, in diagnostics for various types of lesions. An exemplary and nonlimiting list of such lesions includes clots, hard plaque, soft plaque, refractory plaque and/or solid plaque. The lesions can be located in any body lumen of interest, including, for example, neuro lumens, carotid lumens and/or coronary lumens.

In addition, in some embodiments, the medical devices and systems can be designed so that the information of interest can be accessed remotely. For example, the system can be configured so that the signal sent to the controller is wireless.

Further embodiments are in the claims.

WHAT IS CLAIMED IS:

1. An expandable catheter, comprising

a catheter body having an expandable portion, the expandable portion including a plurality of spaced piezoelectric elements, and

a controller that controllably produces and receives signal from elements of said plurality.

2. The system of claim 1 wherein the expandable member is an inflatable balloon.

3. The system of claim 2 wherein the balloon is substantially nondistendable.

4. The system of claim 3 wherein the balloon includes a generally cylindrical expandable portion and the expandable portion includes said piezoelectric elements.

5. The system of claim 4 wherein the piezoelectric elements are in a regular array.

6. The system of claim 5 wherein the piezoelectric elements are disk shaped members.

7. The system of claim 6 wherein the piezoelectric elements are embedded in a polymer layer.

8. The system of claim 7 wherein the polymer layer has a thickness of about 0.005 inch or less.

9. The system of claim 3 wherein the balloon includes a first layer of non-distendable polymer.

10. The system of claim 9 wherein the piezoelectric elements are embedded in a second layer of a different polymer than the first layer.

11. The system of claim 10 wherein the second polymer layer is an outer layer.

12. The system of claim 11 wherein the second layer is more compliant than the first layer.

13. The system of claim 1 wherein the controller produces an acoustic signal from a first piezoelectric element and receives the signal in another piezoelectric element.

14. The system of claim 13 wherein the signal is received by multiple other piezoelectric elements.

15. The system of claim 1 including a stent positioned over said expandable portion.

16. A balloon catheter, comprising

a catheter body having an expandable polymeric balloon, the expandable balloon including a first layer and a second layer, the first layer including embedded therein a plurality of piezoelectric transducers.

17. A method, comprising

providing a medical instrument having a piezoelectric element,

locating the medical device in a lumen to position the piezoelectric element near a region of interest,

launching and/or receiving an acoustic signal into and/or from the region of interest using the piezoelectric element,

detecting an acoustic signal from the region of interest, and

determining a mechanical property of the region of interest.

18. The method of claim 17 comprising analyzing the signal to indicate a mechanical or morphological property of tissue below the surface of the region.

19. The method of claim 18 comprising providing a radial map of said property.

20. The method of claims 18 or 19 comprising providing an axial map of said property.

21. The method of claim 17 wherein the medical device is an elongate flexible device.

22. The method of claim 21 comprising delivering the device into the vascular system.

23. The method of claim 17 wherein the medical device includes an inflatable balloon.

24. The method of claim 17 wherein the piezoelectric element is embedded in a polymer.

25. The method of claim 17 comprising wherein the medical device includes a plurality of piezoelectric elements.

26. The method of claim 17 comprising detecting said signal after dilation of the region.

27. The method of claim 17 comprising detecting said signal during dilation of said region.

28. The method of claim 17 comprising providing a stent in said region.

29. The method of claim 27 wherein the stent includes a drug.

30. A medical device, comprising

a member for delivery into a lumen including a piezoelectric member, and

a controller for launching and/or receiving an acoustic signal into and/or from the lumen using the piezoelectric element, the controller analyzing acoustic signal from the region of interest to indicate a mechanical or morphological property below the surface of the region.

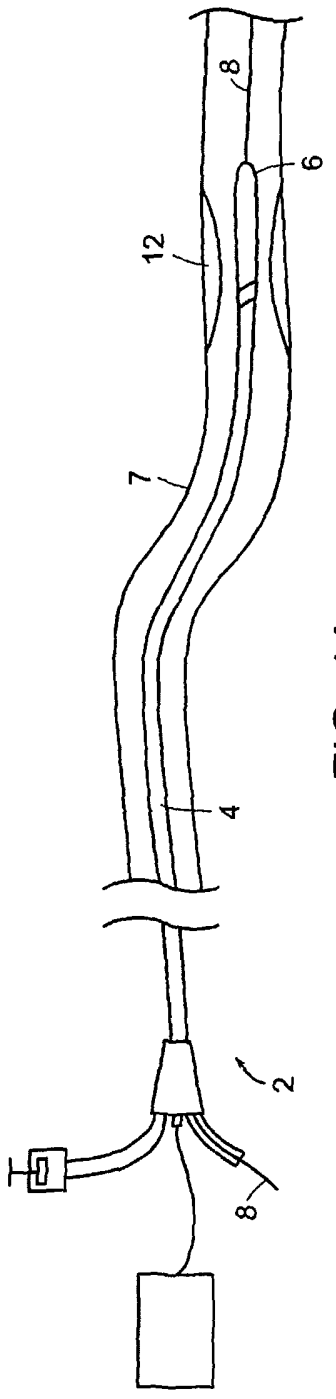


FIG. 1A

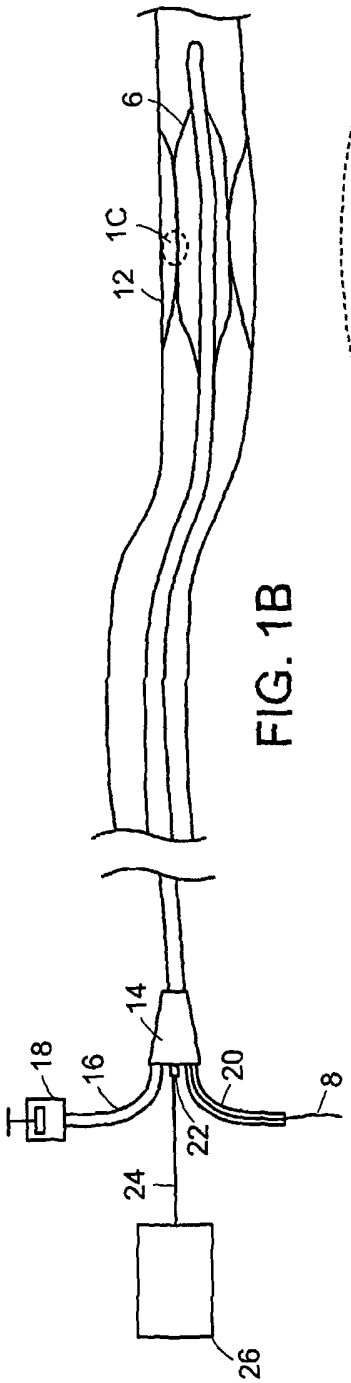


FIG. 1B

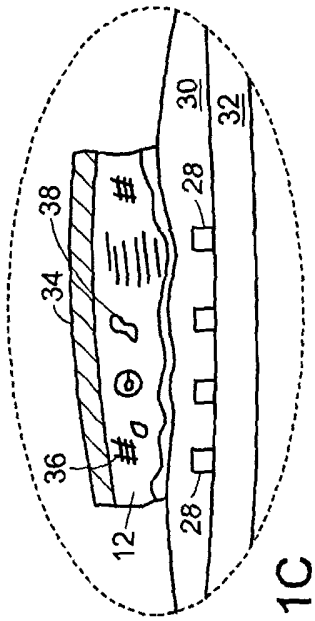


FIG. 1C

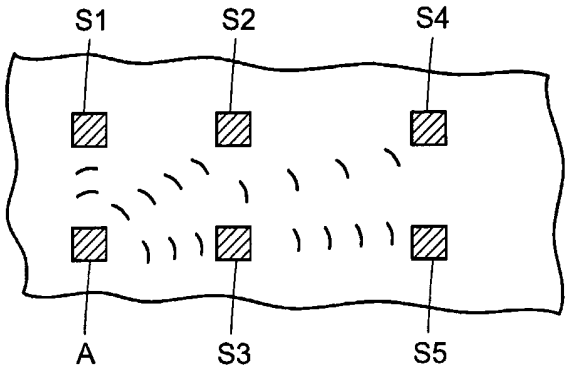


FIG. 2A

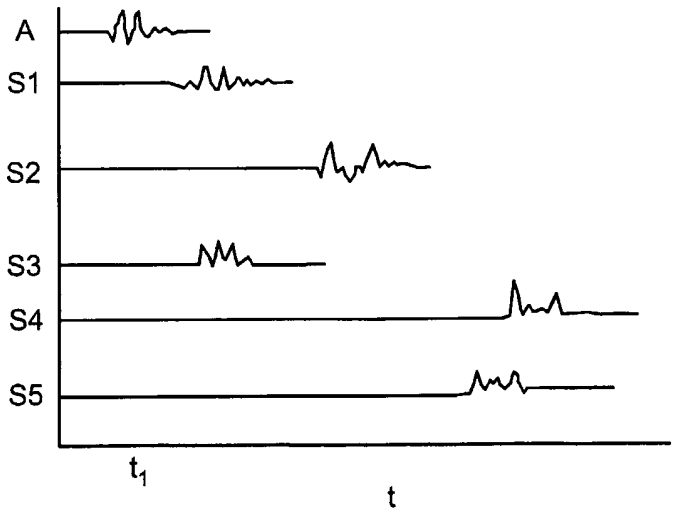


FIG. 2B

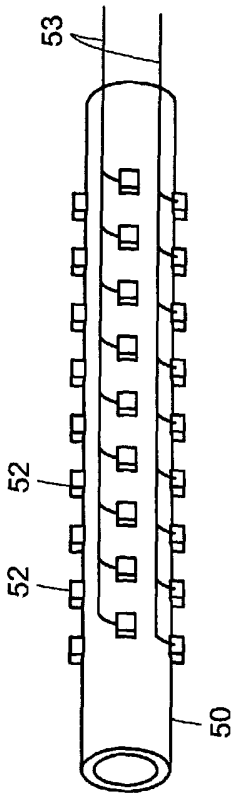


FIG. 3A

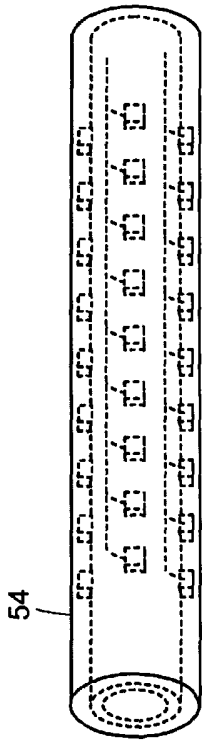


FIG. 3B

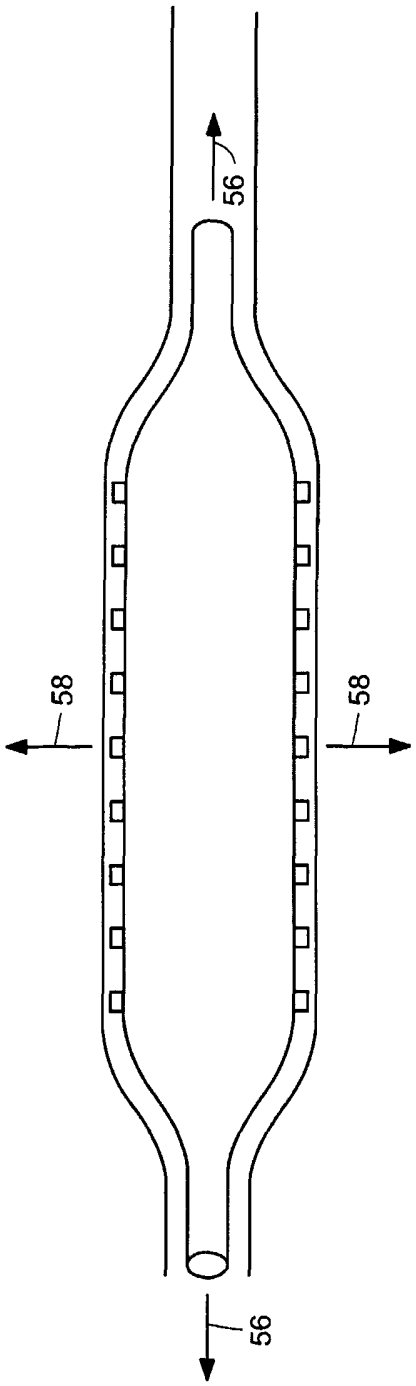


FIG. 3C

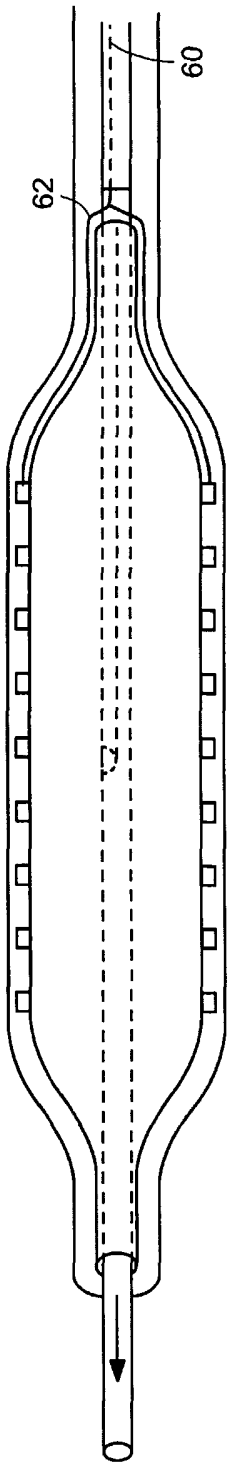


FIG. 3D

INTERNATIONAL SEARCH REPORT

In ial Application No
PCT/US 02/32516

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/22 A61M25/00 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 843 275 A (RADICE PETER F) 27 June 1989 (1989-06-27) column 2, line 58 -column 3, line 20; figures 1-7	1-14
X	US 5 443 495 A (BILGE FERTAC ET AL) 22 August 1995 (1995-08-22) column 6, line 31 - line 38; figures 1-10 column 3, line 39 - line 60; figures 4,6	1-16,30
A	WO 99 58059 A (SPIVAK VICTOR ;VARDI GIL M (US)) 18 November 1999 (1999-11-18) page 5, line 24; figure 2	1
A	US 5 840 031 A (CROWLEY ROBERT J) 24 November 1998 (1998-11-24) column 8, line 11 - line 20; figure 5	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 December 2002	27/12/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ehrsam, F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

In nal Application No
PCT/US 02/32516

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 611 807 A (O'BOYLE MATTHEW) 18 March 1997 (1997-03-18) abstract -----	1

national application No.
PCT/US 02/32516

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-29
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Int onal Application No
PCT/US 02/32516

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