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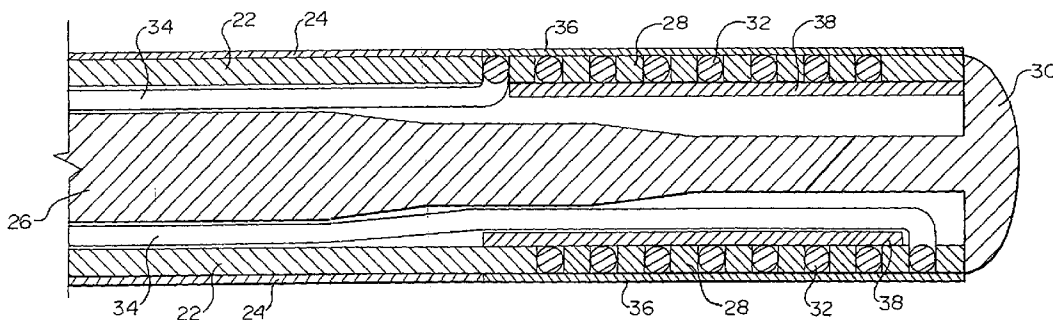
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(54) Title: GUIDE WIRE WITH ADJUSTABLE FLEXIBILITY



(57) Abstract: A guide wire with a distal portion having adjustable flexibility. The guide wire may include a distal polymeric member and a heat source. The heat source may be activated to cause the polymeric member to increase in temperature and increase in flexibility. The increase in flexibility of the distal portion of the guide wire enhances the ability of the guide wire to navigate tortuous vasculature to a target site. After the guide wire has been navigated to the target site, the heat source may be deactivated to cause the polymeric member to decrease in temperature and increase in stiffness. The increase in stiffness of the distal portion of the guide wire enhances support provided for devices (e.g., catheters) advanced thereon.



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GUIDE WIRE WITH ADJUSTABLE FLEXIBILITY

Field of the Invention

The present invention generally relates to intravascular guide wires. In particular, the present invention relates to intravascular guide wires having adjustable flexibility.

Background of the Invention

Intravascular guide wires are often used to facilitate the delivery of therapeutic and diagnostic devices to remote vascular sites in the human body. In particular, intravascular guide wires are used to navigate through a patient's vasculature from a convenient location outside the patient's body, to a target site inside the patient's body requiring diagnosis and/or therapy. Once access to the target site has been provided by the guide wire, a therapeutic or diagnostic device (e.g., catheter) may then be advanced over the guide wire to the target site, and the desired therapeutic or diagnostic steps may be performed.

To facilitate navigation in tortuous vasculature, it is desirable that the guide wire have a relatively flexible distal end. To provide good support for devices advanced over the guide wire, it is desirable that the guide wire have a relatively stiff distal end. Conventional guide wires typically address these competing needs by establishing a compromise in flexibility and stiffness. However, it would be desirable to have a guide wire that does not compromise these competing needs.

Summary of the Invention

To address these needs, the present invention provides, in one exemplary embodiment, a guide wire that has a distal portion with adjustable flexibility. In one example, the guide wire includes a distal polymeric member and a heat source. The heat source may be activated by a power supply, which causes the polymeric member to increase in temperature, to thereby increase the flexibility of the distal portion of the guide wire. The polymeric member may comprise a shape memory polymer having a glass transition temperature, wherein the increase in temperature is across the glass transition temperature.

The increase in flexibility of the distal portion of the guide wire enhances the ability of the guide wire to navigate vasculature of varying degrees of tortuosity.

After the guide wire has been navigated to the target site, the heat source may be deactivated, which causes the polymeric member to decrease in temperature, to thereby increase the stiffness of the distal portion of the guide wire and provide enhanced support for devices advanced thereon.

5

Brief Description of the Drawings

Figure 1 is a plan view of a guide wire system, including a guide wire, a controller/power source and a coupling/lead therebetween, in accordance with an exemplary embodiment of the present invention; and

10 Figure 2 is a longitudinal cross-sectional view taken along line 2 – 2 in Figure 1, illustrating in detail the distal portion of the guide wire shown in Figure 1.

Detailed Description

The following description should be read with reference to the drawings
15 wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings illustrate embodiments by way of example, not limitation.

Refer now to Figure 1 which illustrates a guide wire system in accordance with an exemplary embodiment of the present invention. The guide wire system
20 includes a guide wire 10 connected to a controller and power source 50 by a coupling 40 and lead 60.

Guide wire 10 includes an elongate shaft 12 having a proximal portion 14 and a distal portion 16. Distal portion 16 includes a soft atraumatic tip 18. The proximal portion 14 of the shaft 12 is relatively stiff to provide pushability and torquability, and
25 the distal portion 16 has adjustable flexibility to provide trackability in navigating tortuous vasculature and support for devices advanced thereover.

Except as described herein and implicit in the drawings, the guide wire 10 may have conventional dimensions and may be formed of conventional materials using conventional techniques known for intravascular guide wires used to navigate the
30 human vasculature to remote locations including, but not limited to, the neurovasculature, the coronary vasculature, and the peripheral vasculature.

As will be discussed in more detail with reference to Figure 2, the distal portion 16 of the guide wire 10 includes a heat source that is thermally connected to a

polymeric member that increases in flexibility when heated, and increases in stiffness (e.g., returns to its nominal flexibility or stiffness at body temperature) when cooled. Thus, by activating or deactivating the heat source, the flexibility of the polymeric member, and thus the flexibility of the distal portion 16, may be adjusted. For example, the flexibility of the distal portion 16 may be increased by activating the heat source, which enhances the ability of the guide wire 10 to navigate tortuous vasculature to a target site. After the guide wire 10 has been navigated to the desired target site, the heat source may be deactivated to cause the distal portion 16 to increase in stiffness, which enhances guide wire 10 support provided for devices (e.g., catheters) advanced thereon.

To control activation and deactivation of the heat source, a controller/power supply 50 is connected by lead 60 to a coupling 40 which is releasably and rotatably connected to the proximal portion 14 of the guide wire shaft 12. Controller/power supply 50 may comprise a conventional power supply with conventional control circuitry to provide a constant or modulated AC or DC signal. The signal is transmitted by lead 60, which may comprise two (or more) conductors. The conductors in the lead 60 may be connected to leads in the shaft 12 of the guide wire by coupling 40. Coupling 40 may be removable to permit devices such as catheters to be advanced over the proximal end of the guide wire 10. Coupling 40 may also be rotatable to permit the guide wire to be rotated and steered during intravascular navigation.

Refer now to Figure 2 which illustrates in detail certain aspects of the distal portion 16 of the guide wire 10, which may be in common with certain aspects of the proximal portion 14. As seen in Figure 2, the shaft 12 includes a hypotube 22 which may comprise, for example, stainless steel or a super elastic metal such as a nickel titanium alloy, Nitinol, MP35N, Inconel, etc. The hypotube 22 may extend from the proximal end of the guide wire shaft 12, and may include an outer sleeve 24 comprising a polymer such as polyurethane. A tapered core wire 26 may extend through the lumen in the hypotube 22, and may comprise stainless steel or a super elastic metal such as a nickel titanium alloy, Nitinol, MP35N, Inconel, etc. The distal end of the hypotube 22 in the region of the distal tip 18 may be helically slotted 28 to enhance flexibility. The distal end of the core wire 26 may be welded to the distal end of the slotted portion 28 of the hypotube 22 to form an atraumatic weld ball 30.

As mentioned previously, the distal portion 16 of the guide wire shaft 12 includes a heat source. In this particular example, the heat source comprises a resistive element 32. Resistive element 32 may comprise a tungsten or steel alloy that may be formed into a coil and heated by electro-resistive heating. Heater coil 32 may
5 be disposed between adjacent turns in the slotted portion 28 of the hypotube 22. The resistive heater coil 32 is connected to insulated leads 34 which may be disposed in the lumen of the hypotube 22 around the core wire 26. Leads 34 are connected to coupling 40, which in turn is connected to controller/power supply 50 via lead 60.

A polymeric outer tube 36 may be disposed about the resistive heater coil 32,
10 and a polymeric inner tube 38 may be provided to support the heater coil 32. The polymeric outer tube 36 and/or the polymeric inner tube 38 may be formed of a polymer that changes in stiffness when heated. For example, the polymeric outer tube 36 and/or the polymeric inner tube 38 may be formed of a polymer that is relatively stiff at temperatures at or below body temperature (37°C or less) and relatively
15 flexible at temperatures above body temperature. For example, a polymer may be selected with a glass transition temperature (T_g) that is above body temperature, such that heating the polymer above T_g results in the distal portion 16 of the guide wire 10 becoming relatively more flexible, and cooling the polymer below T_g , even when the guide wire 10 is disposed in the patient's body, results in the distal portion 16 of the
20 guide wire 10 becoming relatively more stiff. In a preferred embodiment, the polymeric outer tube 36 and/or the polymeric inner tube 38 may be formed of a shape memory polymer (SMP) such as a shape memory polyurethane available from Mitsubishi. Other examples of suitable SMPs include polynorbornenes, polycaprolactones and copolymers thereof available from Pnemoscience. Some
25 SMPs, such as polynorbornene, may change flexibility without changing temperature across T_g . Such SMPs may be above T_g at room temperature or body temperature, and may exhibit SMP characteristics at or near the melt temperature (T_m).

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size,
30 arrangement of parts and order of steps without departing from the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A variable stiffness guide wire, comprising:
a guide wire shaft having a proximal portion and a distal portion, the distal portion having a flexibility;
a polymeric member disposed on the distal portion of the shaft, the polymeric member having a first flexibility at a first temperature and a second flexibility at a second temperature, wherein the first temperature is less than the second temperature and the first flexibility is less than the second flexibility; and
a heat source disposed on the distal portion of the shaft, the heat source being in thermal communication with the polymeric member, whereby activation of the heat source causes the polymeric member to rise from the first temperature to the second temperature to thereby change the flexibility of the distal portion of the guide wire.
2. A variable stiffness guide wire as in claim 1, wherein the polymeric member comprises a shape memory polymer.
3. A variable stiffness guide wire as in claim 2, wherein the shape memory polymer has a glass transition temperature, and wherein the first temperature is below the glass transition temperature.
4. A variable stiffness guide wire as in claim 3, wherein the second temperature is above the glass transition temperature.
5. A variable stiffness guide wire as in claim 1, wherein the heat source comprises a resistive heating element.
6. A variable stiffness guide wire as in claim 5, wherein the distal portion of the shaft includes a tip portion.
7. A variable stiffness guide wire as in claim 6, wherein the tip portion includes the polymeric member and resistive heating element.

8. A variable stiffness guide wire as in claim 7, wherein the polymeric member comprises a tube.
9. A variable stiffness guide wire as in claim 8, wherein the resistive heating element comprises a coiled wire.
10. A variable stiffness guide wire as in claim 9, further comprising one or more lead wires connected to and extending proximally from the coiled wire.
11. A variable stiffness guide wire as in claim 10, wherein the polymeric tube is disposed on the coiled wire.
12. A variable stiffness guide wire as in claim 11, wherein a core wire extends through the tip portion.
13. A variable stiffness guide wire as in claim 12, wherein the proximal portion of the guide wire shaft includes a hypotube.
14. A variable stiffness guide wire as in claim 13, wherein the distal portion of the guide wire shaft includes a slotted hypotube.
15. A variable stiffness guide wire as in claim 14, wherein the coiled wire is disposed in the slots of the slotted hypotube.
16. A variable stiffness guide wire, comprising:
 - a guide wire shaft including a proximal portion and a distal portion having a flexibility;
 - a polymeric member disposed on the distal portion of the shaft; and
 - a heat source in thermal communication with the polymeric member, whereby activation of the heat source causes the polymeric member to change the flexibility of the distal portion of the guide wire shaft.

17. A variable stiffness guide wire as in claim 16, wherein the polymeric member comprises a shape memory polymer.

18. A variable stiffness guide wire as in claim 17, wherein activation of the heat source causes the shape memory polymer to change temperature.

19. A variable stiffness guide wire as in claim 18, wherein the shape memory polymer has a glass transition temperature, and wherein the change in temperature is across the glass transition temperature.

20. A variable stiffness guide wire as in claim 18, wherein the shape memory polymer has a glass transition temperature, and wherein the change in temperature is near the melt temperature.

21. A variable stiffness guide wire as in claim 16, wherein the heat source comprises a resistive heating element.

22. A variable stiffness guide wire as in claim 21, wherein the distal portion of the shaft includes a tip portion.

23. A variable stiffness guide wire as in claim 22, wherein the tip portion includes the polymeric member and resistive heating element.

24. A variable stiffness guide wire as in claim 23, wherein the polymeric member comprises a tube.

25. A variable stiffness guide wire as in claim 24, wherein the resistive heating element comprises a coiled wire.

26. A variable stiffness guide wire as in claim 25, further comprising one or more lead wires connected to and extending proximally from the coiled wire.

27. A variable stiffness guide wire as in claim 26, wherein the polymeric tube is disposed on the coiled wire.

28. A variable stiffness guide wire as in claim 27, wherein a core wire extends through the tip portion.

29. A variable stiffness guide wire as in claim 28, wherein the proximal portion of the guide wire shaft includes a hypotube.

30. A variable stiffness guide wire as in claim 29, wherein the distal portion of the guide wire shaft includes a slotted hypotube.

31. A variable stiffness guide wire as in claim 30, wherein the coiled wire is disposed in the slots of the slotted hypotube.

32. A variable stiffness guide wire system, comprising:
a guide wire including a distal portion having a flexibility, a distal polymeric member, and a heat source in thermal communication with the polymeric member;
and
a power supply connected to the heat source, whereby activation of the heat source by the power supply causes the polymeric member to change the flexibility of the distal portion of the guide wire.

33. A method of using a variable stiffness guide wire, comprising the steps of:
providing a guide wire including a distal portion having a flexibility, a distal polymeric member, and a heat source in thermal communication with the polymeric member; and
changing the flexibility of the distal portion of the guide wire by activating or deactivating the heat source.

34. A method of using a variable stiffness guide wire as in claim 33, wherein the flexibility changing step comprises activating the heat source to increase the flexibility of the distal portion of the guide wire, the method further comprising the step of navigating the guide wire through a patient's vasculature to a target site.

35. A method of using a variable stiffness guide wire as in claim 34, further comprising the step of deactivating the heat source to decrease the flexibility of the distal portion of the guide wire.

36. A method of using a variable stiffness guide wire as in claim 35, further comprising the step of advancing a device over the guide wire to the target site.

37. A method of using a variable stiffness guide wire as in claim 33, wherein the polymeric member comprises a shape memory polymer having a glass transition temperature, and wherein the flexibility changing step comprises heating the polymeric member near the melt temperature.

38. A method of using a variable stiffness guide wire as in claim 33, wherein the polymeric member comprises a shape memory polymer having a glass transition temperature, and wherein the flexibility changing step comprises heating the polymeric member above the glass transition temperature.

39. A method of using a variable stiffness guide wire as in claim 33, wherein the heat source comprises a resistive heating element, and wherein the activating step comprises supplying electrical energy to the resistive heating element.

Fig. 1

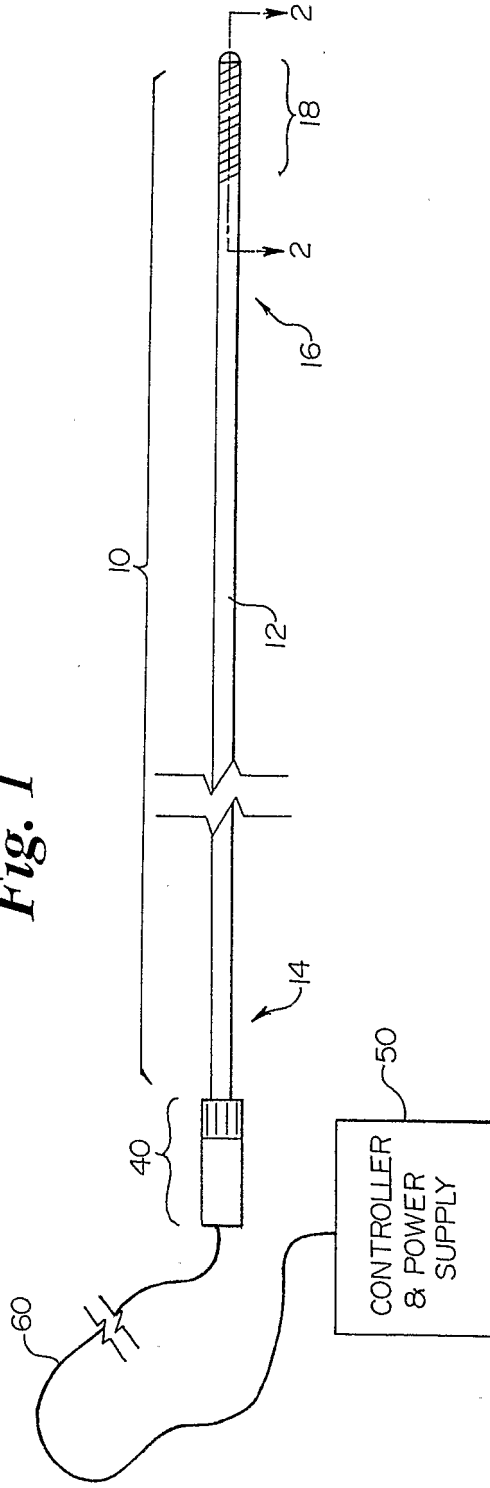
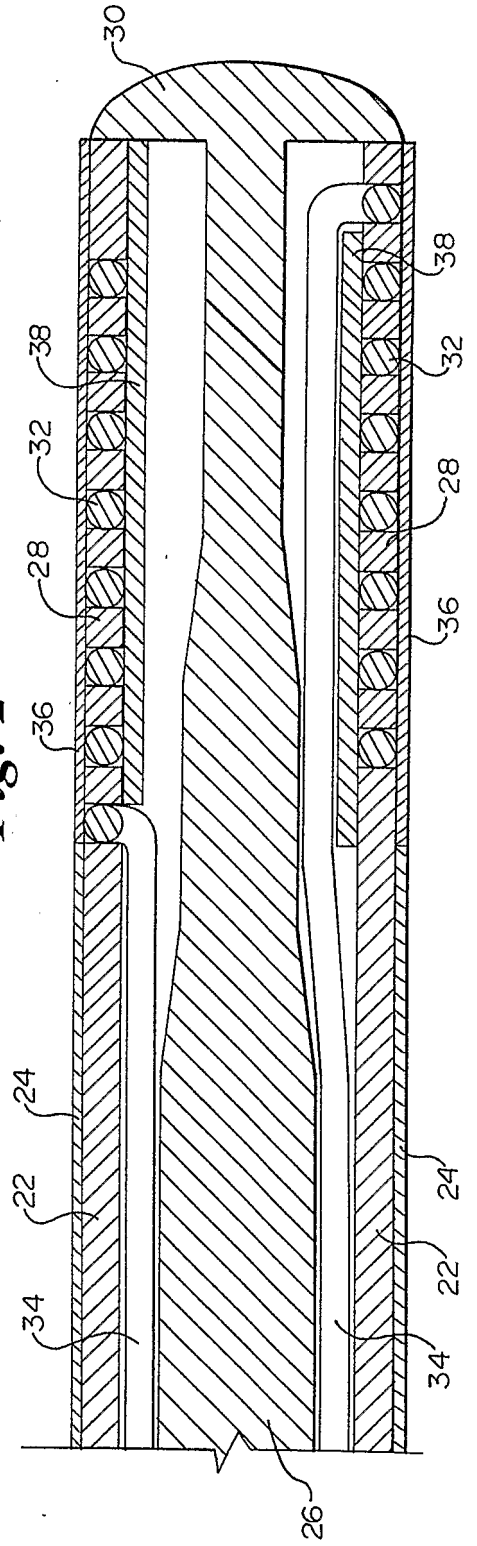


Fig. 2



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/30771

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/01

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 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 5 349 946 A (MCCOMB R CARTER) 27 September 1994 (1994-09-27) column 1, line 15,16 ---	1,5-8, 16, 21-24,32
A	US 5 957 966 A (SCHROEPEL EDWARD A ET AL) 28 September 1999 (1999-09-28) column 5, line 46 -column 6, line 21 ---	2-4, 17-19
A	US 2001/039412 A1 (FARIABI SEPEHR) 8 November 2001 (2001-11-08) the whole document ---	1-32
A	US 5 938 623 A (QUIACHON DIGNAH B ET AL) 17 August 1999 (1999-08-17) the whole document ---	1-32
	-/--	

Further documents are listed in the continuation of box C.

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
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- *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.
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Date of the actual completion of the international search

17 April 2003

Date of mailing of the international search report

09/05/2003

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/30771

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 449 369 A (IMRAN MIR A) 12 September 1995 (1995-09-12) the whole document -----	1-32

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 02/30771

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. Claims Nos.: 33-39
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

International Application No

PCT/US 02/30771

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			WO 9412234 A1	09-06-1994
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专利名称(译)	导丝具有可调节的灵活性		
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申请号	EP2002776024	申请日	2002-09-26
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申请(专利权)人(译)	BOSTON SCIENTIFIC LIMITED		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC LIMITED		
[标]发明人	GRIFFIN STEPHEN MIRIGIAN GREGORY E		
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摘要(译)

一种导丝，其远端部分具有可调节的柔韧性。导丝可包括远端聚合物构件和热源。可以激活热源以使聚合物构件的温度升高并增加柔韧性。导丝远端部分的柔韧性的增加增强了导丝将曲折脉管系统导向目标部位的能力。在导丝已经导航到目标位置之后，可以停用热源以使聚合物构件的温度降低并且增加刚度。导丝远端部分的刚度的增加增强了对在其上前进的装置（例如，导管）提供的支撑。