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(54) GUIDEWIRE FOR POSITIONING A CATHETER AGAINST A LUMEN WALL

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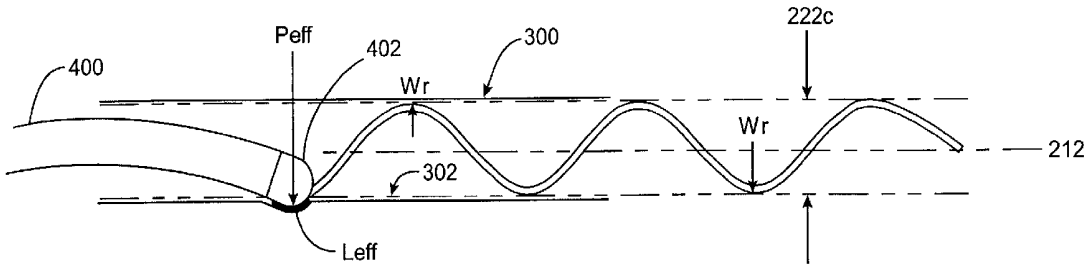
Publication Classification

(51) **Int. Cl.**[7] **A61B 5/00**

(52) **U.S. Cl.** **600/585**

(57) **ABSTRACT**

The present invention relates to a guidewire having a shaped three dimensional guide section. In the preferred embodiment the guide section is helical, and exerts an outward radial force on a lumen the guidewire is constrained in. The outward radial force can be measured or calculated according to methods of the present invention. Also described is a system comprising a guidewire and catheter where the force of the catheter exerts on a body lumen can also be calculated. Apparatus and methods of making the guidewire are also disclosed, as well as alternative embodiments of the guidewire.



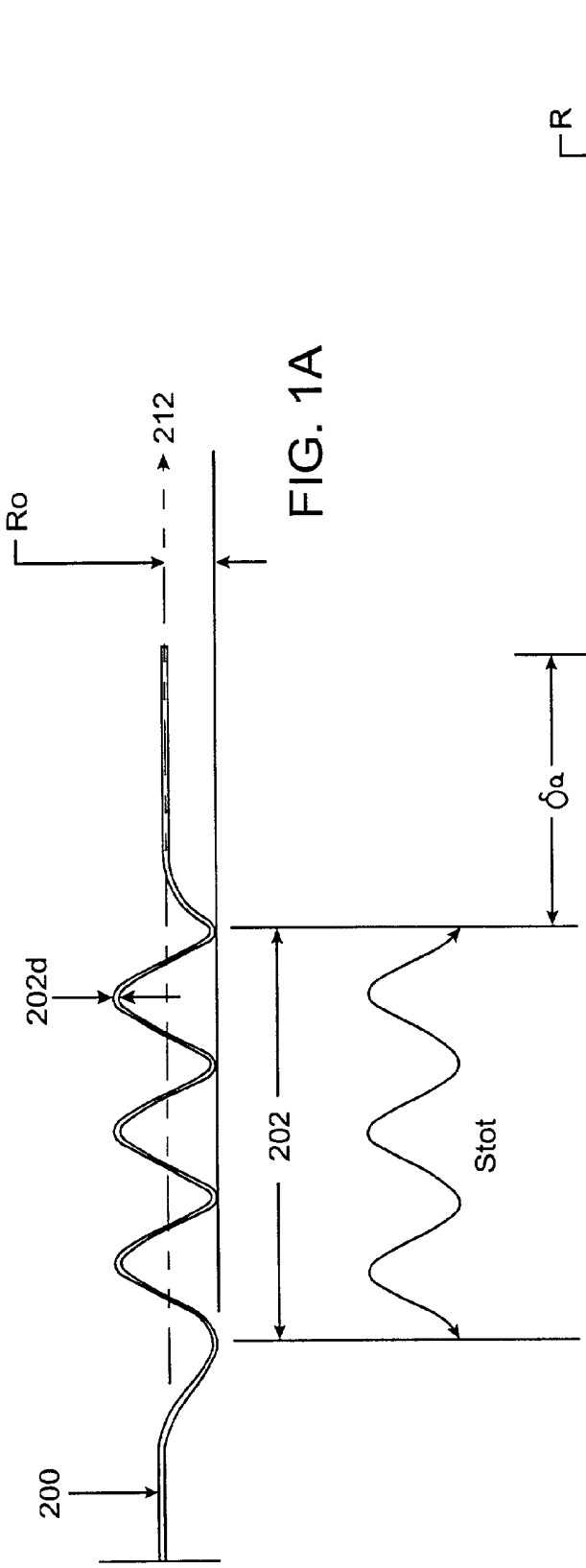


FIG. 1A

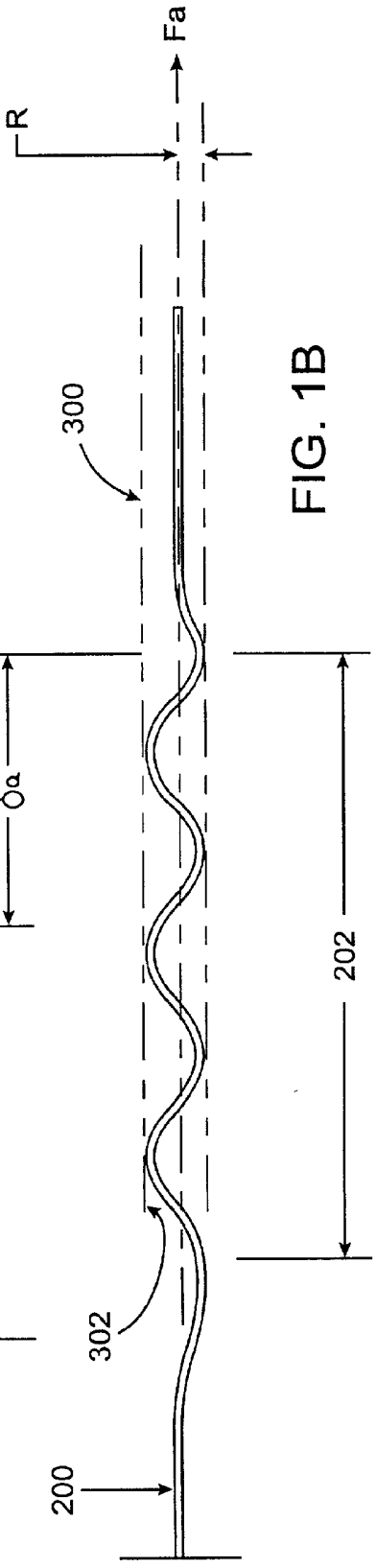


FIG. 1B

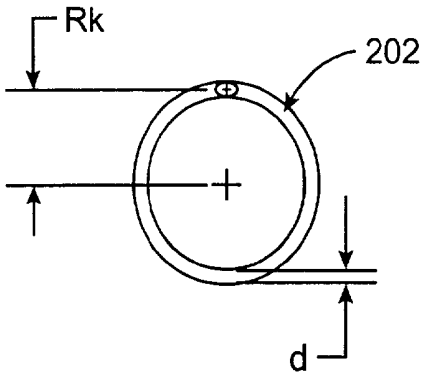


FIG. 1c

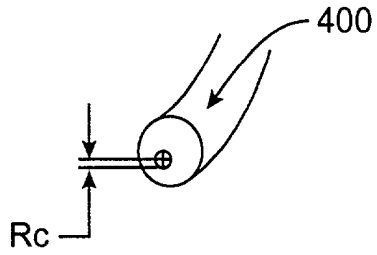


FIG. 1c'

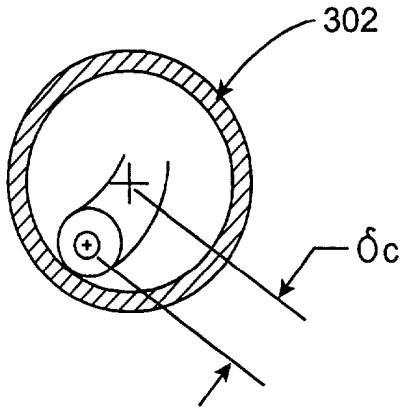


FIG. 1c"

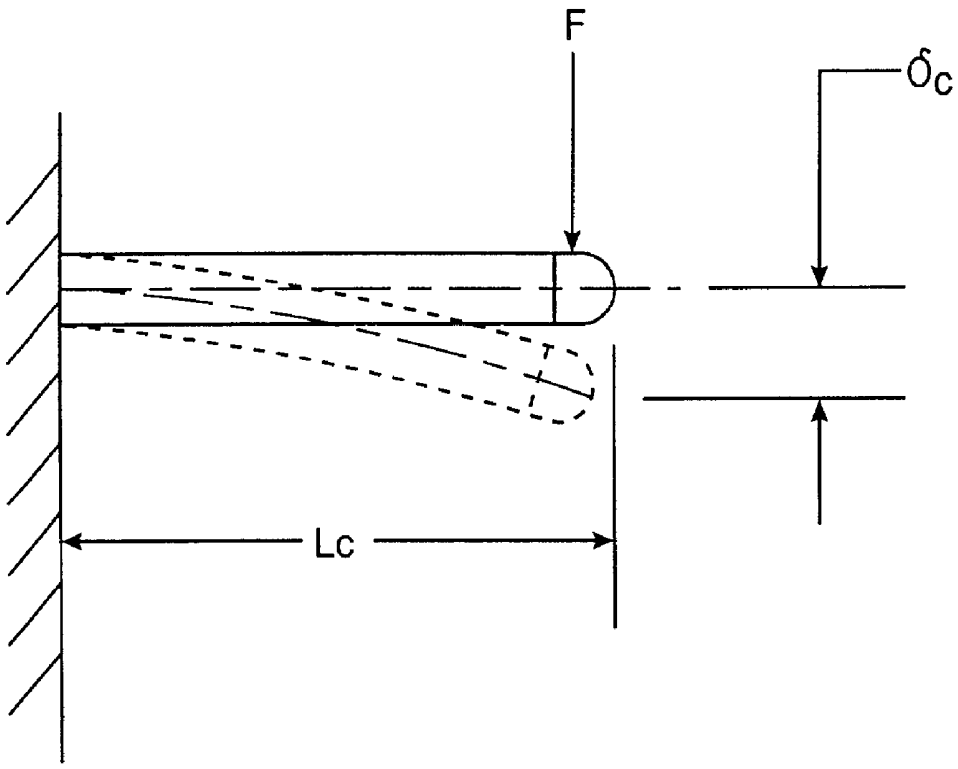


FIG. 1D

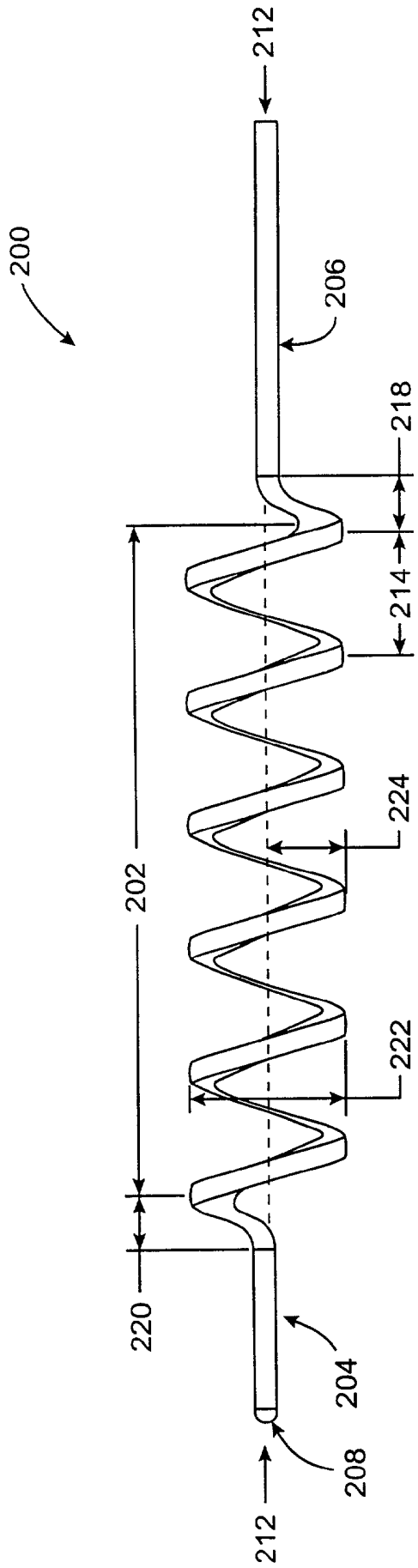


FIG. 2A

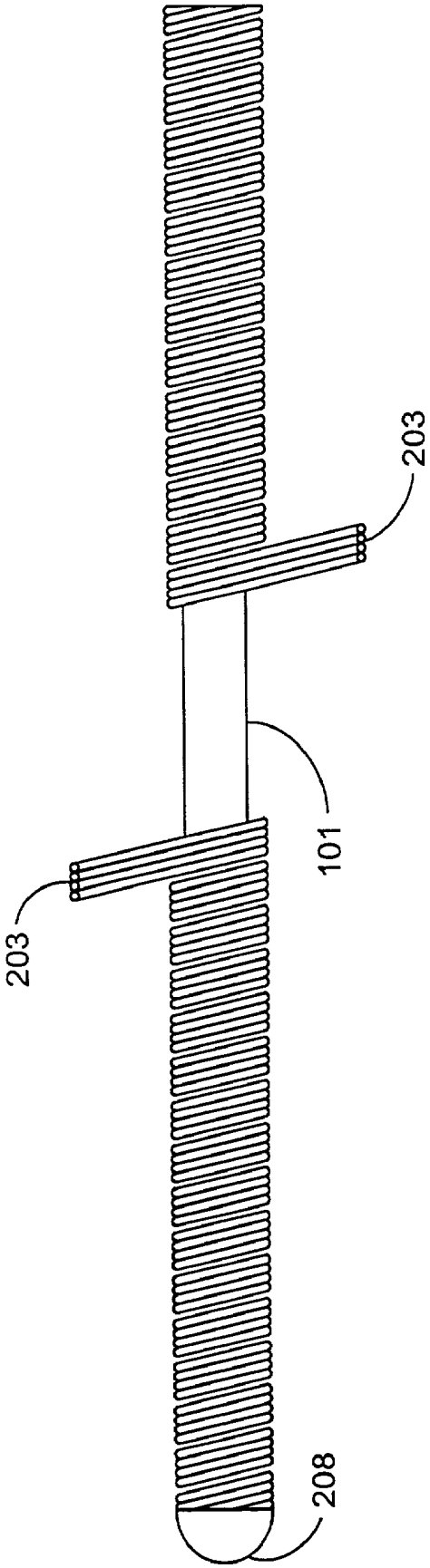


FIG. 2B

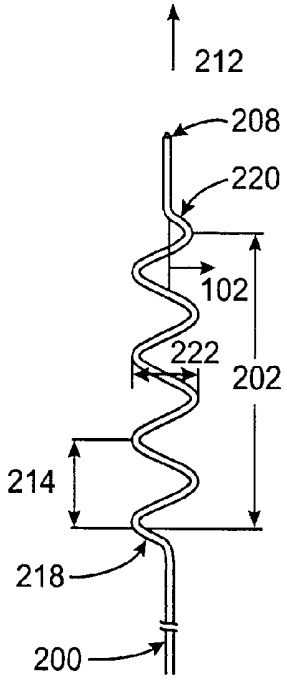


FIG. 3A

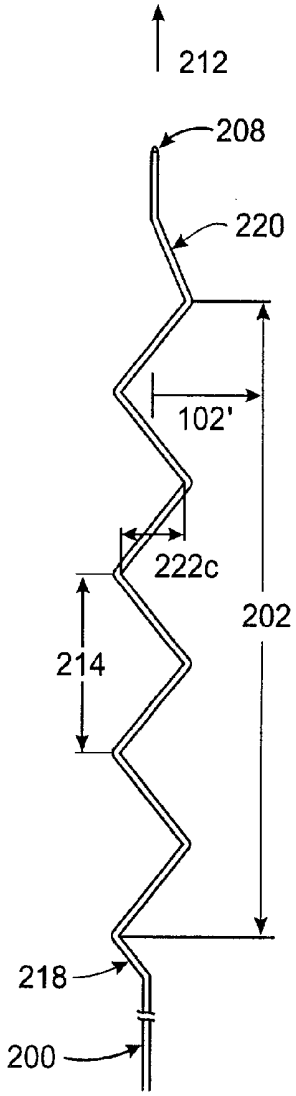


FIG. 3B

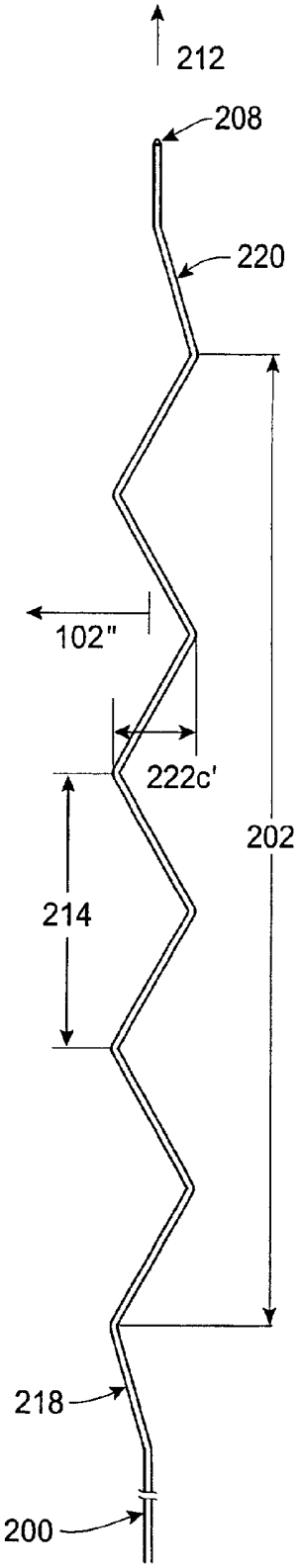


FIG. 3C

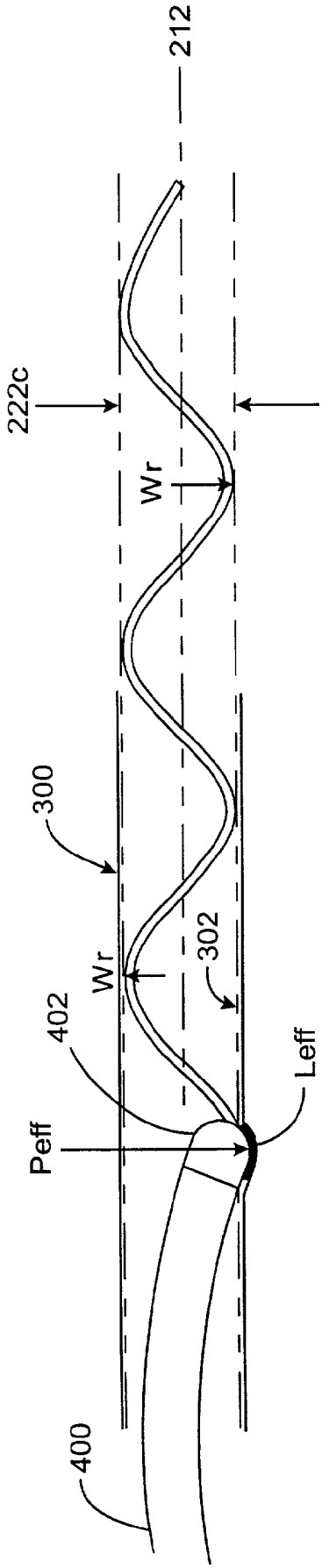


FIG. 4

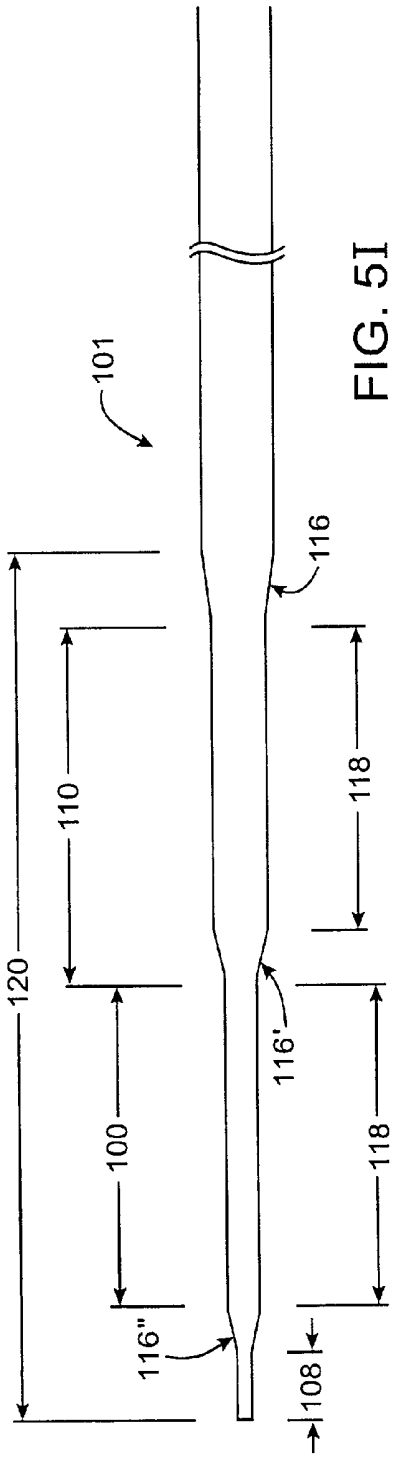


FIG. 5I

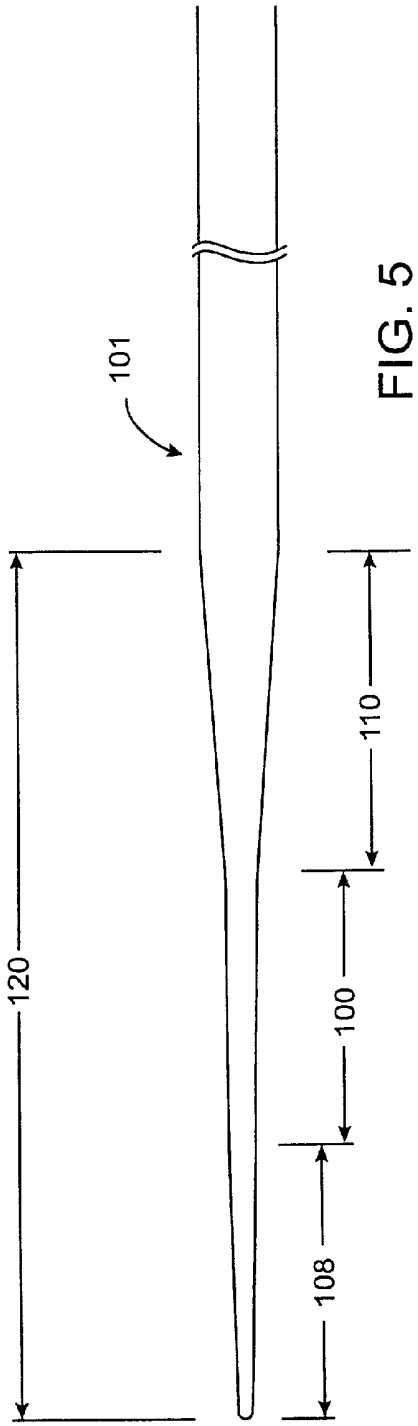


FIG. 5

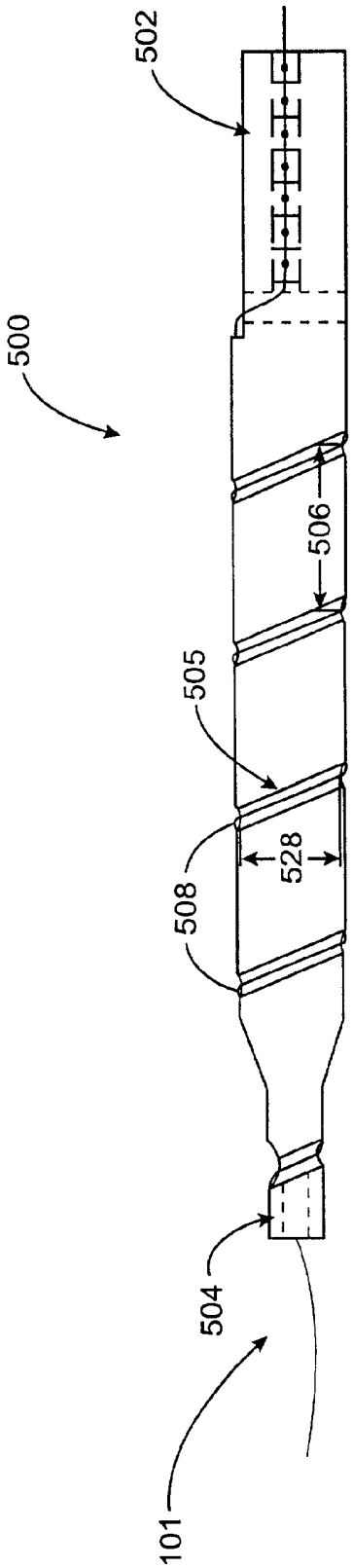


FIG. 5A

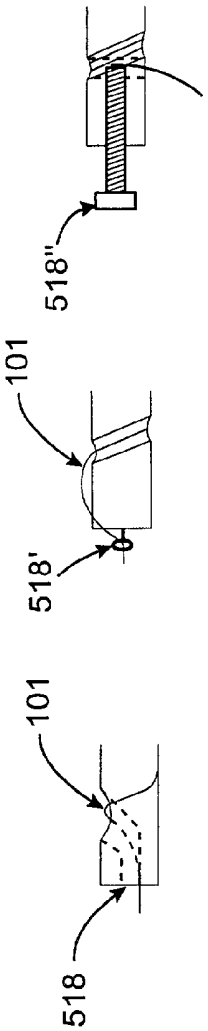


FIG. 5F

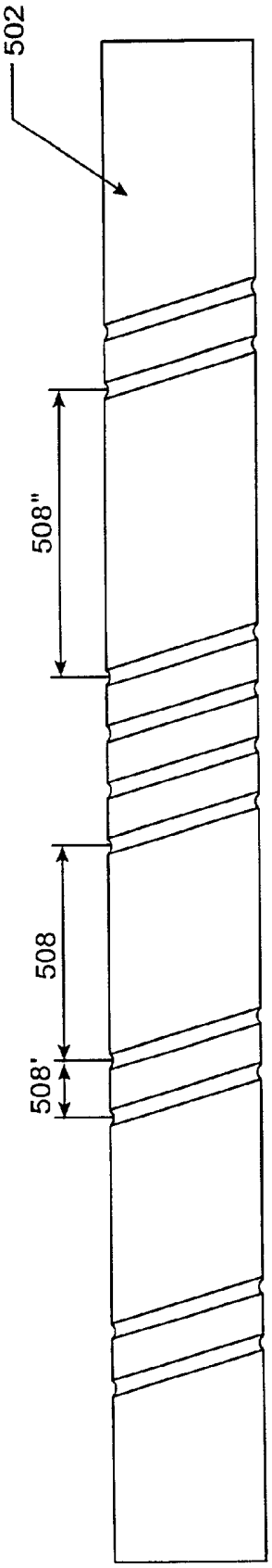


FIG. 5B

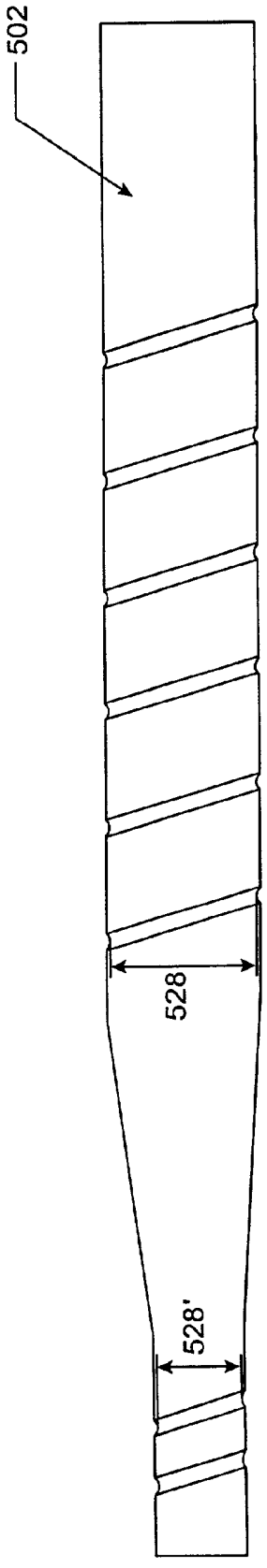


FIG. 5C

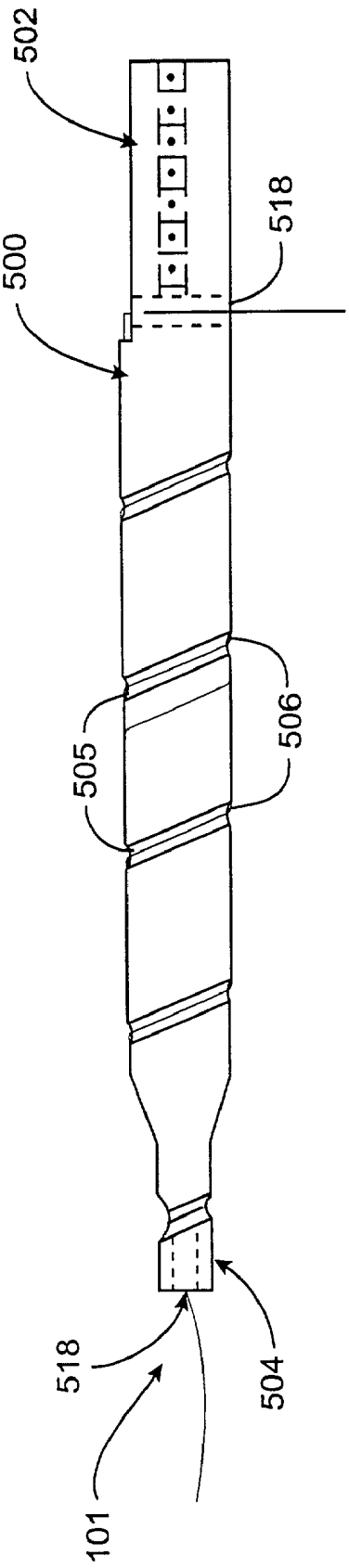
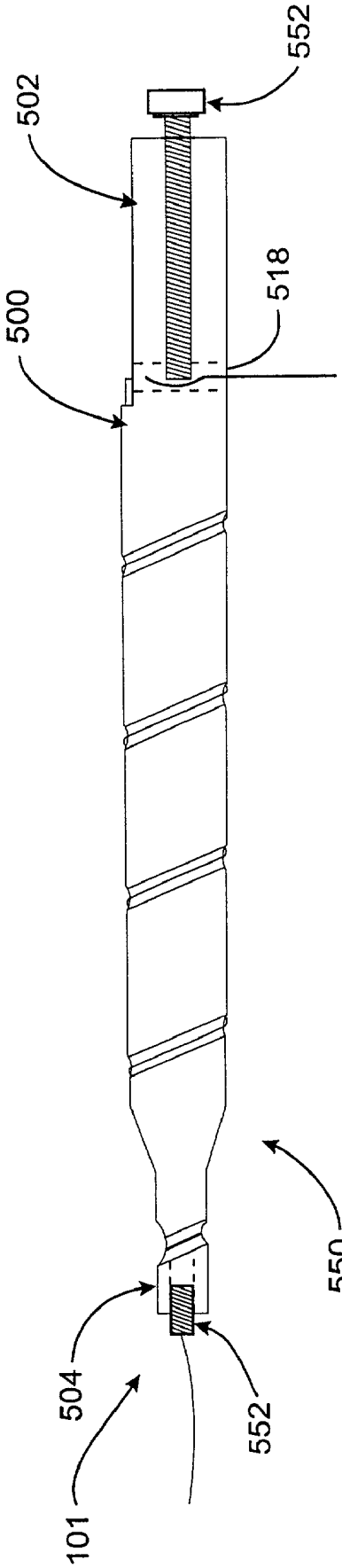


FIG. 5D



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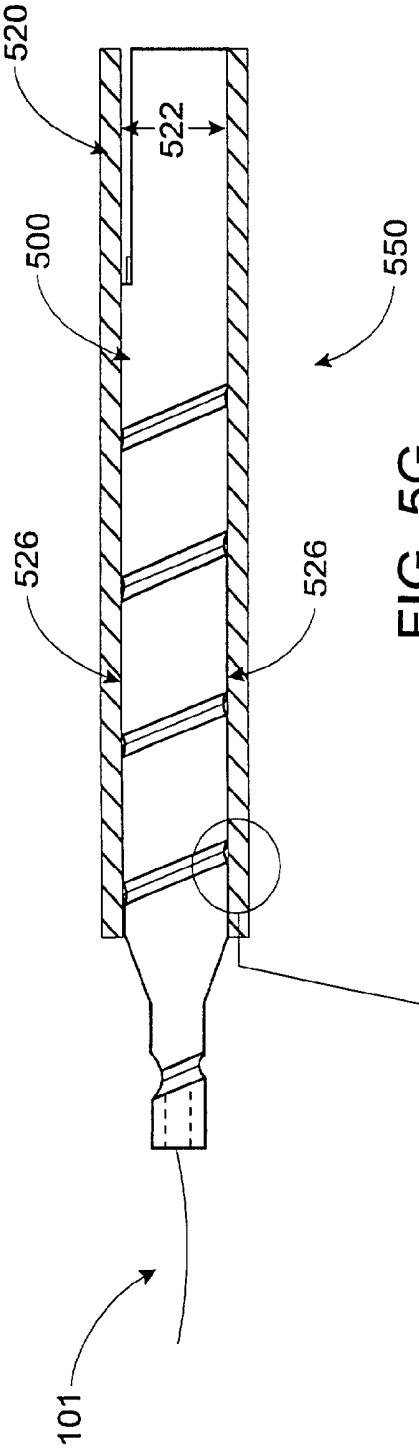

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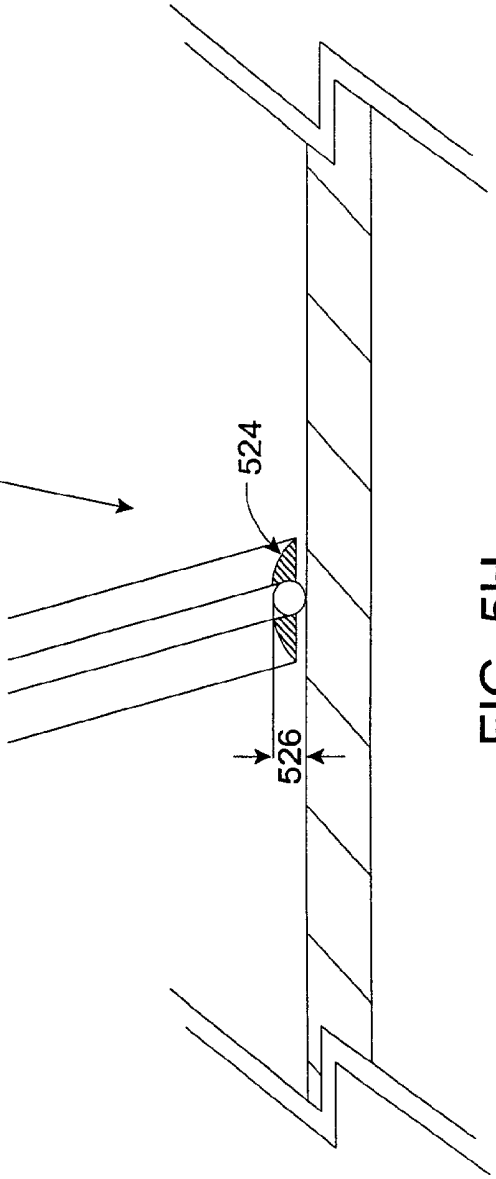

FIG. 5H

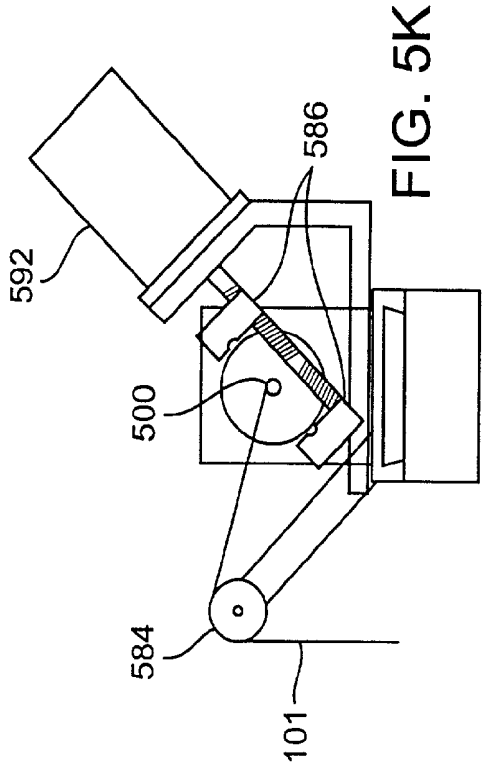

FIG. 5K

FIG. 5J

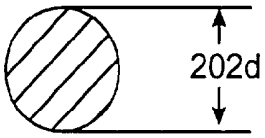

FIG. 5L

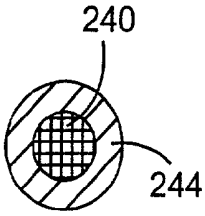

FIG. 5M

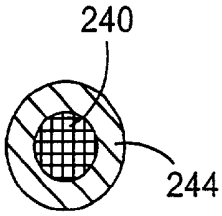

FIG. 5N

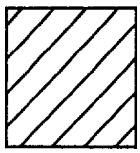

FIG. 5O

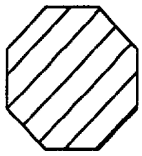

FIG. 5P

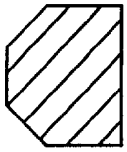

FIG. 5Q

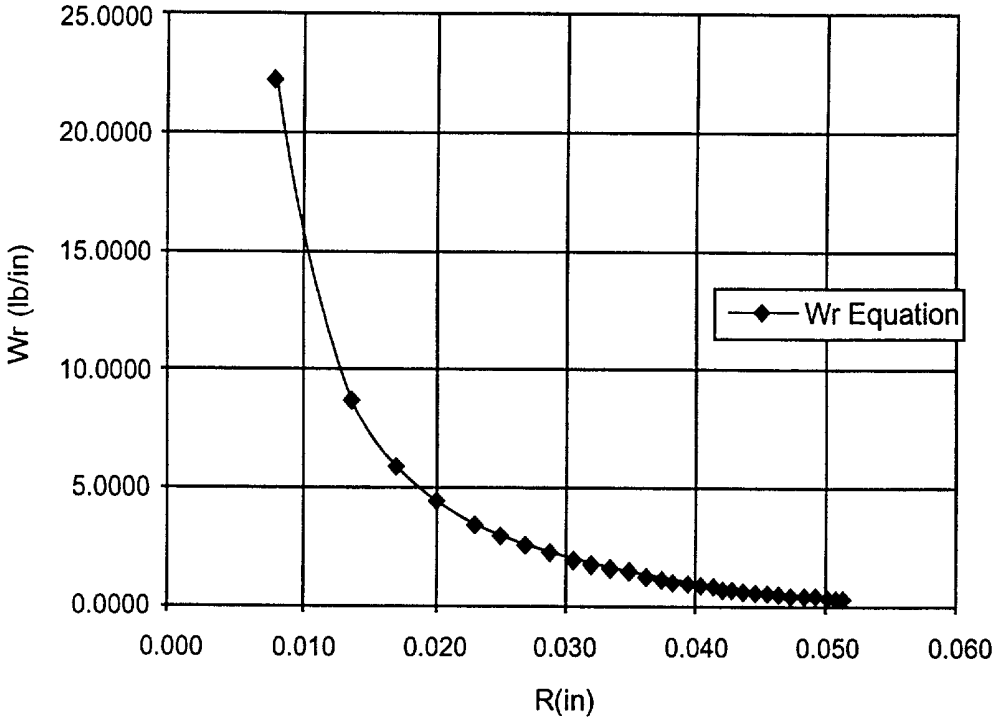
25.0000
20.0000
15.0000
10.0000
5.0000
0.0000
Wr (lb/in)
0.000
0.010
0.020
0.030
0.040
0.050
0.060
R(in)
Wr Equation

FIG. 6

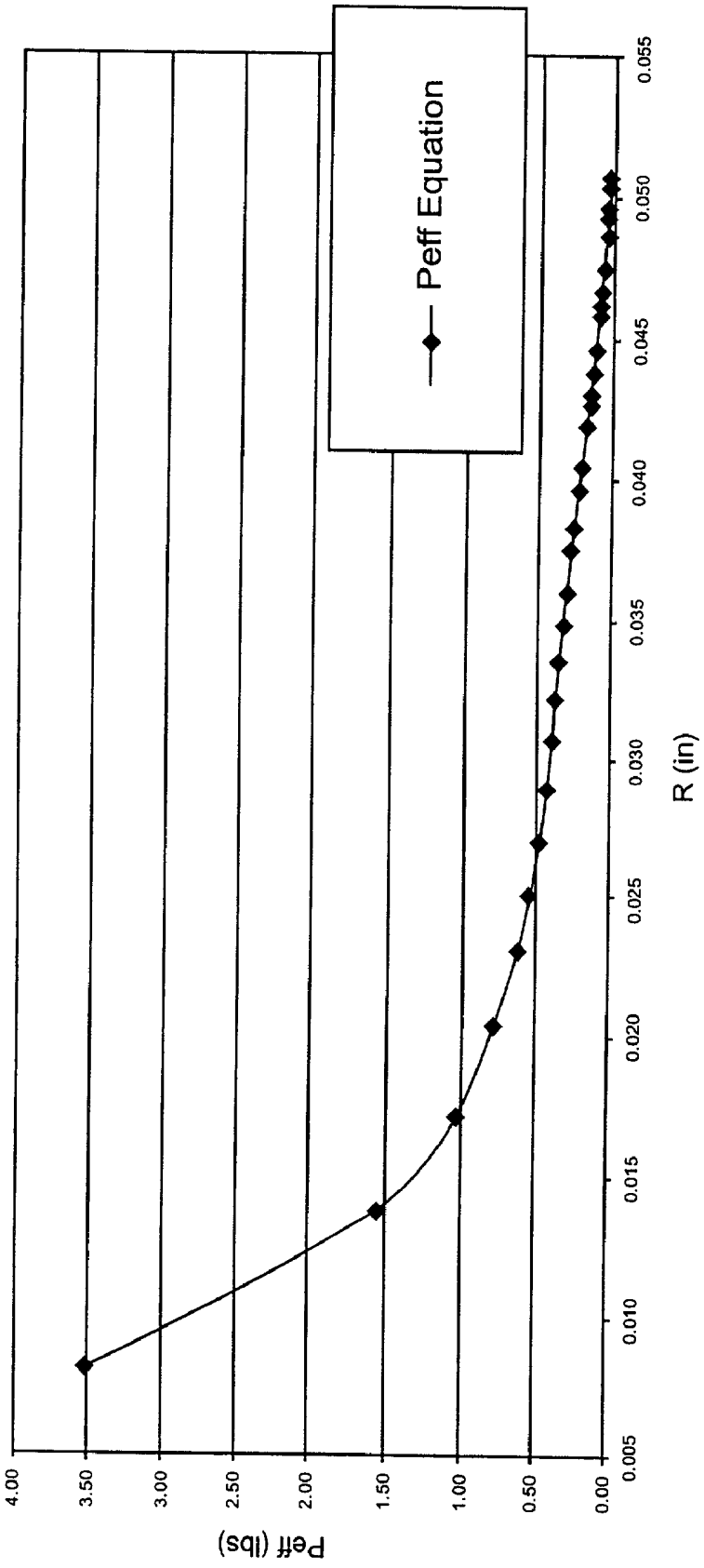
Peff Equation
Peff (lbs)
4.00
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
R (in)
0.005
0.010
0.015
0.020
0.025
0.030
0.035
0.040
0.045
0.050
0.055

FIG. 7A

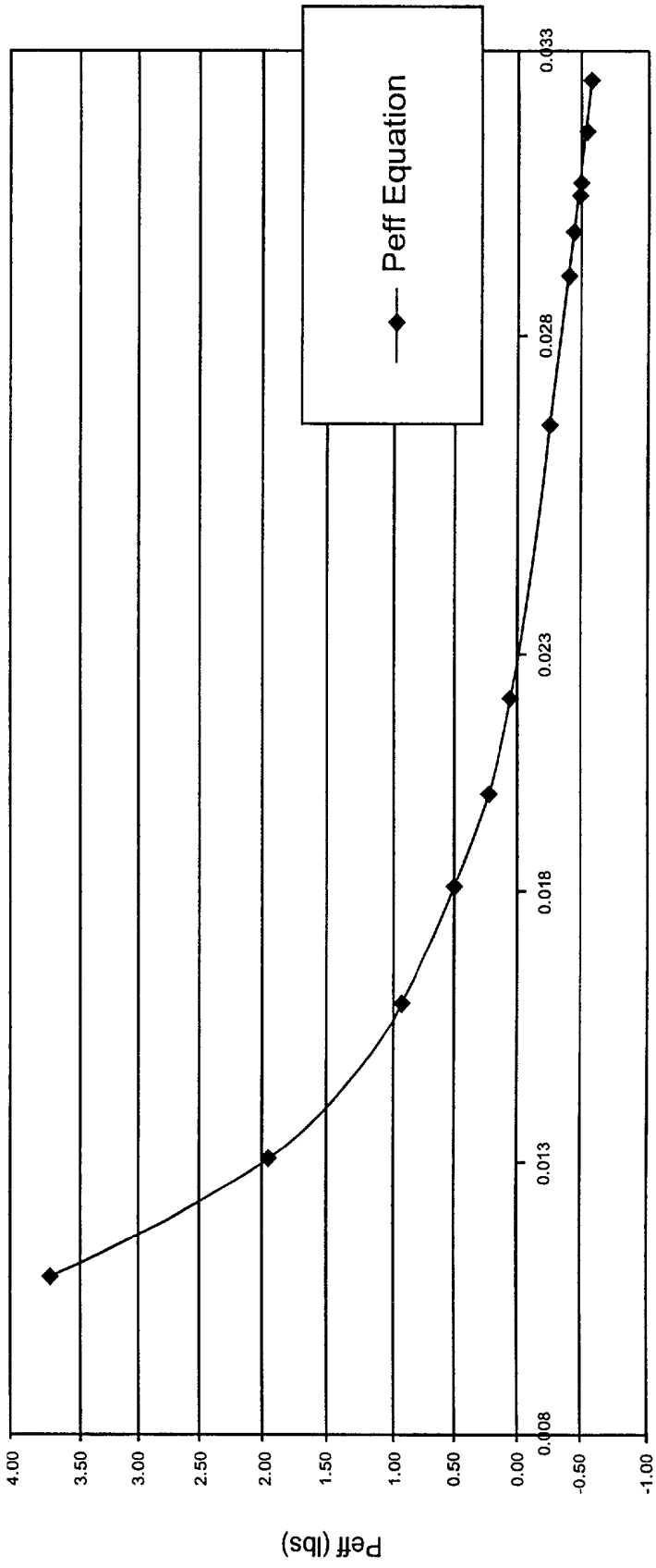
Peff Equation
Peff (lbs)
4.00
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
-0.50
-1.00
0.008
0.013
0.018
0.023
0.028
0.033
R (in)

FIG. 7B

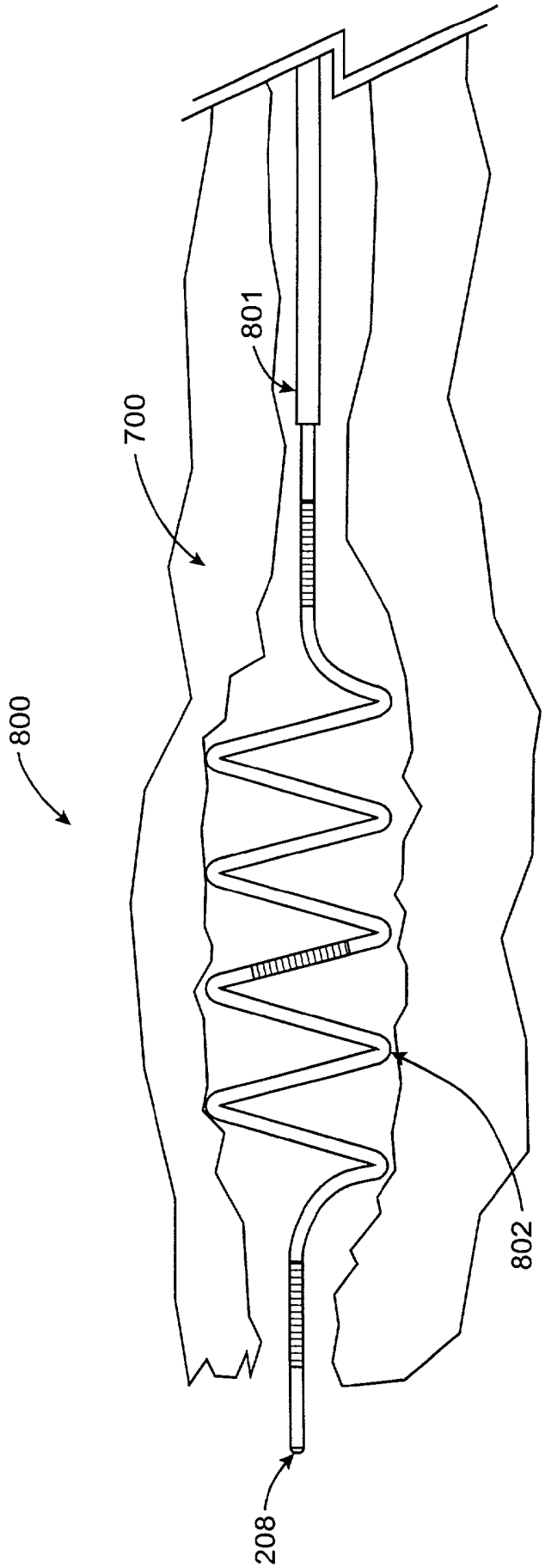

FIG. 8

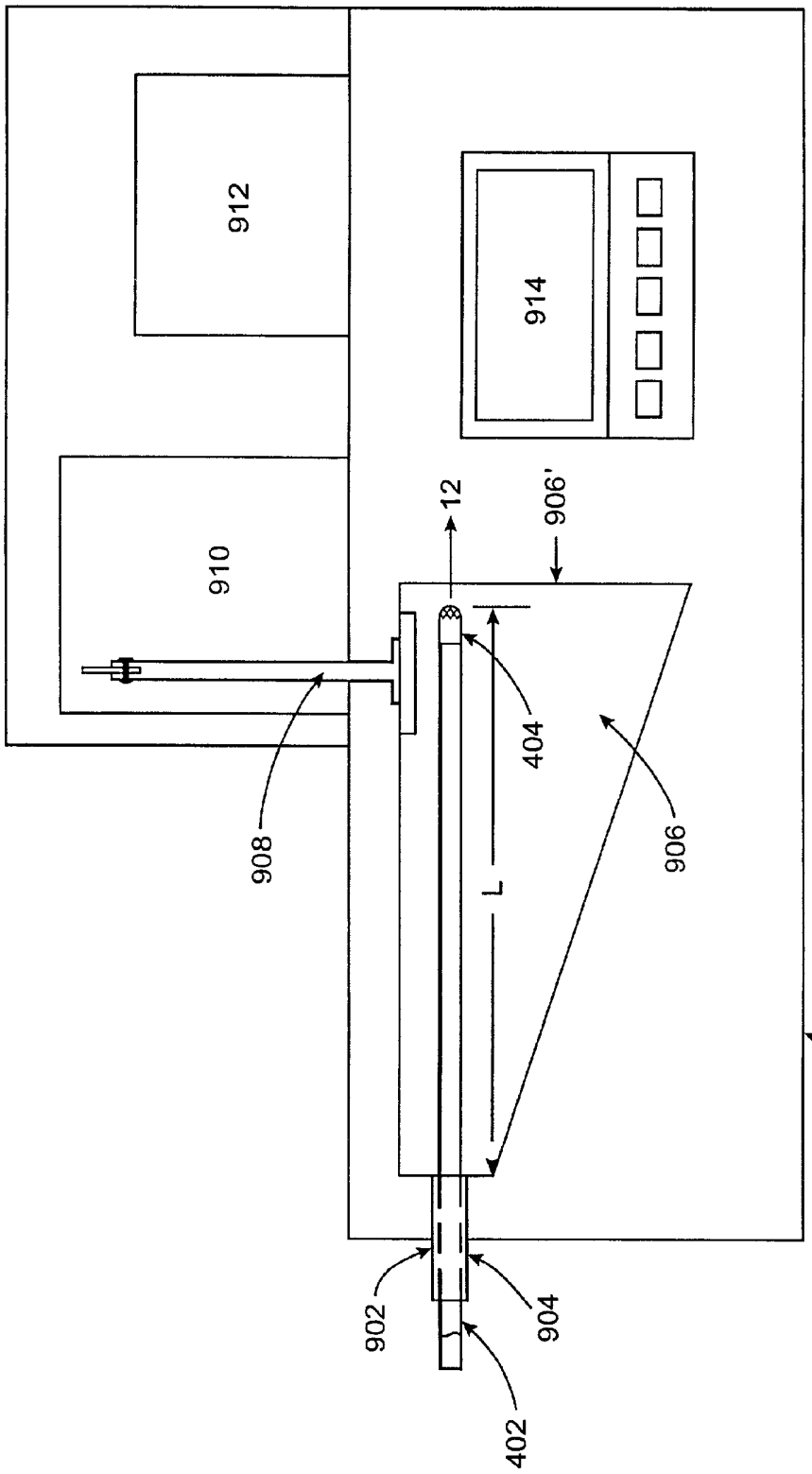

FIG. 9A

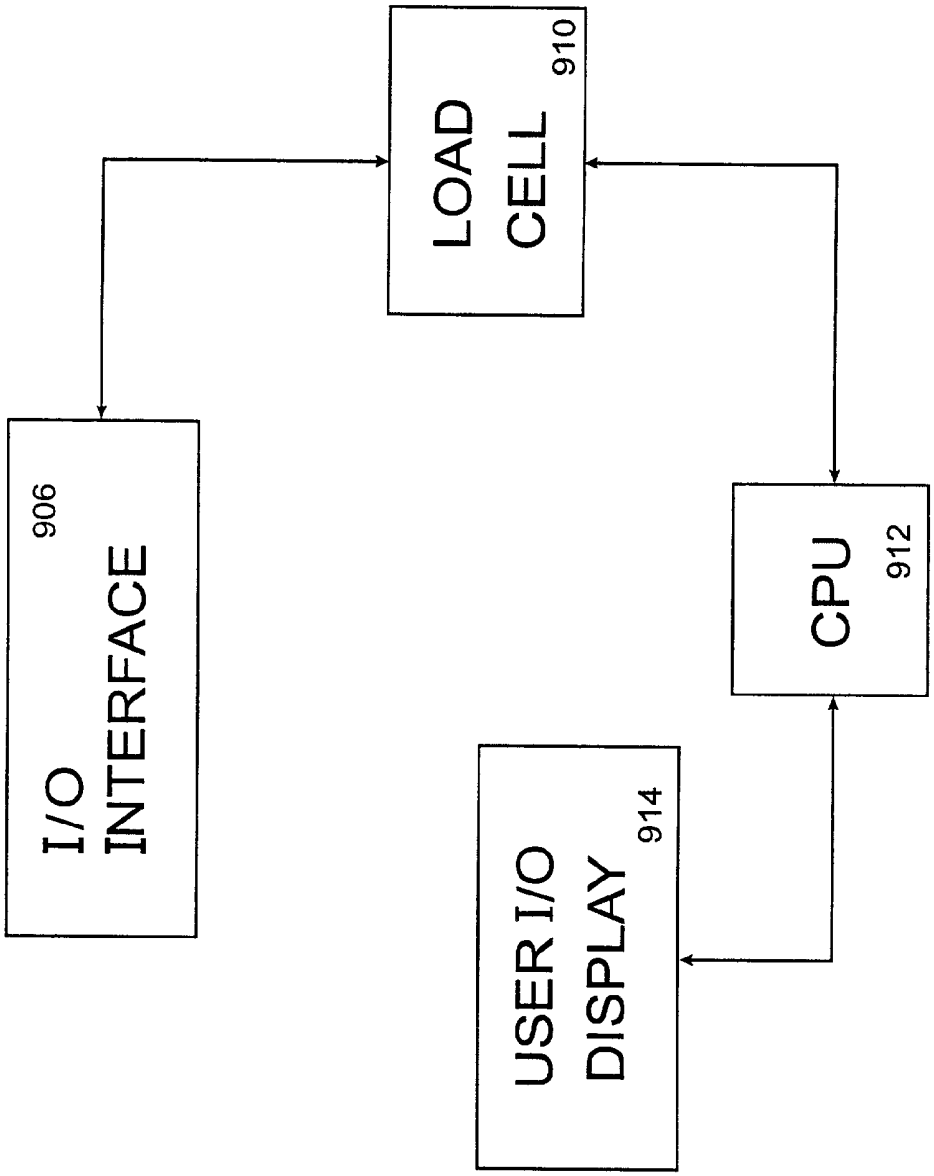

FIG. 9B

GUIDEWIRE FOR POSITIONING A CATHETER AGAINST A LUMEN WALL

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a division from U.S. patent application Ser. No. 09/417,228 (Attorney Docket No. 017903-000580) filed Oct. 13, 1999, which is a continuation-in-part of application Ser. No. 09/289,850 (Attorney Docket No. 017903-000560) filed Apr. 12, 1999, which claimed the benefit of provisional application no. 60/081,631; (Attorney Docket No. 17903-000520), and No. 60/081,614 (Attorney Docket No. 017903-000510) both filed Apr. 13, 1998, and No. 60/103,447 (Attorney Docket No. 017903-000530) filed Oct. 7, 1998; a continuation-in-part of application Ser. No. 08/966,001 (Attorney Docket No. 017903-000500) filed Nov. 7, 1997; of application Ser. No. 09/290,510 (Attorney Docket No. 017903-000550) filed on Apr. 12, 1999, which claimed the benefit of provisional application Nos. 60/081,631; 60/081,614; and 60/103,447; and a continuation-in-part of application Ser. No. 09/389,772 (Attorney Docket No. 017903-001010) filed on Sep. 3, 1999; of which claimed the benefit of provisional application No. 60/099,079 (Attorney Docket No. 017903-001000) filed on Sep. 4, 1998. The full disclosures of each of these prior regular and provisional applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to an apparatus and method of making a guidewire with a preformed three dimensional profile for use in guiding a catheter or other medical device to a desired location within a body lumen.

[0004] 2. Description of the Background Art

[0005] Medical guidewires are used primarily to facilitate the placement of catheters and endoscopic instruments within the tortuous paths of body conduits. For example, if it is desirable to place a catheter within the vascular system of a patient, a guidewire is first inserted into the vessel and then guided through the tortuous path desired for the catheter. Then the catheter is threaded over the guidewire. As the catheter is advanced it tends to follow the direction of the guidewire so that it ultimately negotiates the same tortuous path. Once the catheter is in its final operative position, the guidewire can be removed leaving the catheter to perform its desired function.

[0006] Guidewires are traditionally utilized to negotiate the complex vascular system of a patient to guide a medical device, (e.g., a catheter) to a desired location. It has been in the past of paramount importance for the guidewire to have a shape which provides for superior navigation a patient's vascular system. Inventions in the field include guidewires with floppy tips, improved methods of manufacturing, increased torqueability and improved friction reducing features to help catheters move over the guidewires. Thus the focus of the prior art has been to create a guidewire with the ability to create a path along which a catheter could follow to reach a particular site of the body.

[0007] Guidewires often use transition areas of changing diameter along their length. A smooth transition gives the guidewire the ability to better negotiate tight bends in the anatomy of the patient. The transition area of a guidewire may be long or short, that is the change from one diameter along the length of the guidewire may occur over a few millimeters, or several centimeters. In the past the use of transition areas has been combined with the use of a filament wire which covers the narrower distal section of the guidewire. The combination, well understood in the art, provides the distal tip of the wire with a greater flexibility to steer through the vasculature of a patient, while the filament wire provides added strength and radiopacity. The filament wire can also be used as a fastening point for the attachment of an atraumatic tip. Examples of guidewires using the combination of transition areas and filament wires are described in Colon et al., (U.S. Pat. No. 5,402,799) and Ashby et al., (U.S. Pat. No. 5,622,184). Others have modified the basic design by using other materials, such as Johanson et al., (U.S. Pat. No. 5,596,996). However all of the prior art to date has used guidewires for essentially the same purpose, to navigate the anatomy of a patient and direct a catheter to a particular sight within a body lumen. The medical procedure to be carried out is then conducted by the catheter. There are specialized guidewires which have been developed which attempt to do the job of a catheter using a modified guidewire. Two examples are guidewires with imaging and non-imaging sensors.

[0008] However there remains a need for a guidewire which can steer a catheter more particularly to a precise position within the vascular system of the patient. More particularly it would be beneficial to be able to manufacture a guidewire able to direct a catheter to a particular side of a lumen in the event a physician wishes to treat one side of a body lumen and not another, or be able to direct a catheter to precise locations of a body lumen. Straight guidewires are unable to perform this feat, however a novel guidewire has been disclosed in co-pending patent application Ser. No. 08/966,001 which is capable of steering catheters to a particular side of a body lumen. At least some of these objectives will be met by the embodiments of the present invention described below.

BRIEF SUMMARY OF THE INVENTION

[0009] The present invention relates to medical wires, specifically guidewires and perfusion wires. In general the wires share a generally straight proximal section and a distal section having a curved three dimensional profile. The three dimensional profile usually defines a helical section having a relaxed diameter and a constrained diameter. The use of various materials and manufacturing techniques produces the variety of wires disclosed.

[0010] In a first embodiment, a guidewire for guiding another device to a desired location within a body lumen is described. The guidewire has a generally straight proximal section, and a guide section which defines a helical or other curved three dimensional profile. The three dimensional profile of the guide section is diametrically larger than the profile of the proximal section. The guide section is preferably made from a shape memory alloy and provides a curved path for another medical device to follow. The guide section has sufficient flexibility to assume a generally straight configuration when the guide section is extended through the lumen of a guiding member, such as a catheter, or is otherwise constrained.

[0011] In a second embodiment, a guidewire having a generally straight proximal section and a distal section having a helical support section is described. The helical support section defines a curved three dimensional profile that is diametrically larger than the proximal section. The helical support section is capable of elongation into a substantially straight profile when constrained and expansion into a wider diameter when unconstrained. The helical support section exerts an outward radial force (W_r) less than 20 pounds per inch, preferably less than 15 pounds per inch, usually less than 10 pounds per inch, and often less than 5 pounds per inch when axially extended so the diameter of the helical guide section is half the relaxed diameter. Exemplary ranges of outward radial force are from 0.001 pound per inch to 3 pounds per inch, usually from 0.01 pound per inch to 1 pound per inch.

[0012] In a third embodiment, a perfusion wire is disclosed with a generally straight proximal section and a distal section having a helical support section. The helical support section defines a curved three dimensional profile that is diametrically larger than the diameter of the proximal section. The helical perfusion section is capable of elongation into a substantially straight profile hen constrained and expansion to a larger diameter (W_r) when unconstrained. The helical perfusion section exerts an outward radial force in excess of 10 pounds per inch, preferably 20 pounds per inch, and often 100 pounds per inch, or higher, when axially extended so the constrained diameter is half the unconstrained diameter.

[0013] A system is described comprising a guidewire having a straight proximal section and a distal section. The distal section having a helical guide section capable of changing geometry when constrained in a lumen. The helical guide section exerts and outward radial force less than 15 pounds per inch, preferably less than 15 pounds per inch, usually less than 10 pounds per inch, and often less than 5 pounds per inch. Exemplary ranges of outward radial force are from 0.001 pound per inch to 3 pounds per inch, usually from 0.01 pound per inch to 1 pound per inch. A catheter is included in the system that is capable of tracking over the guidewire wherein the catheter is capable of following the three dimensional profile of the helical guide section. The catheter exerts an outward radial force (Peff) on a lumen at substantially the point of entry of the guidewire into the catheter, thus causing the catheter to exert an outward radial force less than 4 pounds per inch, preferably less than 2 pounds per inch, usually less than 1 pound per inch. Exemplary ranges of outward radial catheter force are from 0.0001 pound per inch to 2 pounds per inch, usually from 0.001 pound per inch to 1 pound per inch. The precise outward radial force can be determined using an equation.

[0014] The guidewire of the present invention may be manufactured using an apparatus comprising a mandrel with a heat stable core. The mandrel has at least one screw thread having spaced apart roots for receiving a guidewire. The mandrel also has at least one retainer for ensuring the guide wire is securely fixed to the mandrel. The method of using the apparatus follows the steps of wrapping a guidewire around the mandrel, securing the wire about the mandrel with the retaining device, heating the mandrel to a desired temperature, stopping the heating, cooling the mandrel and unwrapping the wire from the mandrel. A system for automating the manufacturing process is also described.

[0015] These and other embodiments are further detailed in the descriptions that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] **FIG. 1A** shows a plan view of a unconstrained guide section.

[0017] **FIG. 1B** shows a constrained guide section.

[0018] **FIG. 1C** shows three key relationships in a simple visual format.

[0019] **FIG. 1D** show the beam stiffness variables for a catheter.

[0020] **FIGS. 2A and 2B** show a guidewire with a helical guide section.

[0021] **FIGS. 3A, 3B**, and **3**C shows a guide section with reference to the elements for a low outward radial force (W_r).

[0022] **FIG. 4** shows the relationship between a catheter, guidewire and lumen.

[0023] **FIGS. 5 and 5**I show two core wire geometries prior to treatment according to the present invention.

[0024] FIGS. **5**A-**5**H illustrate various mandrels and mandrel assemblies.

[0025] **FIGS. 5J and 5K** show a system for automated manufacturing of the guide section.

[0026] FIGS. **5**L-**5**Q illustrate various cross sections of the guide section wire.

[0027] **FIG. 6** is a graph of the outward radial force (W_r).

[0028] **FIGS. 7A and 7B** are graphs of the P_{eff} value against radius of the guide section.

[0029] **FIG. 8** show various forms of the perfusion wire.

[0030] **FIGS. 9A and 9B** show a portable force resistance meter.

DETAILED DESCRIPTION OF THE INVENTION

[0031] The following detailed descriptions are the best presently contemplated modes of carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating general principles of embodiments of the invention. The scope of the invention is best defined by the appended claims. In certain instances, detailed descriptions of well-known devices, compositions, components, mechanisms and methods are omitted so as to not obscure the description of the present invention with unnecessary detail.

[0032] 1. Definitions and Table of Variables.

[0033] While common guidewire terminology is used herein, clarification of certain terms are necessary. Terms used in the field of guidewire manufacturing and guidewire usage often vary among physicians and practitioners. The present invention is designed to take a straight core wire and reshape it into a form suitable for use in interventional procedures. The "core wire" is the back bone of a guidewire. Frequently made from a bio-compatible alloys such as stainless steel or nickel-titanium, these wires are usually

larger at the proximal side and tapered to a thinner diameter at the distal end. The taper of the guidewire can be constant along the length, or broken up into transition lengths. Along the distal tip of the guidewire, a small coil is often slid over and secured to the core wire. The small wire which is used to make the coil is referred to herein as the "filament wire." The diameter of a regular guidewire used in cardiology procedures at the present time is generally about 0.014." For purposes of discussion the core wires used in the present invention follow the same geometries of the core wires used in other guidewires.

[0034] A tapered core wire is used as the starting material for making a guidewire having a three dimensional profile. By "three dimensional profile" we refer to the shape the wire assumes after it has gone through the procedure detailed below. Once the shape setting step is complete, the core wire can be modified as any other guidewire may be by techniques well understood in the art. While most guidewires are used to guide a catheter from a point of entry from outside a patients body to a desired location, the guidewire of the present invention is preferably utilized to direct a catheter to precise locations in a body lumen after the catheter has already been guided to the general site of interest using a standard guidewire. The present invention may be used for both introducing the catheter and for localized guidance if the guidewire is composed of a two way shape memory material.

[0035] Shape memory alloys are commonly used in medical devices. Shape memory alloys are often used for making guidewires and stents. A wide variety of shape memory alloys are currently available (see Table 1). Among the more common alloys used is nickel-titanium. The principle feature these alloys possess is their ability to deform in a super elastic range. This alloys these alloys to change their shape to a greater degree than other materials, without being permanently deformed. This ability makes shape memory alloys a preferred material for the present invention. However the present invention does not depend on super elastic properties and can function with in the elastic range of standard metal alloys such as stainless steel. Furthermore full recovery of the material is not necessary so materials may also operate according to the present invention with a small degree of plastic deformation.

TABLE 1

Shape Memory Alloys

Alloy	Sample Composition	Transformation-Temp Range (Degrees Celsius)
Ag-Cd	44/49 at. % Cd	−190 to −50
Au-Cd	46.5/50 at % Cd	30 to 100
Cu-Al-Ni	14/14.5 wt % Al 3 to 4.5 wt % Ni	
Cu-Sn	15 at. % Sn	−120 to 30
Cu-Zn	38.5/41.5 wt % Zn	−180 to −10
Cu-Zn-X	(X = a few wt % Si, Sn, Al)	−180 to 200
In-Ti	18/23 at % Ti	60 to 100
Ni-Al	36/38 at. % Al	−180 to 100
Ni-Ti	49/51 at % Ni	−50 to 110
Fe-Pt	25 at % Pt	−130
Mn-Cu	5/35 at % Cu	−250 to 180
Fe-Mn-Si	32 wt % Mn, 6 wt % Si	−200 to 150

[0036] Examples of superelastic metal alloys, including nickel-titanium, which are usable to form the core of the guidewire of the present invention are described in detail in U.S. Pat. No. 4,665,906. The disclosure of U.S. Patent No. 4,665,906 is expressly incorporated herein by reference insofar as it describes the compositions, properties, chemistries, and behavior of specific metal alloys which are super elastic within the temperature range at which the guide section of the guidewire of the present invention operates, any and all of which super elastic metal alloys may be usable to form the core of the guide section of the guidewire.

[0037] Regardless of the materials used the helical guide section or perfusion section according to the present invention will exert an outward radial force (W_r) when constrained to a helical radius less than the unconstrained helical radius. The variables that are used to determine the outward radial force (W_r) of the helical guide section and the perfusion section, as well as the force a catheter exerts at the point of contact (Peff) over a helical guide section are given in Table 2.

TABLE 2

Variables for Determination of W_r and P_{eff}

Symbol	Definition
P_{eff}	Force the distal end of the catheter exerts against the lumen wall
D	Diameter of the wire comprising the guide section
R	Radius of guide section measured from axis of guide section
R_0	Initial radius of guide section measured from axis of guide section
R_k	Distance between the axis of the helical guide section and the center of the wire comprising the helical guide section
S_{tot}	Total length of wire used to make the helical guide section
N	Number of active turns in guide section
E_g	Modulus of elasticity of the wire comprising the guide section
I_g	Moment of inertia of the wire comprising the guide section
G	Shear modulus of elasticity of the wire comprising the guide section
F_a	Axial force
δ_a	Axial displacement of the guide section
R_c	Radius of the center lumen of the catheter through which the guide wire passes
L_c	Effective length of the catheter in bending
E_c	Modulus of elasticity of the catheter
I_c	Moment of inertia of the catheter
δ_c	End displacement of catheter
L_{eff}	Effective length of contact between the distal section of the catheter and the lumen wall
W_r	Outward radial force of a helical support section when constrained

[0038] By "outward radial force" the description means a force exerted by a compressed helical guide section as it seeks to recover the strain it has experienced while being compressed. There are two predominate sources for compression of the helical guide section. First the helical guide section may be deployed within a lumen having a smaller diameter than the unconstrained diameter of the helical guide section. Under this condition the entire helical guide section may experience a uniform compression or constraining force preventing the helical guide section from releasing the strain energy it possesses. The outward radial force can be uniform along the entire length of the helical guide section, or can vary based on the amount of compression the guide section is experiencing. The second manner a guide section experiences compression, causing an outward radial force, is when a catheter tracking over the guide section

causes further compression of the guide section. As the catheter advances, local deformations immediately proximal and distal to the catheter appear on the length of the guide section. These deformations are the result of the strain the catheter exerts on the guidewire as it is advanced. The guide section seeks to resist deformation and recover the strain to return to its natural, relaxed shape. Any force the guide section exerts as it seeks to recover its natural state is an "outward radial force" with respect to the intended operation and usage of the present invention. The outward radial force of the guide section less the beam stiffness of the catheter and the adjustments for the local deformations of the guidewire as the catheter is tracking over it constitute the value (P_{eff}).

[0039] A "catheter resistance force" is the force the catheter exerts on the guide section. This resistive force is a result of the catheter being displaced by the guide section off of its natural axis. The catheter may be stiff or flexible in the distal end as it moves over the guidewire. The stiffer the catheter, the greater the force the catheter exerts on the guide section. Any force the catheter exerts on the guide section at the distal tip of the catheter moving forward is the "catheter resistance force" with respect to the intended operation and usage of the present invention.

[0040] Referring now to **FIG. 1A**, the helical guide section **202** is shown in an unconstrained state. When the helical guide section **202** is unconstrained, it is possible to measure the radius R_o of the helical guide section **202**. R_o is measured from the center axis of the guide section **212** to the outside of the wire comprising the helical guide. The total length of the wire comprising the helical guide section (S_{tot}) can either be measured directly from the straightened helical guide section or calculated using geometric relationships and measured parameters of the helical guide section **202**. The total number of active coils of the helical guide section (N) can be measured directly from the helical guide section **202**. The diameter of the wire **202***d* comprising the helical guide section **202** can be measured directly from the wire comprising the helical guide section. Lastly, the shear modulus of elasticity of the wire (G) may be determined from any readily available engineering reference manual.

[0041] **FIG. 1B** shows the helical guide section **202** axially extended so the constrained radius R is half the unconstrained radius R_o. At this time it is possible to measure or calculate the distance from the center axis of the helical guide section **212** to the center of the wire comprising the helical guide section (R_k) (**FIG. 1C**). The axial displacement of the helical guide section (δ_a) **216***c* is the axial extension of the helical guide section **202** as a result of the helical guide section **202** being constrained by a lumen **300** of a certain radius (R). Because the helical guide section **202** is in contact with the wall of the lumen **302**, the helical guide section **202** conforms to the radius of R. Conversely, when an axial force F_a is applied to the helical guide section **202**, the result is an axial displacement δ_a that will also result in the helical guide section **202** reducing to the radius of R. The two situations are equivalent in terms of the mechanical response of the helical guide section **202**. The axial force (F_a) applied to the helical guide section **202** results in the axial displacement δ_a.

[0042] The beam stiffness of the guidewire is needed to determine the outward radial force (W_r). In the system of the present invention a determination of the catheter stiffness is also required. Using a standard beam stiffness test it is possible to calculate or measure the beam stiffness of a catheter. The effective beam length of the catheter in bending (L_c) can also be measured. Finally it is necessary to determine the effective length of contact between the catheter distal end **406** and the wall of the lumen (L_{eff}). Once the beam stiffness measurements or calculations are completed, it is possible to determine the modulus of elasticity and the moment of inertia for both the helical guide section **202** and the catheter **400**. These calculations produce the necessary EI data to determine W_r and P_{eff}. The details of determining W_r and P_{eff} are described below in section 7 and 8 respectively.

[0043] **FIG. 1C** shows the value of R_k as the distance from the axis of the helical guide section **212** to the center of the wire comprising the helical guide section **202**. **FIG. 1C'** shows R_c as the radius of the center lumen of the catheter **400** through which the guidewire **200** passes. FIG. IC" shows δ_c as the displacement of the catheter **400** from its neutral, undeflected axis. The catheter is shown in the drawing in a perspective view with the front along the lumen circumference. For clarity the helical guide section **202** is not shown in this figure.

[0044] **FIG. 1D** shows the catheter under going a beam stiffness test (also known as a cantilever test) where L_c is the effective beam length, F is the force applied to deflect the tip of the catheter **402** a distance δ_c.

[0045] 2. Guidewire with Curved Three Dimensional Profile.

[0046] **FIG. 2A** illustrates an embodiment of a guidewire **200** according to the present invention. The guidewire **200** is preferably provided with a configuration to enable it to guide, in a controlled manner, a catheter distal tip **402** (not shown) at and along the location of a body lumen **300**.

[0047] Referring to **FIGS. 2A and 2B**; the guidewire **200** is provided with a generally helical guide section **202** adjacent its distal end **204**. As shown in **FIG. 2**A, the helical guide section **202** has a three-dimensional configuration that approximates the configuration of a cylindrical lumen wall. The distal end **204** of the guidewire **200** is generally straight and preferably has an atraumatic distal tip **208**. The remainder of the guidewire **200**, and in particular, the proximal section **206**, is generally straight, as with conventional guidewires. The distal section **204** and the proximal section **206** are axially coplanar with each other, and are preferably coaxial with respect to each other. In other words, the distal section **204** and the proximal section **206** are oriented along the same longitudinal axis. In addition, the distal section **204** and the proximal section **206** are concentric, and can also be eccentric, with respect to the guide section **202**. The proximal and distal extremities of the helical guide section **202**, or the entire helical section, are preferably provided with sufficient radiopacity so that the helical guide section **202** can be clearly viewed during fluoroscopic visualization. The radiopacity can be provided by the use of a radiopaque wire **203**, as shown in **FIG. 2**B, which can be made of platinum or gold alloys or other radiopaque wires, and which is wound around the core wire **101**.

[0048] The helical guide section **202** of the guidewire **200** can be modified so that it has a generally tapered or stepped, or both tapered and stepped, configuration (not shown).

[0049] For example, the helix of the guide section **202** can be tapered from the proximal extremity to the distal extremity thereof so that the helical diameter decreases from the proximal extremity to the distal extremity. The helix can also be stepped at certain discrete locations of the guide section **202**. In addition, although the helical guide section **202** of the guidewire **200** is illustrated as having uniformly configured helixes, it is also possible to provide the helixes in a manner that they are non-uniform to each other across the helical length **202**.

[0050] As yet another alternative, a plurality of guide sections **202** can be provided in spaced-apart manner at the distal end of the guidewire **200**. For example, two spaced-apart guide sections **202** would be helpful in treating body lumens where restenosis has occurred at the locations of two spaced-apart implanted stents.

[0051] 3. Guidewire Having a Helical Guide Section with a Low Radial Force.

[0052] **FIGS. 3A, 3B**, and **3**C show the preferred embodiment of the present invention. A guidewire **200** with an atraumatic tip **208** is shown with a helical guide section **202** capable of exerting an outward radial force (W_r) **102** when compressed. The vectors **102**, **102**' and **102**" represent the larger radial forces generated from the increased compression of the helical guide section **202**. It is important to note that while the drawings show these as vector arrows, the outward radial force (W_r) is a distributed force along the entire length of the **20** helical guide section **202**. The helical guide section **202** further comprises a plurality of helical winds **214** with a proximal transition period **218** and a distal transition period **220**. The helical guide section **202** also has a relaxed helical diameter **222** and an axis of extension **212**. The guidewire **200** has a core wire **101** made of a shape memory material such as nickel-titanium or other shape memory alloy. The actual outward radial force (W_r) of the helical guide section **202** depends on the composition of the helical guide section **202** when it is made, the shape it is fashioned into, and the amount of constraint it experiences. In general for interventional procedures the total outward radial force (W_r) must be sufficient to provide a force that can deflect a catheter tip **402** (not shown) in a controlled manner to abut a lumen wall **302** while at the same time not damaging the lumen wall **302**. The helical guide section **30202** exerts an outward radial force (W_r) when compressed which is proportional to the axial extension of the helical guide section **202**. The outward radial force (W_r) is distributed along each helical wind **214** of the guide section **202** in proportion to the radial compression of the particular wind. That is, those helical winds **214** that are more compressed, will have a greater outward force (W_r). Since it is difficult to accurately measure the force values of the helical guide section **202** in vivo (when it is compressed inside a body lumen), the current description uses a test model in an in vitro setting. That is a bench top test is used to determine the force values of the helical guide section **202**. In general the helical guide section **202** has a maximum outward radial force (W_r) less than fifteen (15) pounds per inch when constrained to a radius that is half the unconstrained radius. Preferably the outward radial force (W_r) is in between of 0.0001 pound and 3.0 pounds. The actual outward radial force (W_r) of the helical guide section **202** can be calculated using the formula:

$$W_r=(((E_gI_g)F_a\delta_a)/(2S_{tor}R_kR_cR^2))^{1/2}$$

[0053] Wherein the formula variables are defined above.

[0054] 4. System with Guidewire and Catheter.

[0055] **FIG. 4** illustrates the relationship between the guide section **202** and the catheter distal tip **402**. Competing factors must be considered when the helical guide section **202** is made. A helical guide section **202** having a helical diameter **322** smaller than the vessel it may operate in will not provide the necessary relationship between the guidewire **200** and a catheter distal tip **402** to provide precision location of the catheter distal tip **402** in a lumen **300**. Likewise if the core wire **101** is too stiff, the helical guide section **202** will not deform when the catheter distal tip **402** tracks over it. In general the helical guide section **202** of the present invention will operate using materials generally the same as used for straight guidewires.

[0056] The use of a shape memory material in the helical guide section **202** allows the helical guide section **202** to be deformed in the elastic and super elastic range of the material and return to the original shape of the helical guide section **202**. The inherent unloading of force, or relaxing of the helical guide section **202** when it is compressed, produces the outward radial force (W_r). The thicker the core wire **101** of the guidewire **200**, the stronger the outward radial force (W_r), or the greater the resistance to deformation the helical guide section **202** possesses. The combination of elements and properties provide the guide section **202** of the guidewire **200** with an outward radial force (W_r) sufficient to deflect a catheter distal tip **402** into the lumen wall **302** as the catheter **400** is being advanced over the guide section **202**. This relationship holds true as the helical diameter **322** of the guide section **202** compresses from its free state to conform to the lumen diameter.

[0057] When a catheter **400** is tracking over the guide section **202** while the guide section **202** is pushing against the lumen wall **302**, the outward radial force the catheter exerts (P_{eff}) against the lumen wall **302** is determined from the value of the force the guide section exerts (W_r) plus a term for the energy release of the guide section and the torsional energy of the guide section less the catheter beam stiffness. The relationship can be expressed as:

$$P_{eff}=(((E_gI_g)F_a\delta_a)/(2S_{tor}R_kR_cR^2))^{1/2}(L_{eff})+E_gI_g[((1/R_c)-(1/R))((1/R_cR^2)-(1/R_cR^2))]^{1/2}+((96F_a^2R^2N)/(d^4G))-((3(E_cI_c)\delta_c)/(L_c^3)).$$

[0058] Wherein the variables are defined above.

[0059] 5. Apparatus and Methods for Manufacturing Wire with a Helical Guide Section.

[0060] **FIGS. 5 and 5**I illustrate a typical core wire **101** that has been ground down for use in the present invention. The core wire **101** has a tapered region **120** that begins at the most proximal grind down **116**, or at the point the core wire begins to taper if the grind down is a gradual and constant type **110**. In a step down grind configuration (**FIG. 5I**) of the core wire **101**, the barrels **118** between step down grinds **116**, **116**' and **116**" have a constant diameter. In the preferred embodiment, three step down regions are used. However the present invention may be made with a single grind down that

is either gradual along the entire length of the grind down region, or of variable decreasing diameter along the length of the grind down region. It should be appreciated that the strength of the guide section of the wire will be decreased as the diameter of the core wire **101** is reduced. Thus it is preferred to maintain the core wire diameter along the length of the core wire to be consistent. The most distal barrel is the distal tip **108**. The intermediate barrel **100** forms the guide section **202** after heat setting in the preferred embodiment. The proximal barrel is the proximal section **110**. Proximal to the proximal grind **116** is unmodified core wire **101**.

[**0061**] **FIG. 5A** illustrates a plan view of a mandrel **500** in its basic form. The mandrel **500** has a proximal end **502** and a distal end **504** for reference. A helical screw thread **505** is engraved into the mandrel **500**. The screw thread **505** has a defined pitch **508** used to establish the distance between the coils of the core wire once the shape setting procedure is complete. The screw thread **505** has spaced apart roots **506** for receiving the core wire **101**. It is important the mandrel **500** be made from a temperature stable material for the operation of making the shaped guidewire. The mandrel **500** may be made of brass, steel, ceramics or any other material which will retain its shape at temperatures up to 800 degrees Centigrade. The diameter of the mandrel between the bottom of the roots **506** is the minor diameter **528**. The minor diameter **528** determines the minimum inner diameter of the core wire **101** after the shape setting is complete.

[**0062**] **FIG. 5B** shows a mandrel **500** with three different pitches **508**, **508'508"** that can be used to produce a guidewire where the pitch is uneven along the length of the three dimensional profile of the wire. **FIG. 5C** shows another mandrel **500** where the diameter of the helical winds may be varied. Because of the ability of shape memory alloys to assume a tremendous assortment of shapes, the mandrel **500** may be designed with any combination of cross section geometries and diameters. However it should be apparent that the smoother the outer perimeter of the wire during usage, the less traumatic the guidewire will be to the patient. Thus it is preferred to utilize a regularly curved helical structure when possible.

[**0063**] **FIGS. 5D and 5E** show a series of drawings where the method of the present invention is employed to produce a guidewire having a shaped three dimensional profile. The mandrel **500** in **FIG. 5D** is shown with a core wire **101** being introduced into the proximal end **502**. The winding procedure may be done by hand. If done by hand, the operator feeds a predetermined length of the core wire **101** through the wire entry port **518** on the proximal tip **502**. Once the appropriate amount is fed through the first wire entry port **518**, the core wire **101** is secured at the proximal end **502** with a securing means **552**. The core wire **101** is wound around the screw threads **505** either by a machine or an operator, and the core wire **101** is wound tightly so tension remains in the core wire **101** during the shape setting procedure. The operator must be careful to make sure each wind in the roots **506** is tight. If the wire is not tightly wound around the mandrel **500** during the shape setting step the wire will not retain the shape of the mandrel **500**. Alternatively the operator may feed any length of the core wire **101** through the first wire entry port **518** and simply clip off any excess core wire **101** that remains after the winding procedure.

[**0064**] **FIG. 5E** shows the core wire **101** fully wrapped around the mandrel **500**. The core wire **101** is fed through both wire entry ports **518** on the distal tip **502** and the distal end **504**. Once the core wire **101** is fully wrapped around the mandrel **500**, a second core wire securing means **552** is used at the distal end **504** to make sure tension remains in the core wire **101** about the mandrel **500**. The core wire **101** and mandrel **500** together comprise the mandrel assembly **550**. The mandrel assembly **550** is then heated to the appropriate shape setting temperature which corresponds to that of the shape memory alloy being used. For nickel-titanium alloys, the temperature is preferably between 200 and 800 degrees Centigrade. In the case of two way shape memory alloys, the shape setting temperature should also be between 200 and 800 degrees centigrade while the transition temperature between austenite and martensite phases can be any temperature which is not the same as the heat set temperature.

[**0065**] **FIG. 5F** shows the mandrel **500** with a variety of wire entry ports **518**. The main consideration in the design of the wire entry port **518** is simply to be able to secure the core wire **101** to the mandrel **500** without damaging the core wire **101**. Thus the wire entry port **518** may be a simple channel, an eyelet **518'**, threaded pin **518"** or any other receptacle capable of holding the wire in place.

[**0066**] Alternatively, the core wire **101** may have a filament wire attached to it before the shape setting procedure is done. In the alternative method the core wire will have a filament wire tightly wrapped around the core wire, then be wrapped about the mandrel **500** as detailed above. Either method will produce the guidewire of the present invention. The completed shape set wire has a form similar to that shown in **FIG. 2A**.

[**0067**] **FIG. 5G** shows another variation on the securing means used to provide the tension fit between the core wire **101** and the mandrel **500**. A sleeve **520** with an inner diameter **522** frictionally engages the outer diameter of the mandrel **500** when the core wire **101** is wrapped around the mandrel **500**. Using this embodiment it is necessary for the core wire **101** to be at least as high as the mandrel **500** outer surface so the core wire **101** can also frictionally engage the sleeve **520**. Alternatively the sleeve **520** may have a heat stable cushion **524** (**FIG. 5H**) so that the cushion **524** may fill the gaps **526** in between the root **506** and the core wire **101**. The sleeve **520** may be a cylinder or a foldable device which can be wrapped around the mandrel assembly **550** and then itself secured in place.

[**0068**] **FIG. 5J** shows a plan view of a system according to the present invention. The system **580** comprises a rotatable chuck **582** for holding the mandrel **500**, and a spring tension arm **584** for maintaining the tension of the core wire **101** while the core wire **101** is loaded onto the mandrel **500**. The system **580** also includes a heating element **586** for providing the heat necessary for accomplishing the shape setting step of the method described below. The rotatable chuck **582** may be turned by hand or mounted on a modified lathe **588**. Furthermore the system **580** may be automated by using a computer controller **590** for handling the rotational speed of the chuck **582**. Speed determination and the proper winding of the core wire **101** around the mandrel **500** is handled by a plurality of stepper motors **592**. The heating element **586** need not be actual heaters, but can be any means known in the art to increase thermal tempera-

tures, such as a salt bath, induction or RF system. An air cooling fan or blower **594** can be used to cool the mandrel **500** after the shape setting is finished. **FIG. 5K** shows an end view of the system described in **FIG. 5J**.

[**0069**] **FIGS. 5L through 5Q** show alternative core wires **101** which may be used in the present invention. Any material that can be shape set at a particular temperature, and has a high degree of elastic or super elastic behavior may be used in the current invention. Aside from a core wire of a single material or single alloy (**FIG. 5L**), the core wire may represent a complex structure such as a shape memory alloy hypo-tube **244** with a high density metal as the core **240** (**FIG. 5M**). An example would be a gold core wire with a nickel-titanium hypo-tube, the combination then being co-axial, and then the two being shape set using the method described above. The advantage of using a core wire comprising a sandwich or tube arrangement is greater radiopacity or lateral strength may be imparted to the core wire, depending on the particular desire of the manufacturer. **FIG. 5N** shows a shape memory alloy **240** as the core element and a different material **244** as the cladding. FIGS. **5O-5Q** show three different cross sections for a shape memory alloy core wire **101**.

[**0070**] When using the methods below for determining the outward radial force (W_r) and the force a catheter exerts on a lumen (P_{eff}) it should be noted that only the method for the most common wire diameter (**FIG. 5L**) has been detailed. The radial forces for a guide section with a non-circular cross section can be determined by simply adapting the methods below, and the formula to adjust for the change in the core wire cross-section.

[**0071**] **6**. Method of Determining the Outward Radial Force of a Helical Guide Section.

[**0072**] A method of determining the outward radial force (W_r) of the guide section **202** using the physical and geometric properties of the helical guide section **202** as defined above and solving the following equation for Wr:

$$W_r=(((E_gI_g))F_a\delta_a)/(2S_{tor}R_kR_oR^2))^{1/2}$$

[**0073**] As detailed above, the modulus of elasticity for the guide section (Eg) can be found in published sources. The moment of inertia for the guide section (Ig) can be calculated from the known geometry of the wire comprising the guide section **202**. If the wire comprising the helical guide section **202** is a composite, the effective E_g and I_g can be calculated for the composite. The product of E_g I_g in the first term of the equation for W_r can alternately be determined empirically by performing a beam stiffness test on a section of the wire comprising the helical guide section **202**.

[**0074**] The shear modulus of elasticity (G) for the guide section **202** can also be found in published sources. If the wire comprising the helical guide section **202** is a composite, the effective shear modulus of elasticity (G) can be calculated for the composite. Alternately, the shear modulus of elasticity (G) can be determined empirically by performing a torsional beam stiffness test on a section of the wire comprising the helical guide section **202**.

[**0075**] Utilizing geometric relationships, the axial displacement of the guide section (δ_a) and the distance between the axis of the helical guide section **202** and the center of the wire comprising the helical guide section (R_k) can be written in terms of the radius of the guide section measured from the axis **212** of the guide section to the outer edge of the guide section (R).

[**0076**] The axial force (F_a) can be expressed as $F_a=k\delta_a$, where k is the axial spring constant for the helical guide section **202**. As such, Fa can be written in terms of R. Alternately, δ_a and F_a can be determined empirically as a function of R: The axial force is measured by placing the guide section **202** in a force-displacement measuring instrument (such as an Instron™ model 5543, using a 10-pound load cell). The guide section **202** is subject to a standard axial force displacement test, with the ends of the guide section **202** fixed in rotation. The load cell of the Instron™ is slowly moved apart so that the guide section **202** of the guide section **202** is slowly stretched. The Instron™ can be programmed to measure on an incremental basis the force required to stretch the guide section **202**. For example, if the guide section **202** is stretched at a rate of 1 cm per minute, force measurements can be taken every millimeter or every six seconds. Once the guide section **202** is extended to a point such that the guide section **202** is substantially straight, the test should be stopped.

[**0077**] Following completion of the axial force and displacement testing, the guide section **202** is removed from the Instron™ and the radius of the guide section **202** measured using an optical measurement device. The guide section **202** is displaced axially with the ends of the guide wire fixed in rotation. The radius R is recorded at axial displacements δ_a corresponding to those at which the axial displacement δ_a and axial force F_a measurements were taken.

[**0078**] Using the experimental setup described above, we can exert an axial force Fa on the guide section **202** over substantially its full range of deflection. For example, when measuring a 1 cm length guide section, use 10-50 discrete deflections. At each deflection, measure and record the axial displacement δ_a, axial force F_a and radius R of the guide section **202**. Utilizing this data, δ_a and F_a can be determined as a function of R. Following the determination of the values and relationships described above, calculate and graph W_r as a function of R of the helical guide section. An example of which is shown in **FIG. 6**.

[**0079**] 7. Method of Determining the Force Exerted by a Catheter (P_{eff}).

[**0080**] A method of determining the outward radial force P_{eff} a catheter distal tip **402** exerts against a lumen wall **302** while traversing a given helical guide section **202** using the physical and geometric properties of the helical guide section **202** and catheter **400** as defined above and solving the following equation for Peff:

$$P_{eff}=(((E_gI_g)F_a\delta_a)/(2S_{tor}R_kR_oR^2))^{1/2}(L_{eff})+E_gI_g[((1/R_o)-(1/R))((1/R_cR^2)-(1/R_cR^2))]^{1/2}+((96F_a^2R^2N)/(d^4G))-((3(E_cI_c)\delta_c)/(L_c^3))$$

[**0081**] The equation for P_{eff} is comprised of four terms: the first three terms are expressions of the outward radial force the helical guide section **202** exerts on the distal end of the catheter **406**, the fourth term is the resistive force of the catheter due to its beam stiffness. Subtracting the resistive force of the catheter from the total force exerted outwardly by the helical guide section **202** on the catheter **400** results in the net force of the distal end of the catheter **406** against the lumen wall **302**. If P_{eff} is positive the catheter **400** is exerting an outward force on the wall of the lumen **302**. If

P_{eff} is zero the resistive force of the catheter distal tip **402** is balanced with the outward radial force the helical guide section **202** is exerting on the catheter distal tip **402** and the catheter distal tip **402** is resting on the wall of the lumen **302** but not exerting any force on the wall of the lumen **302**. If P_{eff} is negative the resistive force of the catheter exceeds the outward force of the helical guide section **202** on the catheter distal tip **402** and the catheter distal tip **402** is no longer in contact with the wall of the lumen **302**.

[**0082**] The modulus of elasticity of the catheter (E_c) can be found in published sources. The catheter's moment of inertia (I_c) can be calculated from the known geometry of the catheter. If the catheter is a composite, the effective E_c and I_c can be calculated for the composite. The product $E_c I_c$ in the catheter (fourth) term of the equation for P_{eff} can alternately be determined empirically by performing a beam stiffness test on the catheter **400**.

[**0083**] When determining the effective length of the catheter in bending (L_c) careful consideration must be given to competing factors. In practice, when using a catheter **400** in a body lumen **300**, the maximum distance that the catheter can be deflected is determined by the diameter of that lumen **300**. The distance the catheter **400** will be deflected in use in a body lumen **300** is estimated to be between 0.5 mm and 5 mm. The specific maximum deflection can be determined by the greatest radius of the largest guide section **202** intended for use with this catheter **400**. The effective beam length of the catheter being used in a body lumen **300** varies depending on the body lumen **300** in which the catheter **400** is inserted. In the tortuous anatomy of the coronary arteries the effective beam length of the catheter **400** may be short. However, if the catheter **400** is inserted into a straight lumen, the effective beam length **410** of the catheter **400** will be longer. Here, the effective beam length L_c of the catheter **400** in use is estimated to be between 1 cm and 5 cm.

[**0084**] The intent of the cantilever beam test is to model the effective beam length of the catheter in use. Determining an effective beam length L_c that models the actual use of the catheter can be difficult. The effective beam length L_c of the catheter in the cantilever beam test should best be determined based on its specific usage. Because the stiffness of a beam increases inversely with length, a limit on the minimum length of the catheter used during the cantilever beam test is defined. For definition purposes in the present invention, it will be defined that the minimum effective beam length L_c of the catheter **400** will be that distance that the catheter **400** can be deflected in the largest lumen **300** expected for use from the center axis of the lumen **300** to the lumen wall **302** without permanent deformation to the catheter **400**. The maximum deflection distance is defined as the largest radius of the largest guide section **202** intended for use with the catheter **400**.

[**0085**] The effective beam length L_c of the catheter **400** for the cantilever beam test will be determined based on competing considerations involved for the specific use of the device. It will be appreciated by those schooled in the art that if the catheter distal tip **406** is a rigid section, the resistance value of the catheter **400** could exceed the outward force of the guide section **202**. Should the minimum deflection required above result in permanent deformation to the catheter distal tip **406** during the cantilever beam test, that effective beam length L_c is too short to be a representative model of the catheter **400** in actual use.

[**0086**] To measure the force of the catheter, mount the catheter **400** in an instrument capable of measuring force and deflection (e.g., an Instron™), with the catheter **400** having an effective beam length L discussed above. The catheter **400** must be prepared such that its stiffness will be that seen during its use. Thus if the guide section **202** passes through a lumen in the catheter during use, the guide section **202** must be inserted into the catheter **400** prior to testing in such a way that the guide section **202** contributes to the stiffness of the catheter **400** but does not externally restrict the deflection of the catheter **400**. Measure and record the force required to deflect the catheter orthogonal to its major axis from zero deflection (its natural, free state) to a deflection at a minimum equal to the greatest free state **30** radius of the largest guide section **202** intended for use with this catheter **400**.

[**0087**] To graph the equation of P_{eff} for all possible R of the helical guide section, there are several possible methods to generate the dependent variables R_k, δ_a, F_a, δ_c and L_{eff}: Utilizing geometric relationships, δ_a, R_k and δ_c can be written in terms of the R. L_{eff} can be calculated using the theory of contacting surfaces (e.g., Hertz contact theory) and as such, L_{eff} can be written in terms of R.

[**0088**] Alternately, L_{eff} can be determined empirically (e.g., deploy the catheter **400** and helical guide section **202** in a plastic tube and measure L_{eff} using polarized light to visualize the contact between the catheter distal end **406** and the tube wall).

[**0089**] Following the determination of the values and relationships described above, calculate and graph P_{eff} for all possible values of R. If P_{eff} is zero or positive for all possible values of R (See **FIG. 7A**), the catheter distal end **406** will remain in contact with the wall of the lumen **302** for all possible values of R. If P_{eff} is negative for any possible value or R (See **FIG. 7B**), the distal end of the catheter **406** will not be in contact with the lumen wall **302** for any value of R. The lower limit on R is the radius from the center of the catheter to the outside of the catheter. Because the helical guide section **202** conforms to the lumen **300**, a lumen **300** with a radius equal to the radius of the catheter is the smallest lumen in which the catheter will fit. If the lumen radius is smaller than that of the catheter **400**, the catheter **400** cannot operate within that lumen **300**. As such, the lower limit on R of the helical guide section is the radius of the outside of the catheter. The upper limit on R is the free, unconstrained radius of the helical guide section R_0. At R_0 the helical guide section **202** is in its free, non-deformed state and as such, the helical guide section **202** is no longer capable of exerting a force against the wall of the lumen **300**.

[**0090**] 8. Helical Perfusion Wire with a High Radial Force.

[**0091**] **FIG. 8** shows an alternative embodiment of the present invention. The perfusion wire **800** can be made having an outward radial force (W_r) in excess of **20** pounds per inch. Many of the features of the perfusion wire are similar to the wire previously described. However the perfusion wire requires a helical support section **802** made of a more robust material than that of the helical guide section **202**. The wire cross sections illustrated in **FIGS. 5M and 5N** provide greater structural integrity and outward radial force (W_r) when made of a strong inner material such as stainless steel with a shape memory cladding like nickel-titanium.

[0092] The perfusion wire **800** is designed for deployment within a blood vessel **700** that is either diseased and substantially occluded, or has been perforated and collapsed due to loss of local blood pressure. In deployment of the perfusion wire a guide catheter **801** is used to cross the region where the perfusion wire **800** is to be deployed. The guide catheter **801** is then retracted while the perfusion section **802** is deployed. Once free of the constraints of the guide catheter **801**, the perfusion section **802** resumes its natural shape. The perfusions section exerts an outward radial force (W_r) sufficient to open a passage through a collapsed blood vessel, or substantially occluded blood vessel without danger of damaging the vessel further, or deforming the guide catheter **801**.

[0093] 9. Portable Force Resistance Meter.

[0094] **FIGS. 9A and 9B** illustrate a portable force measuring unit **900**. The force measuring unit **900** of the present invention is used for determining a catheter resistance force value. The preferred embodiment is a small, hand held unit having a port **902** for receiving the distal tip **404** of a catheter **402**. The receiving port **902** is generally large enough to receive any catheter **402** ordinarily used in a body lumen with an adaptable entry collar **904** which can be secured around the catheter **402** to lock it in place. The receiving port **902** leads to a test lumen **906** where the catheter distal tip **404** extends into. The catheter distal tip **404** enters at the proximal end **906'** of the test lumen **906** and the distal tip **404** extends to the distal end **906'** of the test lumen **906**. At the distal end **906'** of the test lumen **906** a deflection gauge **908** can be used to push the catheter tip **404** a precise distance off the axis **12** of the test lumen **906**. A load cell **910** is connected to the deflection gauge **908** to determine the beam stiffness of the catheter **402**.

[0095] A microprocessor **912** is used to collect and interpret the data collected by the load cell **910** and the test lumen **906**. A display unit **914** then indicates the catheter beam stiffness value for use in matching an appropriate guidewire **200** to the catheter **402**. **FIG. 9B** illustrates the electronic element organization of the hand held force meter **900**.

[0096] While the present invention has been described in the above description, the scope of the present invention is broader than can be reasonably described in a single document as will be come clear to an individual of skill in the art upon review of the present disclosure and the appended claims.

What is claimed is:

1. A portable force resistance meter for determining a catheter resistance value comprising:

an aperture for receiving a catheter distal end;

a deflection lever for moving said catheter distal end a quantifiable distance;

a load cell linked to said deflection lever for determining a beam stiffness value for said catheter distal end;

a microprocessor for converting said beam stiffness value into a force resistance value using the quantifiable distance and the length of the catheter distal end; and

a display unit.

2. A method of determining the outward radial force of a helical guide section comprising the steps of:

(a) securing a helical guide section in a force measuring device;

(b) fixing each end of the helical guide section in said force measuring device;

(c) pulling the ends of the helical guide section apart;

(d) measuring the force required to pull the helical guide section apart while tracking the linear displacement of the helical guide section during the pull;

(e) measuring the corresponding radial displacement of the guide section while the guide section is being pulled; and

(f) determining the radial force of the guide section from the measured axial force, the measured linear displacement and the measured radial displacement.

3. A method of determining the outward radial force of a catheter over a helical guide section comprising the steps of:

(a) measuring the beam stiffness of a catheter;

(b) measuring the beam stiffness of a helical guide section;

(c) measuring the axial force required to elongated a helical guide section to one half the helical guide section unconstrained diameter; and

(d) determining P_{eff}.

4. The method of claim 2, wherein said force measuring device is a portable hand held device.

5. A method of matching a catheter to a guidewire for a medical procedure requiring precision radial positioning comprising the steps of:

(a) determining a lumen diameter of a body lumen to be treated;

(b) selecting a catheter to be used in said body lumen;

(c) choosing the effective length of said catheter;

(d) measuring a catheter resistance value of said catheter over said effective length; and

(e) matching a guidewire having a compressible guide section to said catheter resistance value to ensure said guidewire has sufficient outward radial force when compressed to deflect said catheter into said lumen wall.

6. The method of claim 5, wherein step (d) further comprises measuring the beam stiffness in a portable force measuring device and converting the beam stiffness of said catheter into said catheter resistance value.

7. An apparatus for shape setting a wire with a curved three dimensional guide section, said apparatus comprising:

a mandrel having a temperature stable core, at least one screw thread having spaced apart roots capable of mechanically receiving a wire; and

at least one retaining device for securing said wire within said spaced apart roots and preventing said wire from slipping or shifting.

8. The apparatus of claim 7, wherein said mandrel has a minor diameter between 0.5 and 20 mm.

9. The apparatus of claim 7, wherein said mandrel has a non-uniform minor diameter.

10. The apparatus of claim 7, wherein said mandrel has a uniform linear geometry.

11. The apparatus of claim 7, wherein said mandrel has a non-uniform linear geometry.

12. The apparatus of claim 7, wherein the mandrel has a plurality of cross section geometries.

13. The apparatus of claim 7, wherein said cross sectional geometries are any combination of regular and irregular shapes.

14. The apparatus of claim 7, wherein the distance between said roots is between 0.026 mm and 12.7 mm.

15. The apparatus of claim 7, wherein the distance between said roots is preferably between 1 mm and 6 mm.

16. The apparatus of claim 7, wherein said mandrel is hollow.

17. The apparatus of claim 7, wherein said mandrel is made of brass.

18. The apparatus of claim 7, wherein said mandrel is made of any form of steel.

19. The apparatus of claim 7, wherein said mandrel is made of a ceramic material.

20. The apparatus of claim 7, wherein the retaining device is a clip.

21. The apparatus of claim 7, wherein the retaining device is a tube slidably fit over said mandrel.

22. A system for shape setting a guidewire comprising:

a rotatable chuck;

a mandrel having at least one screw thread engraved along at least a portion of said mandrel axial length;

at least one spring tension arm for providing tension to a core wire as said core wire is wrapped around a mandrel; and

a heating element for heating said core wire to a shape setting temperature.

23. The system of claim 22, wherein said rotatable chuck is mounted on a lathe.

24. The system of claim 22, further comprising an automated operation of the core wire winding and heating process through a series of stepper motors .

25. The system of claim 22, wherein said spring tension arm is a restraining means for securing said core wire about said mandrel.

26. The system of claim 24, wherein the automated operation is handled by a computer.

27. A method of manufacturing a guidewire with a curved three dimensional guide section comprising the steps of:

(a) wrapping a core wire around a mandrel;

(b) securing the core wire about the mandrel;

(c) heating the mandrel assembly to a temperature between 300 degrees C. and 800 degrees C.;

(d) stopping the heating;

(e) cooling the mandrel assembly to room temperature; and

(f) unwrapping the core wire from the mandrel.

28. The method of manufacturing a guidewire as in claim 27, further comprising the steps of:

(g) coating the core wire with a biocompatible material;

(h) attaching a filament wire to the core wire; and

(i) providing an atraumatic tip at the distal end.

29. The method of claim 27, wherein step (a) comprises a core wire composed at least partially of a shape memory material.

30. The method of claim 27, wherein step (a) comprises a core wire composed at least partially of a shape memory alloy.

31. The method of claim 27, wherein step (a) comprises a core wire composed of nickel-titanium.

32. The method of claim 27, wherein step (a) comprises a core wire composed of stainless steel with a shape memory material laminate coating.

33. The method of claim 27, wherein step (a) comprises a core wire composed of a stainless steel and shape memory sandwich.

34. The method of claim 27, wherein step (a) comprises a core wire composed of at least one wire within a shape memory material matrix, said shape memory matrix being formed in particular to operate as a guidewire.

35. The method of claim 27, wherein step (a) further comprises a core wire having a diameter between 0.0005" and 0.020".

36. The method of claim 27, wherein the mandrel further comprises a fixed channel for providing a predetermined shape setting.

37. The method of claim 36, further comprising a mandrel minor diameter between 0.5 mm and 20 mm.

38. The method of claim 37, wherein the mandrel preferably comprises a mandrel diameter of 1 to 6 mm.

39. The method of claim 27, wherein step (a) further comprises ensuring the core wire is wound such that there is no slack in the wire coils.

40. The method of claim 27, wherein step (b) further comprises a means for securing the wire about the mandrel to assure the core wire does not unravel or slip.

41. The method of claim 27, wherein step (c) further comprises heating the mandrel assembly to a temperature between 450 and 550 degrees C.

42. The method of claim 41, wherein the mandrel assembly remains at temperature from 1 to 10 minutes.

43. The method of claim 27, wherein step (e) further comprises quenching the mandrel assembly.

44. The method of claim 28, wherein step (g) is omitted.

45. The method of claim 28, wherein step (h) is omitted.

46. The method of claim 28, wherein step (i) is omitted.

47. The method of claim 28, wherein step (g) further comprises coating the core wire with a laminate material for reducing the guidewire coefficient of friction.

48. The method of claim 28, wherein step (i) further comprises attaching an atraumatic element to said core wire.

* * * * *

专利名称(译)	用于将导管定位在腔壁上的导丝		
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[标]申请(专利权)人(译)	PROLIFIX医疗		
申请(专利权)人(译)	PROLIFIX MEDICAL，INC.		
当前申请(专利权)人(译)	PROLIFIX MEDICAL，INC.		
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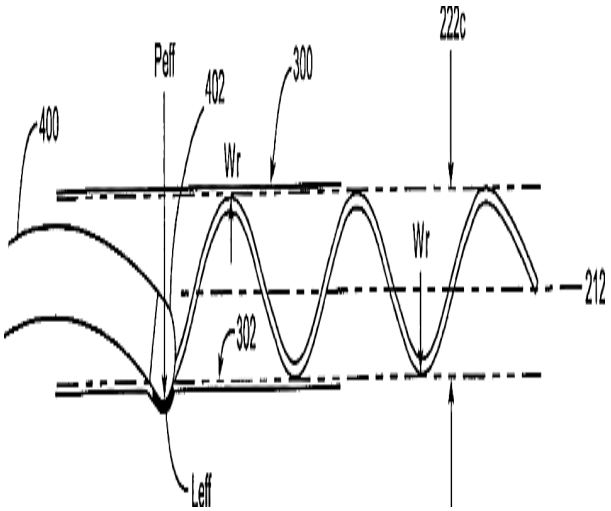
摘要(译)

导丝技术领域本发明涉及一种具有成形的三维导向部分的导丝。在优选实施例中，引导部分是螺旋形的，并且在导管被约束的内腔上施加向外的径向力。可以根据本发明的方法测量或计算向外的径向力。还描述了一种包括导丝和导管的系统，其中还可以计算导管施加在体腔上的力。还公开了制造导丝的装置和方法，以及导丝的替代实施例。


222c
Peff
402
300
400
Wr
Wr
212
302
Leff