(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 326 528 B1

(12) # EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
04.05.2011 Bulletin 2011/18

(21) Application number: **01979991.5**

(22) Date of filing: **11.10.2001**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61M 25/09*** *(2006.01)*

(86) International application number:
PCT/US2001/042636

(87) International publication number:
WO 2002/032344 (25.04.2002 Gazette 2002/17)

(54) **TORSIONALLY COMPENSATED GUIDEWIRE**

TORSIONAL KOMPENSIERTER FÜHRUNGSDRAHT

FIL-GUIDE A TORSION COMPENSEE

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

(30) Priority: **17.10.2000 US 690914**

(43) Date of publication of application:
16.07.2003 Bulletin 2003/29

(73) Proprietor: **Micro Therapeutics, Inc.**
Irvine CA 92618 (US)

(72) Inventors:
- **STRAUSS, Brian, M.**
  Trabuco Canyon, CA 92679 (US)
- **CONNER, Amanda, M.**
  Rancho Santa Margarita, CA 92688 (US)
- **PERALTA, Nelson**
  Rancho Santa Margarita, CA 92688 (US)

(74) Representative: **Wibbelmann, Jobst et al**
Wuesthoff & Wuesthoff
Patent- und Rechtsanwälte
Schweigerstrasse 2
81541 München (DE)

(56) References cited:
EP-A- 0 720 838 **WO-A-99/53824**
US-A- 4 619 274 **US-A- 4 846 186**
US-A- 5 365 942 **US-A- 5 497 783**

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

[0001] There is a demand for increasingly smaller diameter guidewires to enable access to the distal reaches of the vascular system, particularly, the neurovascular system. Micro guidewires are those having a distal diameter of .010 inches or less. Such guidewires are capable in guiding catheters through much of the vascular system. However, there are limitations to the usefulness of micro guidewires.

[0002] One limitation relates to controllability of micro guidewires. Guidewires are typically rotated by twisting the proximal end to steer the distal end through the vasculature. Some of these guidewires have a tip at the distal end with a "J" shape. Rotation of the proximal end of the micro guide wire directs the distal tip to help steer the guidewire through the vasculature.

[0003] A micro guidewire having a small diameter will typically have a reduced torsional stiffness compared with guidewires of larger diameter. Rotation of the proximal end of the micro guide wire may not result in rotation of the distal tip when the micro guidewire is in use in a highly tortuous vessel, thus, reducing the ability to steer the distal tip of the micro guidewire to a desired target.

[0004] U.S. Patent No. 5,313,967 to Lieber et al. discloses a guidewire having a helical length for transmitting torque and axial force. The distal tip tapers from the helix and is brazed to the tip spring. While the helical shape of the guidewire is beneficial, the Lieber et al fail to teach how improved torque and axial force transmission can be accomplished in the region of the distal tip.

[0005] U.S. Patent No. 4,846,174 to Willard et al. discloses a guidewire having a flattened distal tip with a uniformly rectangular cross section. The spring has two ends. Each end of the spring attaches to the distal tip.

[0006] What is desired is a guidewire having a diameter small enough to access the distal reaches of the vasculature, including the neurovascualture and having sufficient torsional stiffness to enable steering of the guidewire through these tortuous regions. What is also desired is a micro guidewire having a distal end with improved tensile and torsional integrity, yet with the capability to readily bend in any direction.

[0007] European Application EP 0 720 838 A1 discloses a guidewire according to the preamble of claim 1.

SUMMARY OF THE INVENTION

[0008] The invention is defined by the appended claims.

[0009] A micro guidewire includes a core and a coil in composite cooperation. The core has a proximal region having a minimum outside diameter of .012". The distal region includes a flattened end for connecting the core to the coil.

[0010] The coil winds about the distal region and has a maximum outside diameter of 0.0085", a proximal end, a distal end and a length extending between the proximal end and the distal end.

[0011] Three joints attach the coil to the core. A distal joint attaches the distal end of the coil to the tip of the flattened end. A proximal joint attaches the proximal end of the coil to the core. A medial joint attaches the intermediate portion, i.e. length of the coil to the core. These three joints cooperate to provide improved tensile and torsional integrity to the distal region of the core. Accordingly, the coil and the core form a composite structure.

[0012] A discrete portion of the distal region is flattened to form a tang to optimize the torque carrying ability of the distal region. The medial joint forms at the tang, circumscribing the tang to improve the torsional integrity of the distal region of the core. The tang enhances lateral flexibility of the core as compared with a cylindrical section of the same nominal diameter. Furthermore, the tang improves the torsional responsiveness of the distal region. Preferably the tang has a uniform thickness.

[0013] To further optimize torsional responsiveness of the distal region of the core, the medial joint is positioned relatively closer to the distal end than to the proximal end of the coil. This torsionally stiffens the distal end of the coil, enabling composite cooperation between the coil and the core near the distal end of the coil. Preferably, the medial joint attaches no more than 1/3 of the length away from the distal end.

[0014] According to one aspect of the invention, the preferable ratio of the diameter of the proximal end of the core to the outside diameter of the coil is at least 1.4 to 1. Having a relatively thick proximal end of the core improves the torsional efficience of the guidewire. In accordance with the present invention, the torsional efficiency achieved is around 80%, or better when the guidewire is in use within a tortuous vessel.

BRIEF DESCRIPTION OF THE DRAWING

[0015]

FIG. 1 is a perspective view of a guidewire and catheter in use within a tortuous region of the vasculature of a patient in accordance with the present invention.
FIG. 2 is an exploded perspective view of the guidewire of FIG. 1.
FIG. 3 is a perspective view of the guidewire of FIG. 1.
FIG. 4 is a cross-sectional view of an embodiment of the guidewire of FIG. 3 as seen along the line 4-4.
FIG. 5 is a cross-sectional view of an embodiment of the guidewire of FIG. 1 as seen along the line 5-5.
FIG. 6 is a cross-sectional view of an embodiment of the guidewire of FIG. 3 as seen along the line 4-4.
FIG. 7 is a cross-sectional view of an embodiment of the guidewire of FIG. 3 as seen along the line 4-4.

Description:

[0016] FIG. 1 shows a micro catheter 11 disposed within the vasculature 13 of a patient. A guidewire 10 is positioned within the catheter 11 and extends from the distal end 17 of the catheter 11 to guide the catheter 11 through the vasculature 13. The guidewire 10 has two ends.

[0017] The micro catheter 11 has an actuator 15. One end of the guidewire 10 extends from the proximal end the catheter 11. The actuator 15 translates and rotate the guidewire 10. The other end of the guidewire 10 extends from the distal end 17 of the micro catheter 11.

[0018] Rotation of one end of the guidewire 10 through an angle a causes the other end rotates at an angle θ. The angle θ is no less than 80% of the angle α during normal use of the guidewire 10 within highly tortuous regions of the vasculature 13 so that the guidewire 10 achieves at least an 80% torsional efficiency.

[0019] For the purposes of this invention, a tortuous path or a tortuous region of the vasculature are defined. A tortuous region of the vasculature has vessels 19 that branch off from more proximal vessels at angles of greater than 90 degrees. The vessels 19 in the distal reaches typically have lumen diameters of 3 mm or less. Typically, a total path length to access tissue in the tortuous region of vasculature is 5 cm or more.

[0020] A tortuous path for a guidewire may have some angles of 90 degrees or more to reach the small vessels with lumen diameters of less than about 3 mm. The path will have a typical length of at least about 5 cm.

[0021] FIG. 2 and FIG. 3 show the guidewire 10. The guidewire 10 includes a core 12 having a proximal region 14, a distal region 16 and a coil 18 surrounding a part of the distal region 16. The proximal region 14 is formed having a relatively large diameter compared to the distal region 16. Bolstering the size of the distal region 16 diameter enables the core 12 to achieve a high degree of torsional efficiency between the proximal region 14 and the distal tip.

[0022] A target of 80% torsional efficiency is achieved within in a highly tortuous vessel by bolstering the core proximal region 14 with a nominal outside diameter of . 012" or more. The core distal 16 region has a tip 20. The core has a nominal diameter of 0.0024 -0.0018" within 2.2 cm from the tip 20. It can be appreciated that these nominal diameter values are exemplary only to illustrate the relative sizing of the distal and proximal regions of the core. This nominal diameter can be flattened or formed to conform to any of a variety of shapes so that the core may have a squared, oval, rectangular and or round shape. Furthermore, this nominal diameter can be increased, reduced, tapered, stepped, or otherwise modified as various applications require.

[0023] The coil 18 is preferably fabricated from a platinum or iridium alloy, has a hydrophilic coating and a uniform outside diameter. According to one aspect of the invention, the coil 18 outside diameter is 0.0085", or less. One possible ratio between the proximal region 14 of the core 12 to the outside diameter of the coil 18 is 0.012 to 0.0085, or 1.446:1. Preferably, the ratio is 1.4:1 or greater.

[0024] The coil 18 winds about the distal region 16 of the core. The coil 18 has a proximal end 22, a distal end 24 and a length 25 extending between the proximal end 22 and the distal end 24.

[0025] The guidewire 10 includes three joints attaching the core 14 and the coil 18. A distal joint 26 attaches the distal end 24 of the coil 18 to the tip 20 of the core 12. A proximal joint 28 attaches the proximal end 22 of the coil 18 to the core 12. A medial joint 30 attaches the length 25 of the coil 18 to the core 12. These three joints 26, 28 and 30 cause the coil 18 and the core 12 to compositely cooperate. Composite cooperation significantly improves tensile and torsional strength at the distal region 16 of the guidewire 10.

[0026] Preferably the joints 26, 28 and 30 are soldered, but can alternatively be adhesively bonded, or braised.

[0027] The distal region 16 of the core 12 includes a flattened end 32, a first transition region 34 and a second transition region 38. The core 12 has a tang 36 formed between the transition regions 34 and 38. The tang 36 is flattened, providing two opposing flat surfaces that improve the joining of the core 12 and the coil 18. The tang 36 enhances the torsional strength of the distal region 16.

[0028] The transition regions 34 and 38 taper, having relatively rounded shapes. The transition region 34 distances the tang 36 from the flattened end 32. The transition region 38 has a relatively larger nominal diameter than the tang 36 to improve the tensile strength at the joint 30. The transition regions 34 and 36 are rounded to enable the distal region 16 of the core 12 to bend more uniformly in any direction. Optimally, the transition regions 34 and 38 are generally frustum shaped.

[0029] According to one aspect of the invention, the transition regions 34 and 36 have relatively rounded cross sections and rounded edges more readily achieve uniform multi-directional bending. Rounded transition regions 34 and 35 facilitate this bending better than would be achieved by a comparable distal region having a uniformly flattened cross section or rectangular cross section. The generally rounded transition regions 24 and 36 also inhibit the tip 20 from whipping when the guidewire 10 rotates.

[0030] The flattened end 32 is approximately 1 cm in length to enable the flattened end 32 to bend into a "J" configuration. This facilitates steering the guidewire 10 through the narrow, tortuous regions of the vasculature, including the neurovascular system.

[0031] The tang 36 has a length of approximately 1.0 cm. It can be appreciated that the distal region 16 of the core 12 can have multiple tangs 36 and transition regions serially aligned. The dimensions of the tang 36 and the transition regions 34 and 38 can vary. It can be appreciated that the length and configuration of the transition regions 34 and 38 may be relatively longer than the tang 36 and vice versa.

[0032] According to one aspect of the invention, the medial joint 30 and the tang 36 are closer to the distal end 24 of the coil 18 than the proximal end 22 of the coil 18. Preferably, the medial joint 30 attaches the length 25 to the tang 36 at no more than 1/3 of the length away from the distal end 24 to optimize torsional integrity of the distal region 16 of the core 12.

[0033] The tang 36 cooperates with the medial joint 30 to improve the torsional integrity of the distal region 16 of the core 12. The tang 36 is formed from a portion of the core distal region 16, which is flattened to form the tang 36. Accordingly, the tang 36 has a flattened shape. The tang 36 enhances lateral flexibility of the distal region 16 without significantly reducing torsional stiffness of the guidewire 10.

[0034] The coil 18 is fabricated from a radiopaque alloy including, for example platinum, iridium and/or tungsten. The guidewire 10 is preferably a micro guidewire for vascular intervention in the neurovascular system. The coil 18 has a length of less than 20 cm and an outside diameter of 0.0085" or less. The core 12 has a length of at least 50 cm, but typically no more than 200 cm.

[0035] FIG. 4 shows the tang 36 within the coil 18. The medial joint 30 solders the tang 36 to the coil 18. Preferably, the medial joint 30 circumscribes the tang 36, filling the region between the tang 36 and the coil 18, to create a solid annular joining with the coil 18.

[0036] FIG. 5 shows the flattened end 32 of the distal region of the core within the coil 18. The distal joint 26 solders the flattened end 32 within the coil 18. The medial joint (FIG. 3) and the distal joint (FIG. 4) thus cooperate to optimize torsional stiffness of the distal region of the coil and of the guidewire.

[0037] FIG. 6 shows the tang 36 within the coil 18. The tang 36 has two sides 42. The sides 42 contact the coil 18 to optimize the torsional capability of the tang 36 and the area of contact between the tang 36 and the joint 30. Optimizing the area of contact of the joint 30 strengthens the joint 30.

[0038] FIG. 7 shows the tang 36 within the coil 18. The tang 36 has a squared cross section to optimize the torsional capability of the tang 36 and the area of contact between the tang 36 and the joint 30. Optimizing the area of contact of the joint 30 strengthens the joint 30.

[0039] The present invention is described in terms of a preferred embodiment, however, it can be appreciated that the present invention can be modified to achieve various goals. For example, the ratio of the outside diameter of the proximal region of the core and the coil outside diameter can be increased. Further, the shape of the tang and the flattened end of the core can be modified. The relative position of the medial joint can also change. Accordingly, the present invention is to be limited only by the following claims:

Claims

1. A micro guidewire (10) for use in tortuous regions of a vasculature, comprising:

    a core (12) having a proximal region (14) having an outside diameter of at least 0.012" (0,03048 cm) and a distal region (16),
    a single coil (18) wound about and attached to the distal region (16), and having a uniform outside diameter of 0.0085" (0.02159 cm) or less, a proximal end (22), a distal end (24) and a length (25) extending between the proximal end and the distal end; and
    a distal (26) joint attaching the distal end of the coil to a flattened end of the core, a proximal joint (28) attaching the proximal end of the coil to the core;

    and whereby the ratio of the core proximal region outside diameter to the coil outside diameter is at least 1.4 to 1,
    characterized in that the distal region of the core (12) includes the flattened end (32) and a tang (36);
    in that the coil includes a hydrophilic coating;
    and **in that** the guidewire further comprises a medial joint (30) attaching the length of the coil to the tang, said medial joint attaching the length of the coil to the core in a position relatively no more than 1/3 of the length away from the distal end.

2. The micro guidewire as set forth in claim 1, wherein the coil is fabricated from a radiopaque alloy selected from the group consisting of: platinum, iridium and/or tungsten.

3. The micro guidewire as set forth in claim 1, wherein the medial joint is soldered and circumscribes the tang.

4. The micro guidewire as set forth in claim 3, wherein the tang is distanced from the flattened end of the core.

5. The micro guidewire as set forth in claim 3, wherein the tang is flattened and contacts the coil.

6. The micro guidewire as set forth in claim 3, wherein the tang has a square cross section.

7. The micro guidewire as set forth in claim 1, wherein the tang has a uniform thickness.

8. The micro guidewire as set forth in claim 1, wherein the tang has a squared cross section.

9. The micro guidewire as set forth in claim 1, wherein the tang has sides, the sides contact the coil.

Patentansprüche

1. Mikroführungsdraht (10) zur Verwendung in geschwungenen Regionen eines Gefäßsystems, umfassend:

einen Kern (12) mit einer proximalen Region (14) mit einem Außendurchmesser von mindestens 0,012" (0,03048 cm) und einer distalen Region (16),
eine einzelne Spule (18) gewunden um und angebracht an der distalen Region (16), und mit einem uniformen Außendurchmesser von 0,0085" (0,02159 cm) oder weniger, einem proximalen Ende (22), einem distalen Ende (24) und einer Länge (25), die sich zwischen dem proximalen Ende und dem distalen Ende erstreckt; und ein distales (26) Gelenk, das das distale Ende der Spule an einem abgeflachten Ende des Kerns anbringt;
ein proximales Gelenk (28), das das proximale Ende der Spule an dem Kern anbringt;

und wobei das Verhältnis des Kern-proximalen-Region-Außendurchmesser zu dem Spulen- Außendurchmesser mindestens 1,4 bis 1 ist;
dadurch gekennzeichnet, dass die distale Region des Kerns (12) das abgeflachte Ende (32) und ein Verbindungsstück (36) beinhaltet;
dadurch, dass die Spule eine hydrophile Beschichtung beinhaltet;
und **dadurch**, dass der Führungsdraht ferner ein mediales Gelenk (13) umfasst, das die Länge der Spule an dem Verbindungsstück anbringt, wobei das mediale Gelenk die Länge der Spule an den Kern in einer Position anbringt, die relativ nicht mehr als 1/3 der Länge entfernt von dem distalen Ende liegt.

2. Mikroführungsdraht nach Anspruch 1, wobei die Spule hergestellt ist aus einer radiopaquen Legierung ausgewählt aus der Gruppe bestehend aus: Platin, Iridium und/oder Wolfram.

3. Mikroführungsdraht nach Anspruch 1, wobei das mediale Gelenk gelötet ist und das Verbindungsstück umgibt.

4. Mikroführungsdraht nach Anspruch 3, wobei das Verbindungsstück von dem abgeflachten Ende des Kerns beabstandet ist.

5. Mikroführungsdraht nach Anspruch 3, wobei das Verbindungsstück abgeflacht ist und die Spule berührt.

6. Mikroführungsdraht nach Anspruch 3, wobei das Verbindungsstück einen quadratischen Querschnitt aufweist.

7. Mikroführungsdraht nach Anspruch 1, wobei das Verbindungsstück eine uniforme Dicke aufweist.

8. Mikroführungsdraht nach Anspruch 1, wobei das Verbindungsstück einen quadratischen Querschnitt aufweist.

9. Mikroführungsdraht nach Anspruch 1, wobei das Verbindungsstück Seiten aufweist, wobei die Seiten die Spule berühren.

Revendications

1. Microfil-guide (10) destiné à une utilisation dans des régions tortueuses d'une vasculature, comprenant :

un noyau (12) ayant une région proximale (14) ayant un diamètre extérieur d'au moins 0,012 pouce (0,03048 cm) et une région distale (16),
une bobine unique (18) enroulée autour de et fixée à la région distale (16), et ayant un diamètre extérieur uniforme de 0,0085 pouce (0,02159 cm) ou moins, une extrémité proximale (22), une extrémité distale (24) et une longueur (25) s'étendant entre l'extrémité proximale et l'extrémité distale ; et
une articulation distale (26) fixant l'extrémité distale de la bobine à une extrémité aplatie du noyau,

une articulation proximale (28) fixant l'extrémité proximale de la bobine au noyau ;
et d'où il résulte que le rapport du diamètre extérieur de la région proximale du noyau sur le diamètre extérieur de la bobine est au moins 1,4 à 1,
caractérisé en ce que la région distale du noyau (12) inclut l'extrémité aplatie (32) et une soie (36) ;
en ce que la bobine inclut un revêtement hydrophile ;
et **en ce que** le fil-guide comprend en outre une articulation médiane (30) fixant la longueur de la bobine à la soie, ladite articulation médiane fixant la longueur de la bobine au noyau dans une position relativement à pas plus de 1/3 de la longueur à l'opposé de l'extrémité distale.

2. Microfil-guide selon la revendication 1, dans lequel la bobine est fabriquée à partir d'un alliage radioopaque choisi parmi le groupe consistant en : le platine, l'iridium et/ou le tungstène.

3. Microfil-guide selon la revendication 1, dans lequel l'articulation médiane est soudée et entoure la soie.

4. Microfil-guide selon la revendication 3, dans lequel la soie est à distance de l'extrémité aplatie du noyau.

5. Microfil-guide selon la revendication 3, dans lequel la soie est aplatie et est au contact de la bobine.

6. Microfil-guide selon la revendication 3, dans lequel la soie a une section transversale carrée.

7. Microfil-guide selon la revendication 1, dans lequel la soie a une épaisseur uniforme.

8. Microfil-guide selon la revendication 1, dans lequel la soie a une section transversale carrée.

9. Microfil-guide selon la revendication 1, dans lequel la soie a des côtés, les côtés sont au contact de la bobine.

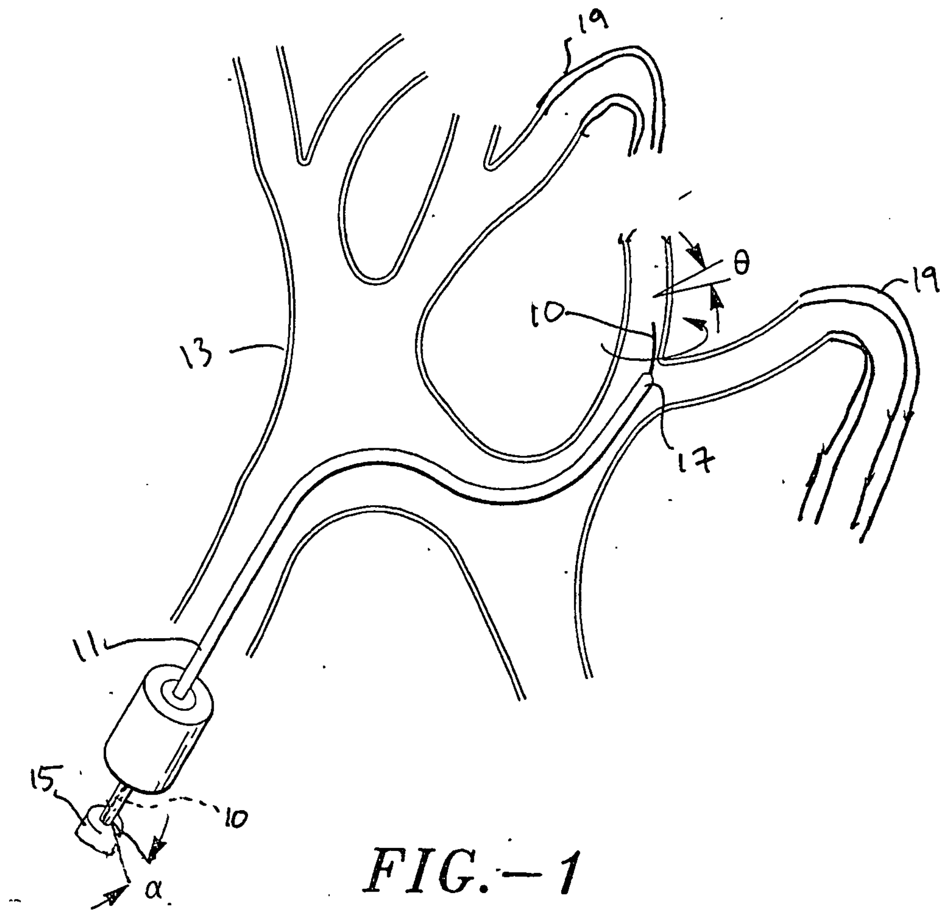

FIG.–1

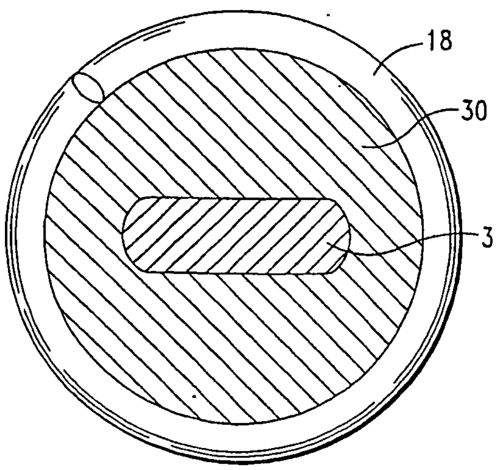

FIG.–4

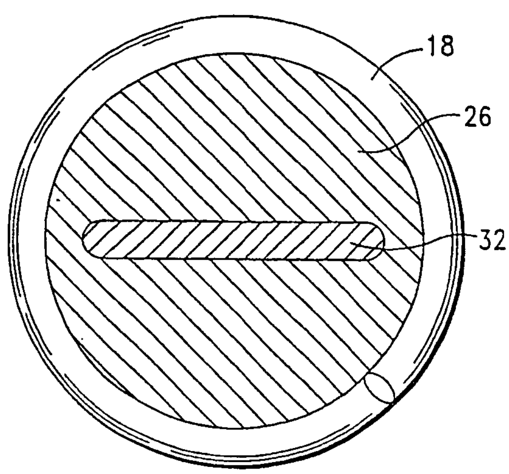

FIG.–5

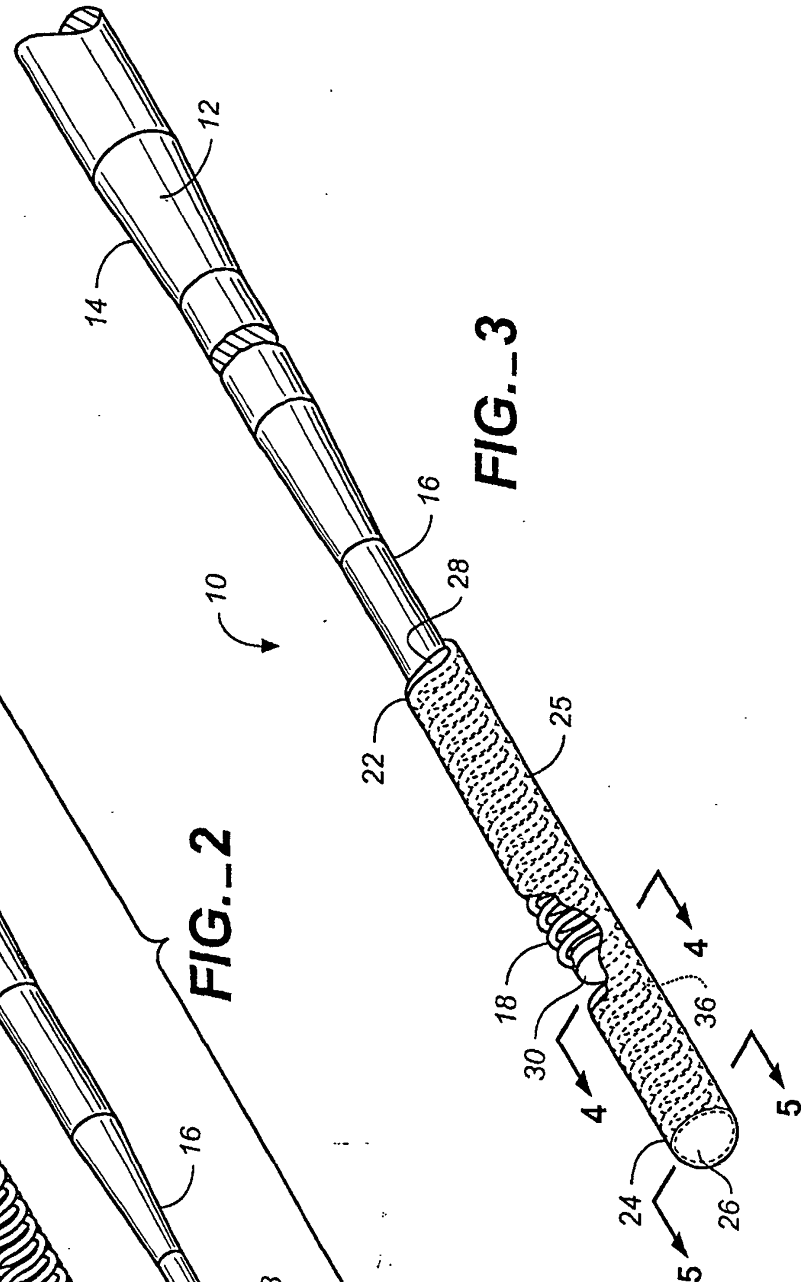
12
14
16
28
10
22
25
18
30
36
4
4
5
5
24
26

FIG._3

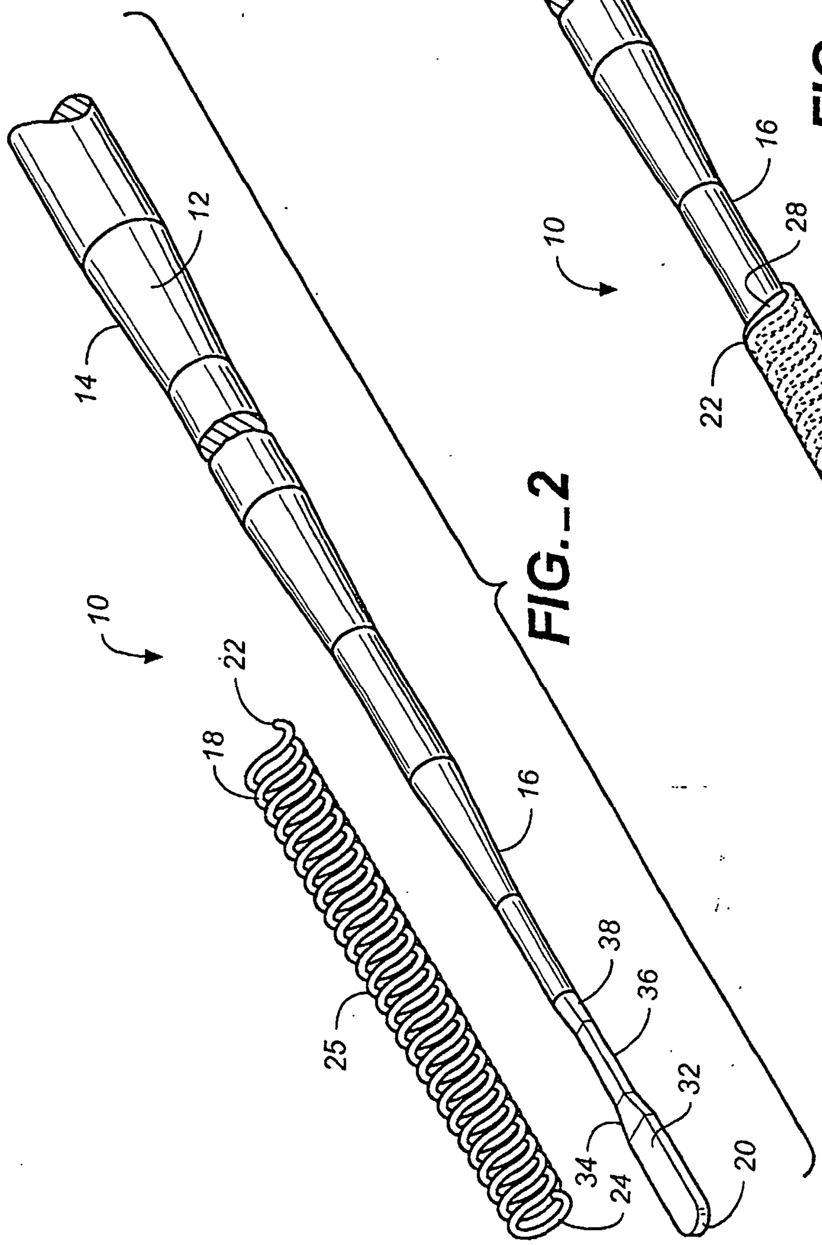
12
14
10
22
18
16
38
36
25
32
34
24
20

FIG._2

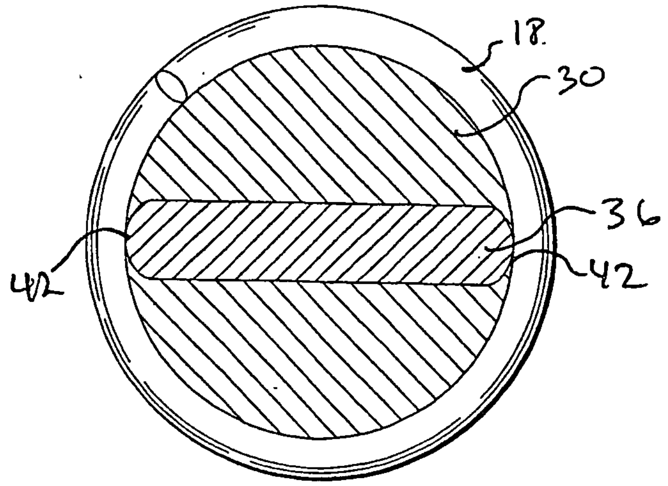

FIG.-6

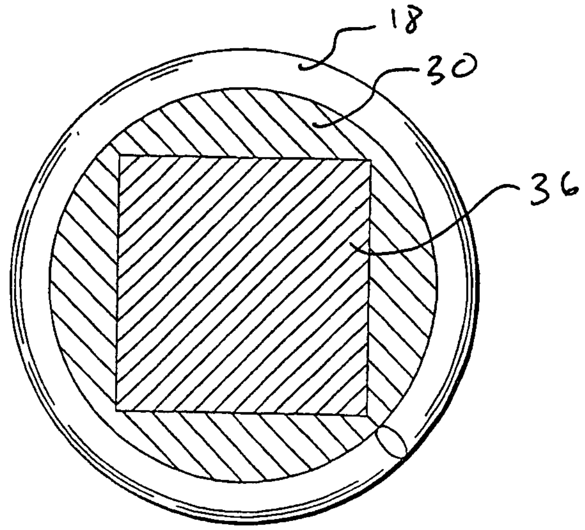

FIG.-7

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 5313967 A, Lieber **[0004]**
- US 4846174 A, Willard **[0005]**
- EP 0720838 A1 **[0007]**

专利名称(译)	扭转补偿导丝		
公开(公告)号	EP1326528B1	公开(公告)日	2011-05-04
申请号	EP2001979991	申请日	2001-10-11
[标]申请(专利权)人(译)	微治疗公司		
申请(专利权)人(译)	MICRO THERAPEUTICS , INC.		
当前申请(专利权)人(译)	MICRO THERAPEUTICS , INC.		
[标]发明人	STRAUSS BRIAN M CONNER AMANDA M PERALTA NELSON		
发明人	STRAUSS, BRIAN, M. CONNER, AMANDA, M. PERALTA, NELSON		
IPC分类号	A61B5/00 A61M25/09 A61M25/01 A61F A61M25/08		
CPC分类号	A61M25/09 A61M2025/09083		
优先权	PCT/US2001/042636 2001-10-11 WO 09/690914 2000-10-17 US		
其他公开文献	EP1326528A4 EP1326528A2		
外部链接	Espacenet		

摘要(译)

导线包括复合配合的芯和线圈，以使导线能够在脉管系统的弯曲区域内使用。 芯具有近端区域和远端区域。 远端区域包括扁平端和用于将铁心连接到线圈的柄脚。 线圈具有近端，远端以及在近端和远端之间延伸的长度。 近端区域与线圈直径之间的比率为1.4：1或更大。 导线包括三个用于将线圈连接到铁心的接头。 远端接头将线圈的远端附接到芯的扁平端。 近端接头将线圈的近端附接到芯。 内侧接头将线圈的长度连接到柄脚上。 三个接头以1.4：1的比例配合使用，以提高导丝的扭矩传递能力，从而使导丝能够通过弯曲度超过90度且管腔直径小于3 mm的血管进行操纵。

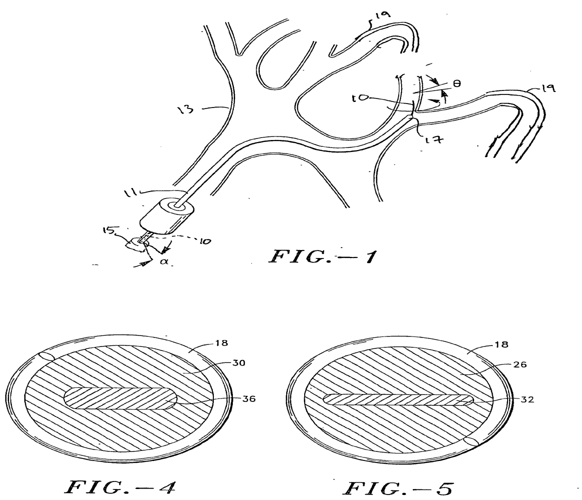

FIG.—1 FIG.—4 FIG.—5