

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
5 February 2004 (05.02.2004)

PCT

(10) International Publication Number
WO 2004/011076 A3

(51) International Patent Classification⁷: **A61M 25/01**,
25/00, A61B 1/005

(21) International Application Number:
PCT/US2003/024837

(22) International Filing Date: 25 July 2003 (25.07.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/399,046 25 July 2002 (25.07.2002) US

(71) Applicant (for all designated States except US): **PRECISION VASCULAR SYSTEMS, INC.** [US/US]; 2405 W. Orton Circle, West Valley City, UT 84119 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **DAVIS, Clark, C.**

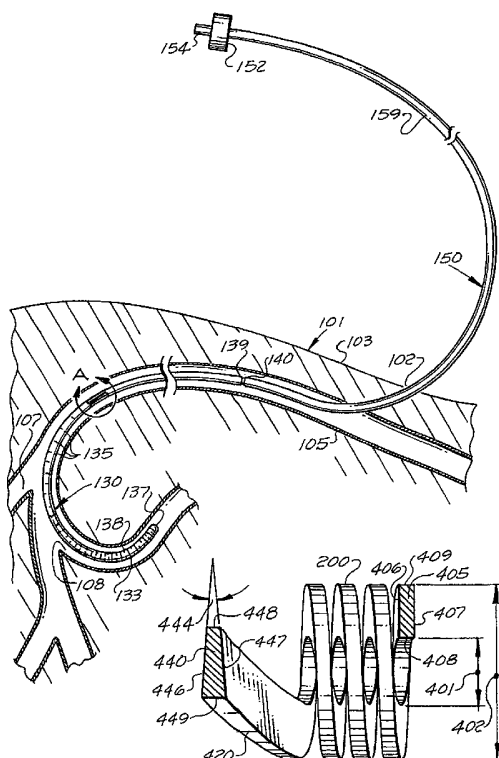
[US/US]; 4564 Wallace Lane, Holladay, UT 84117 (US). **NORTHRUP, Clay, W.** [US/US]; 2917 Cascade Way, Salt Lake City, UT 84109 (US). **LAYMAN, Ted, W.** [US/US]; 7655 North Whileaway Road, Park City, UT 84098 (US). **OLSON, Kevin, T.** [US/US]; 773 East Jeppson Avenue, Salt Lake City, UT 84106 (US). **SNYDER, Edward, J.** [US/US]; 8559 South Ridge Drive, Park City, UT 84098 (US). **BACKMAN, D., Kent** [US/US]; 3299 Splendor Way, Salt Lake City, UT 84124 (US). **TURNLUND, Todd, H.** [US/US]; 3008 Wedge Circle, Park City, UT 84098 (US).

(74) Agent: **WATTS, Allan, W.**; Snell & Wilmer LLP, One Arizona Center, 400 East Van Buren Street, Phoenix, AZ 85004-2202 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,

[Continued on next page]

(54) Title: MEDICAL DEVICE FOR NAVIGATION THROUGH ANATOMY AND METHOD OF MAKING SAME



(57) Abstract: Medical devices for navigation through anatomy, including guidewires (100), which may have a core wire (150), a slotted tubular member (130), or both. Embodiments may have coils (200; 345; 600; 114 1; 1143; 1243; 2238; 2266; 2441), including non-circular cross-section edge-wound marker coils (200), extended coil tips (300), and soldered or glued mesial joint coils (1141; 1143; 1243). Core wires (150) may have a step (1551; 2151; 2152), ridge (1351), or taper (1253) at the joint (140) to the tubular member (130), and may have a flattened section (1057) at the distal tip (257). Radiopaque material (801; 802) may be located inside the tubular member (130), and the distal tip (138) may be heat treated to make it shapeable. Additional tubular members (730; 2062; 2130; 2162; 2439) or coils (200; 345; 600; 1141; 1143; 1243; 2238; 2266; 2441) may be used concentrically or in line.

WO 2004/011076 A3



MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report:
24 June 2004

(15) Information about Correction:

Previous Correction:

see PCT Gazette No. 16/2004 of 15 April 2004, Section II

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/24837

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M25/01 A61M25/00 A61B1/005		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61M A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/57943 A (KLINT HENRIK SONDESKOV ;WILLIAM COOK EUROP APS (DK); COOK INC (US) 5 October 2000 (2000-10-05) page 6, line 5 - page 8, line 28; figures 1-3	1,3,5,6
A	----- EP 0 812 599 A (TARGET THERAPEUTICS INC) 17 December 1997 (1997-12-17) page 2, line 23 - page 4, line 8; figure 1	1,3,5,6
A	----- US 2002/019599 A1 (CHU MICHAEL S H ET AL) 14 February 2002 (2002-02-14) the whole document ----- -/--	1,3,5,6
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search 8 December 2003		Date of mailing of the international search report 05.05.04
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Jameson, P

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/24837

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 338 725 B1 (FREISLINGER KIRSTEN ET AL) 15 January 2002 (2002-01-15) column 9, lines 44-52; figure 1 column 10, lines 20-24; figure 5 column 10, line 55 - column 11, line 6; figure 9	1,2,4
A	----- US 2002/013540 A1 (DAVIS CLARK C ET AL) 31 January 2002 (2002-01-31) the whole document	1-6
A	----- US 4 003 369 A (WADDELL SEID W ET AL) 18 January 1977 (1977-01-18) column 4, line 1 - column 5, line 39; figures 1-3B	1-6
A	----- WO 02/13682 A (HIROSE SHIGEO ;BREEDVELD PAUL (NL); UNIV DELFT TECH (NL)) 21 February 2002 (2002-02-21) the whole document	1-6
A	----- H. A. ROTHBART: "Mechanical Design and Systems Handbook" 1964, MCGRAW- HILL BOOK COMPANY , NEW YORK , XP002264189 pages 33-13	1
A	----- US 5 181 668 A (HOSOYA KOICHI ET AL) 26 January 1993 (1993-01-26) abstract column 4, lines 39-66; figure 3 column 5, lines 39-52; figure 4	1
A	----- US 2 441 166 A (AUGUST RASPET) 11 May 1948 (1948-05-11) the whole document	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/24837

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

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

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6

Remark on Protest

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

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

A medical device for navigation through the anatomy, the medical device comprising
an elongate body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end, and
a helical first coil formed from wire having a substantially non-circular cross-section; and
said cross-section having a greater dimension in the radial direction than in the axial direction.

2. claims: 7-21

A medical device configured to be guided to a target location in anatomy, the medical device comprising:
a first tubular member having a proximal end and a distal end:
a core wire extending proximally from said first tubular member, said core wire being attached with a joint to said first tubular member at least at said proximal end, said joint comprising:
a first coil circumscribing said core wire, said core wire being at least partially inside first tubular member, and
at least one of solder and adhesive.

3. claims: 22-24

A medical device configured to be guided to a target location in anatomy, the medical device comprising:
a tubular member having a proximal end and a distal end and a plurality of slots configured to make the tubular member more flexible in bending; and
a core wire having a proximal section extending from said tubular member, and a distal section located inside said tubular member, and said core wire being attached to said tubular member at least at said proximal end; and
at least part of said proximal section having a substantially round cross section and at least part of said distal section having a flattened cross section.

4. claims: 25-27

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A medical device with a stepped core wire configured to be guided to a target location in anatomy, the medical device comprising:
a tubular member having a proximal end and a distal end and a plurality of slots configured to make said tubular member more flexible in bending; and
a core wire having a proximal section extending from said tubular member, and a distal section located at least partially inside said tubular member, said core wire comprising an abrupt change in cross-sectional dimension between said proximal section and said distal section; and said core wire being attached to said tubular member at least at said proximal end, said proximal end abutting said change in cross-sectional dimension.

5. claims: 28-37

A medical device configured to be guided to a target location in anatomy, the medical device comprising:
a first tubular member having a proximal end and a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
a plurality of slots formed into first tubular member and configured to make said first tubular member more flexible in bending;
a core wire extending proximally from said proximal end of said first tubular member; and
a first coil extending distally from said distal end of said first tubular member.

6. claims: 38-52

A slotted medical device configured to navigate through anatomy, the medical device comprising:
a first tubular member having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
a plurality of groups of slots formed into said first tubular member, at least a plurality of said groups comprising a plurality of slots at substantially the same location along said axis;
at least a plurality of said longitudinally adjacent said groups being rotated at an angle around said axis from previous said group;
at least a plurality of said groups having at least three slots.

7. claims: 53-59

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A medical device configured to navigate through anatomy, the medical device comprising:
 a tubular member having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
 the tubular member comprising a plurality of slots configured to make it more flexible in bending;
 a core wire disposed at least partially within said tubular member and extending proximal therefrom, said core wire having a distal tip;
 a joint attached said core wire to said tubular member at said proximal end of said tubular member; and
 at least one piece of radiopaque material inside said tubular member,
 at or adjacent to said distal end of said tubular member.

8. claims: 60-68

A medical device configured to navigate through anatomy, the medical device comprising:
 a first tubular member having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end, the first tubular member comprising a plurality of slots configured to make it more flexible in bending;
 a second tubular member sharing said longitudinal axis with said first tubular member; and
 a core wire sharing said longitudinal axis with said first tubular member and said second tubular member;
 said first member being attached to at least one of said second and said core wire; and
 said second tubular member being attached to at least one of said first tubular member and said core wire.

9. claims: 69-72

A tapered medical device configured to navigate through anatomy, the medical device comprising:
 a tubular member having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end, at least a portion of said tubular member comprising a plurality of slots, said slots being configured to make said tubular member more flexible in bending;
 a core wire disposed within said tubular member and extending proximally therefrom;
 said core wire being attached to said tubular member at least at said proximal end of said tubular member;
 said tubular member having a taper at least in its outside diameter over at least a portion of its length, said taper having a decreasing outside diameter in the distal direction, said taper being at least one of continuous and incremental.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/24837

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0057943	A	05-10-2000	EP 1040842 A1 04-10-2000
			AU 747321 B2 16-05-2002
			AU 4180000 A 16-10-2000
			CA 2366383 A1 05-10-2000
			EP 1165169 A1 02-01-2002
			JP 2002539900 T 26-11-2002
			WO 0057943 A1 05-10-2000
			US 6383146 B1 07-05-2002

EP 0812599	A	17-12-1997	EP 0812599 A2 17-12-1997
			AT 164088 T 15-04-1998
			AT 221795 T 15-08-2002
			AU 659650 B2 25-05-1995
			AU 1928492 A 21-12-1992
			CA 2086093 A1 08-11-1992
			DE 69224828 D1 23-04-1998
			DE 69224828 T2 09-07-1998
			DE 69232730 D1 12-09-2002
			DE 69232730 T2 28-11-2002
			DK 585359 T3 11-05-1998
			EP 0585359 A1 09-03-1994
			ES 2181963 T3 01-03-2003
			IE 921466 A1 18-11-1992
			JP 2564458 B2 18-12-1996
			JP 6504706 T 02-06-1994
			NO 933963 A 02-11-1993
			PT 100470 A 29-04-1994
			WO 9219151 A1 12-11-1992
			US 5228453 A 20-07-1993

US 2002019599	A1	14-02-2002	US 6306105 B1 23-10-2001
			CA 2331000 A1 18-11-1999
			EP 1077738 A2 28-02-2001
			JP 2002514474 T 21-05-2002
			WO 9958183 A2 18-11-1999

US 6338725	B1	15-01-2002	US 5843031 A 01-12-1998
			US 5599305 A 04-02-1997
			US 2002058910 A1 16-05-2002
			DE 69522528 D1 11-10-2001
			DE 69522528 T2 02-05-2002
			EP 1108442 A2 20-06-2001
			EP 0709108 A2 01-05-1996
JP 8206218 A 13-08-1996			

US 2002013540	A1	31-01-2002	WO 02062540 A2 15-08-2002

US 4003369	A	18-01-1977	US 4080706 A 28-03-1978

WO 0213682	A	21-02-2002	NL 1015783 C2 25-01-2002
			NL 1018282 C1 25-01-2002
			AU 8267701 A 25-02-2002
			WO 0213682 A1 21-02-2002

US 5181668	A	26-01-1993	JP 1064828 A 10-03-1989
			JP 1848586 C 07-06-1994
			JP 5058384 B 26-08-1993
			DE 3832716 A1 05-04-1990

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/24837

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5181668 A		FR 2637043 A1 GB 2224328 A ,B	30-03-1990 02-05-1990
US 2441166 A	11-05-1948	US 2402666 A US 2441167 A	25-06-1946 11-05-1948