(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 13 June 2002 (13.06.2002)

PCT

(10) International Publication Number WO 02/045598 A3

(51) International Patent Classification⁷: A61B 17/22

(21) International Application Number: PCT/US01/46871

(22) International Filing Date: 5 December 2001 (05.12.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

rriority Data:		
60/251,756	5 December 2000 (05.12.2000)	US
60/255,729	14 December 2000 (14.12.2000)	US
60/263,350	22 January 2001 (22.01.2001)	US
60/263,397	22 January 2001 (22.01.2001)	US
60/263,579	22 January 2001 (22.01.2001)	US
60/263,580	22 January 2001 (22.01.2001)	US
60/263,589	22 January 2001 (22.01.2001)	US
60/268,263	12 February 2001 (12.02.2001)	US
60/301,537	27 June 2001 (27.06.2001)	US
60/329,936	17 October 2001 (17.10.2001)	US
	60/251,756 60/255,729 60/263,350 60/263,397 60/263,579 60/263,580 60/263,589 60/268,263 60/301,537	60/251,756 5 December 2000 (05.12.2000) 60/255,729 14 December 2000 (14.12.2000) 60/263,350 22 January 2001 (22.01.2001) 60/263,397 22 January 2001 (22.01.2001) 60/263,579 22 January 2001 (22.01.2001) 60/263,580 22 January 2001 (22.01.2001) 60/263,589 22 January 2001 (22.01.2001) 60/268,263 12 February 2001 (12.02.2001) 60/301,537 27 June 2001 (27.06.2001)

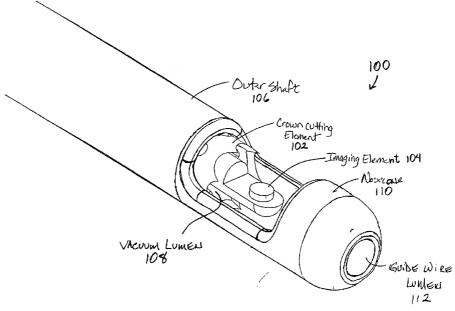
(71) Applicant (for all designated States except US): LU-MEND, INC. [US/US]; 400 Chesapeake Drive, Redwood City, CA 94063 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SPARKS, Kurt, D. [US/US]; 1618 Sand Hill Road, #406, Palo Alto, CA 94304 (US). EMERY, Jeffrey, L. [US/US]; 2104 Meadowview Place, San Mateo, CA 94401 (US). SEYBOLD, Brent, D. [US/US]; 2435 Armstrong Avenue, Santa Clara, CA 95050 (US). KUPIECKI, David, J. [US/US]; 3276 Market Street, San Francisco, CA 94114 (US). PINSON, C., Danielle [US/US]; 711 Eunice Avenue, Mountain View, California 94040 (US). MADSEN, Allen, W. [US/US]; 2878 Kilo Avenue, San Jose, CA 95124 (US). KELEHER, Michael, D. [US/US]; 34330 Dobson Way, Fremont, CA 94555 (US). SALINAS, Sergio [US/US]; 642 Scott Avenue, Redwood City, CA 94063 (US). CLARK, Benjamin, J. [US/US]; 3814 East Lake Way, Redwood City, CA 94062 (US). SELMON, Matthew, R. [US/US]; 99 Walnut Avenue, Atherton, CA 94027 (US).

[Continued on next page]

(54) Title: CATHETER SYSTEM FOR VASCULAR RE-ENTRY FROM A SUB-INTIMAL SPACE



(57) Abstract: A catheter system and corresponding methods are provided for accessing a blood vessel true lumen from a suub-intimal plane of the vessel. The catheter system includes visualiation elements for determining the orientation of the true lumen with respect to the sub-intimal plane at an identified entry site from a position in the sub-intimal plane. The entry site is distal to a chronic total occlusion (CTO). The catheter system also includes a system for physically securing tissue of the sub-intimal plane at the entry site to the catheter system. The attaching system reduces or eliminates catheter float within the sub-intimal space. The catheter system further includes re-entry devices to establish and maintain a path from the sub-intimal plane back into the vessel true lumen.



70 02/045598 A3

WO 02/045598 A3



- (74) Agents: GREGORY, Richard, L. et al.; Perkins Coie LLP, P.O. Box 2168, Menlo Park, CA 94026 (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, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.
- (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, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- (88) Date of publication of the international search report: 16 January 2003

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.

Inter nal Application No
PCT/US 01/46871

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B17/22						
According to International Patent Classification (IPC) or to both national classification and IPC						
Minimum do IPC 7	B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 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						
C. DOCUME	NTS CONSIDERED TO BE RELEVANT					
Category °	Citation of document, with Indication, where appropriate, of the rele	evant passages	Relevant to claim No.			
X	WO 99 35980 A (LUMEND INC ;MILO C (US); VETTER JAMES W (US); HINOHA 22 July 1999 (1999-07-22) page 15, line 1 - line 5; figures page 17, line 29 -page 18, line 1	3				
Υ	*1	4				
Υ	WO 99 35979 A (CO FRED H ;FRENCH (US); HILL RICHARD E (US); LUMEND 22 July 1999 (1999-07-22) abstract; figures 3-4D	4				
Α			3			
A	US 6 068 638 A (MAKOWER JOSHUA) 30 May 2000 (2000-05-30) column 4, line 6 -column 5, line 2	3,4				
		-/				
Further documents are listed in the continuation of box C. Patent family members are listed in annex.						
"A" document defining the general state of the art which is not considered to be of particular relevance "I" 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.						
E earlier document but published on or after the international filing date *X* document of particular relevance; the claimed invention cannot be considered to						
"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 "O" document referring to an oral disclosure, use, exhibition or other means "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 "B' document published prior to the international filing date but later than the priority date claimed "A" document member of the same patent family						
Date of the actual completion of the international search Date of mailing of the international search report						
13 September 2002 23/09/2002						
Name and I	Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL 2280 HV Rijswijk Authorized officer					
	Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ducreau, F				

Inter(nal Application No PCT/US 01/46871

.(Continuation	n) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category ° Cit	tation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
1	US 5 951 541 A (GERTNER KEVIN ET AL) 14 September 1999 (1999-09-14) column 8, line 8 - line 62; figures 2-4	3,4

ational application No. PCT/US 01/46871

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 1.2 because they relate to subject matter not required to be searched by this Authority, namely: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by
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:
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

ormation on patent family members

Inter nal Application No
PCT/US 01/46871

	_			l l	01/03	U1/408/1
Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 9935980	Α	22-07-1999	AU WO	2004999 9935980		02-08-1999 22-07-1999
WO 9935979	Α	22-07-1999	US AU	6231546 745116	B2	15-05-2001 14-03-2002
			AU	1831599		02-08-1999
			BR	9814588		24-10-2000
			CA EP	2318470 1047344		22-07-1999 02-11-2000
			JP	2002508987		26-03-2002
			WO	9935979		22-07-1999
			US	6221049		24-04-2001
			U\$ 	6235000	B1 	22-05-2001
US 6068638	Α	30-05-2000	US	5830222		03-11-1998
			US	6231587		15-05-2001
			AU AU	1275997 733332		11-05-1998 10-05-2001
			AU	1847297		22-08-1997
			ΑÜ	723785		07-09-2000
			ΑU	1847397		22-08-1997
			CA	2244079		07-08-1997
			CA CN	2244080 1218414		07-08-1997 02-06-1999
			CN	1216929		19-05-1999
			EP	0879068		25-11-1998
			EP	0932426	A1	04-08-1999
			JP	2000504594		18-04-2000
			JP		T D1	09-05-2000
			US WO	6283951 9816161		04-09-2001 23-04-1998
			WO	9727893		07-08-1997
			WO	9727898		07-08-1997
			US	6159225		12-12-2000
			US US	6283983 6375615		04-09-2001 23-04-2002
			US	2002002349		03-01-2002
			US	6302875		16-10-2001
			US	2002029079	A1	07-03-2002
			US	2001047165		29-11-2001
			US US	6432127 2002062146		13-08-2002 23-05-2002
			AU	726713		16-11-2000
			ΑU	7431696	Α	30-04-1997
			AU	729466		01-02-2001
			AU	7595396		30-04-1997 17 04 1007
			CA CA	2234361 2234389		17-04-1997 17-04-1997
			EP	1166721		02-01-2002
			EP	0954248	A1	10-11-1999
			EP	0955933	A1	17-11-1999
			EP	0910298		28-04-1999
			JP JP	11513577 11514269		24-11-1999 07-12-1999
				9713471		17-04-1997
			Wiii	9/134/1	AI	1/-(14-133/
			WO WO	9713463		17-04-1997

mation on patent family members

Inter nal Application No
PCT/US 01/46871

cit	Patent document cited in search report		Publication date	F	Patent family member(s)	Publication date
U	S 5951541	Α	14-09-1999	NONE		