

(19) World Intellectual Property  
Organization  
International Bureau



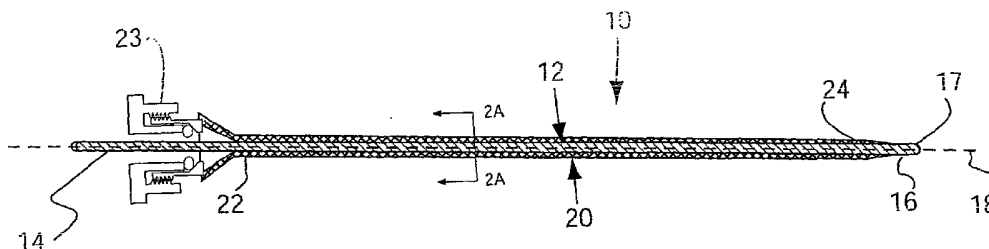
(43) International Publication Date  
6 November 2003 (06.11.2003)

PCT

(10) International Publication Number  
**WO 2003/090834 A3**

- (51) International Patent Classification<sup>7</sup>: **A61M 25/06**
- (21) International Application Number:  
PCT/US2003/013024
- (22) International Filing Date: 24 April 2003 (24.04.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/376,065 25 April 2002 (25.04.2002) US  
10/423,321 24 April 2003 (24.04.2003) US
- (71) Applicant: **THE BOARD OF TRUSTEES OF THE LE-  
LAND STANFORD JUNIOR UNIVERSITY** [US/US];  
1705 El Camino Real, Palo Alto, CA 94306-1106 (US).
- (72) Inventors: **EVERSULL, Christian, Scott**; 2160 Yale  
Street, Palo Alto, CA 94306 (US). **MOURLAS, Nicholas,  
J.**; 230 Monroe Drive, Apt. No. 14, Mountain View, CA  
94040 (US). **LEEFLANG, Stephen, Arie**; 649 Miranda  
Avenue, Stanford, CA 94305 (US). **NAYAK, Asha,  
Shrinivas**; 734 Partridge Avenue, Menlo Park, CA 94025  
(US). **MILLER, David, John**; 1766 San Hill Road, # 404,  
Palo Alto, CA 94304 (US).
- (74) Agent: **ENGLISH, William, A.**; Bingham McCutchen  
LLP, Three Embarcadero Center, Suite 1800, San Fran-  
cisco, CA 94111-4067 (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, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD,  
SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ,  
VC, 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, 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).
- Published:**  
— with international search report
- (88) Date of publication of the international search report:  
19 February 2004
- For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

(54) Title: EXPANDABLE GUIDE SHEATH AND APPARATUS AND METHODS USING SUCH SHEATHS



(57) Abstract: Apparatus and methods are provided for accessing body lumens and/or for delivering instruments into body lumens, e.g., vessels within a patient's vasculature. A flexible sheath (20) is provided that is expandable from a contracted condition to an enlarged condition wherein the sheath at least partially defines a lumen therein. The sheath is lubricious and has a relatively thin wall, thereby providing a collapsible/expandable guide for delivering fluids and/or instruments through tortuous anatomy and/or into relatively narrow passages. The sheath is advanced from an entry site to a body lumen in the contracted condition. Once the sheath reaches a target body lumen, the sheath is expanded to the enlarged condition, thereby defining a lumen within the sheath, and fluids and/or instruments are introduced into the body lumen via the sheath lumen. Upon completing the procedure, the sheath is removed from the body lumen.

WO 2003/090834 A3

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 03/13024

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61M25/06

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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 090 072 A (KEITH PETER T ET AL) 18 July 2000 (2000-07-18)  column 11, line 51 - column 26, line 4; figures 2-7	1-9, 11, 17-19, 27, 28, 33, 36-44, 47-49
X	US 5 413 560 A (SOLAR RONALD J) 9 May 1995 (1995-05-09)  column 5, lines 7-46; figures 7-10	1-4, 7-11, 18, 19, 21-25, 34-38, 40, 43, 44, 49

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "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

11 August 2003

Date of mailing of the international search report

04.12.03

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

Rosenblatt, T.

2

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 03/13024

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 84 01512 A (NISSEN RICHARD BENT) 26 April 1984 (1984-04-26)</p> <p>page 3, line 25 - page 4, line 14; figures 1-3</p>	<p>1,7-11, 18, 21-24, 26,36, 40-44,49</p>
X	<p>-----</p> <p>US 6 197 016 B1 (FOURKAS MICHAEL G ET AL) 6 March 2001 (2001-03-06)</p> <p>column 5, line 23 - column 6, line 19; figures 1-7 column 10, line 60 - column 11, line 65 column 13, lines 9-58; figure 28</p>	<p>1-9,11, 17-19, 21-24, 26, 36-44, 47,49</p>
X	<p>-----</p> <p>US 5 618 267 A (PALESTRANT AUBREY M) 8 April 1997 (1997-04-08)</p> <p>column 6, line 19 - column 9, line 53; figures 1,3,6,9</p>	<p>1-6, 12-16, 18,19, 34, 36-40, 44,45,49</p>
A	<p>-----</p> <p>US 2001/053919 A1 (KIETURAKIS MACIEJ J ET AL) 20 December 2001 (2001-12-20)</p> <p>paragraphs [0055], [0056], [0063] - [0065]; figures 5,6</p> <p>-----</p>	<p>1-6,10, 15,16, 18, 21-25, 27-29, 31,35,36</p>

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 03/13024

## 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.:

1-49

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: 1-49

apparatus comprising an expandable sheath and apparatus comprising an expandable sheath and a flexible stiffening member

---

2. claims: 50-55

apparatus comprising an expandable sheath and a flexible catheter, the sheath being attached to an outer surface of the catheter

---

# INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No  
PCT/US 03/13024

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6090072	A	18-07-2000	US 6183443 B1	06-02-2001
US 5413560	A	09-05-1995	AU 2815299 A	05-08-1999
			AU 2815399 A	22-07-1999
			AU 3556893 A	07-10-1993
			AU 707509 B2	15-07-1999
			AU 7192996 A	06-02-1997
			CA 2091803 A1	01-10-1993
			DE 9305539 U1	12-08-1993
			DE 69325303 D1	22-07-1999
			DE 69325303 T2	14-10-1999
			EP 0564894 A1	13-10-1993
			JP 6197972 A	19-07-1994
			US 5738667 A	14-04-1998
			US 5407432 A	18-04-1995
			ZA 9301941 A	16-11-1993
WO 8401512	A	26-04-1984	DK 447982 A	12-04-1984
			WO 8401512 A1	26-04-1984
			EP 0121556 A1	17-10-1984
US 6197016	B1	06-03-2001	US 5935122 A	10-08-1999
			US 5653697 A	05-08-1997
			US 5484418 A	16-01-1996
			US 5395349 A	07-03-1995
			US 5256150 A	26-10-1993
			AU 8677498 A	22-02-1999
			WO 9906094 A1	11-02-1999
			AU 693472 B2	02-07-1998
			AU 7634594 A	14-03-1995
			CA 2168369 A1	23-02-1995
			EP 0746352 A1	11-12-1996
			JP 9501594 T	18-02-1997
			WO 9505207 A2	23-02-1995
			AU 661064 B2	13-07-1995
			AU 2830992 A	17-06-1993
			CA 2083000 A1	14-06-1993
			DE 69229102 D1	10-06-1999
			DE 69229102 T2	26-08-1999
			EP 0546712 A2	16-06-1993
			JP 6197981 A	19-07-1994
US 5618267	A	08-04-1997	US 5472418 A	05-12-1995
			CA 2196043 A1	08-02-1996
			DE 69524957 D1	14-02-2002
			DE 69524957 T2	14-08-2002
			EP 0772471 A1	14-05-1997
			WO 9603169 A1	08-02-1996
US 2001053919	A1	20-12-2001	US 6312442 B1	06-11-2001
			US 2002107539 A1	08-08-2002
			US 2002091405 A1	11-07-2002
			US 2002077652 A1	20-06-2002
			AT 169475 T	15-08-1998
			AT 204148 T	15-09-2001
			AU 661905 B2	10-08-1995
			AU 3992493 A	09-12-1993
			CA 2097491 A1	03-12-1993

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/13024

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001053919 A1		DE 69320258 D1	17-09-1998
		DE 69320258 T2	08-04-1999
		DE 69330616 D1	20-09-2001
		DE 69330616 T2	29-11-2001
		DK 573273 T3	10-05-1999
		EP 0573273 A2	08-12-1993
		EP 0835638 A1	15-04-1998
		ES 2121584 T3	01-12-1998
		ES 2161408 T3	01-12-2001
		JP 2677947 B2	17-11-1997
		JP 7275203 A	24-10-1995
		PL 299163 A1	10-01-1994
		US 2002111652 A1	15-08-2002
		US 5836961 A	17-11-1998
		US 6514272 B1	04-02-2003
		US 6264604 B1	24-07-2001
		US 6540764 B1	01-04-2003
		US 5607443 A	04-03-1997
		US 5496345 A	05-03-1996
		US 2003120299 A1	26-06-2003
		US 6364892 B1	02-04-2002
		US 6432121 B1	13-08-2002
		US 5730756 A	24-03-1998
		US 5540711 A	30-07-1996
		US 2003191490 A1	09-10-2003
		US 5702416 A	30-12-1997
		US 5817123 A	06-10-1998
		US 5772680 A	30-06-1998
		US 6368337 B1	09-04-2002
		US 2001029388 A1	11-10-2001
		US 6565589 B1	20-05-2003
		US 2002032456 A1	14-03-2002
		US 6004337 A	21-12-1999