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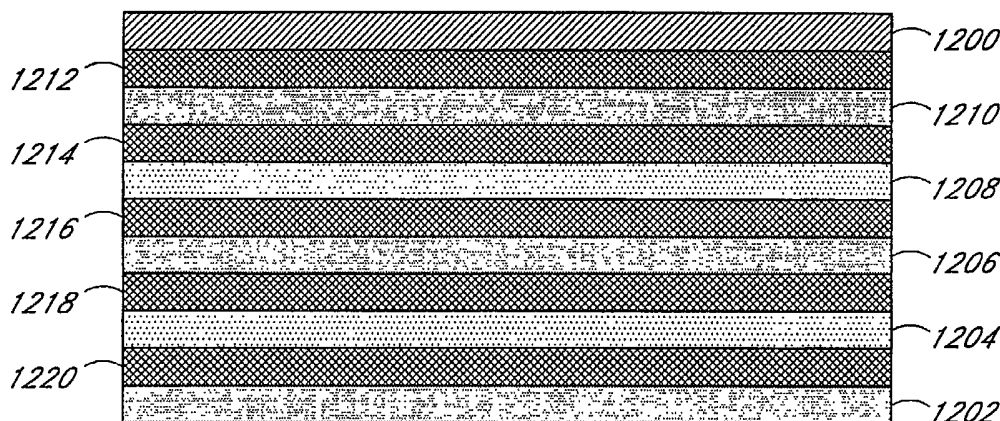
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DEVICES AND METHODS FOR TREATMENT OF STENOTIC REGIONS



(57) Abstract: An improved method and devices for preventing restenosis are provided. A multiple drug combination eluting stent is provided. The stent includes a plurality of drugs which interact to combat restenosis. In some embodiments, the drugs are delivered simultaneously, while in other embodiments, the drugs are delivered sequentially.

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INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06 A61M25/00

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 A61F A61M

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. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 837 313 A (DING NI ET AL) 17 November 1998 (1998-11-17)	1,2,10, 11,14, 16-22, 25-28, 36,37,40
Y	column 2, line 34 - column 11, line 13 -----	3-9,12, 13,15, 23,24, 29-35, 38,39
Y	US 6 451 373 B1 (HOSSAINY SYED F A ET AL) 17 September 2002 (2002-09-17)	3,4,7-9, 12,13, 29,30, 33-35, 38,39
	column 4, line 34 - column 6, line 27 ----- -/--	

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

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"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

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 516 781 A (GREGORY CLARE R ET AL) 14 May 1996 (1996-05-14) column 3, line 45 - column 12, line 27 -----	5,6,31, 32
Y	WO 03/009773 A (ALVEOLUS INC) 6 February 2003 (2003-02-06) figures 1-13 -----	15
Y	US 6 010 530 A (GOICOECHEA GEORGE) 4 January 2000 (2000-01-04) column 5, line 59 - column 6, line 24; figures 4A,4B -----	23,24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/015903

Box II Observations where certain claims were found unsearchable (Continuation of item 2 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.: 41, 44-46, 47, 60-63
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Methods for treatment of the human or animal body by surgery and therapy
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 III Observations where unity of invention is lacking (Continuation of item 3 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.:
1-24, 25-40

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: 1-24,25-40

A drug-delivery stent comprising multiple drug layers and polymer barrier layers between said drug layers.

2. claims: 42,43

A drug-delivery stent comprising a first drug; a second drug; and a third drug, wherein said first drug is an anti-inflammatory drug.

3. claims: 48-59, 65

A stent and a stent delivery catheter comprising a balloon, wherein the proximal and the distal ends of said stent and said balloon having the diameter greater than the diameter of the center portion.

4. claim: 64

A drug impregnation catheter comprising a balloon, wherein said balloon comprises a needle element, wherein said needle element is configured to deliver a drug to a treatment site.

5. claims: 66,67

A mapping catheter comprising a balloon, wherein said balloon is constructed of compliant material, and said balloon conforms to a stenotic region.

6. claims: 68-70

An inspection catheter comprising a first balloon, a second balloon, and an optical inspection element positioned between said balloons.

INTERNATIONAL SEARCH REPORT
 information on patent family members

International Application No
 PCT/US2004/015903

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5837313	A	17-11-1998	AU 703805 B2	01-04-1999
			AU 6965296 A	01-04-1997
			BR 9610607 A	04-05-1999
			CA 2231727 A1	20-03-1997
			CA 2470709 A1	20-03-1997
			EP 1019107 A1	19-07-2000
			IL 123622 A	04-01-2004
			JP 11500047 T	06-01-1999
			NO 981066 A	08-05-1998
			US 6358556 B1	19-03-2002
			US 2002091433 A1	11-07-2002
			US 2002071902 A1	13-06-2002
			WO 9710011 A1	20-03-1997
			US 2004049265 A1	11-03-2004
			US 6120536 A	19-09-2000
			US 2002004101 A1	10-01-2002
			ZA 9607625 A	16-04-1997
			AT 223180 T	15-09-2002
			AU 4952096 A	07-11-1996
			BR 9608021 A	02-03-1999
			CA 2216943 A1	24-10-1996
			DE 29624503 U1	16-09-2004
			DE 69623455 D1	10-10-2002
			DE 69623455 T2	16-01-2003
			EP 0822788 A1	11-02-1998
			WO 9632907 A1	24-10-1996
			JP 10506560 T	30-06-1998
			NO 974823 A	17-10-1997
			US 2002032477 A1	14-03-2002
			ZA 9603075 A	20-10-1997

US 6451373	B1	17-09-2002	US 2002168394 A1	14-11-2002
			US 2004047978 A1	11-03-2004

US 5516781	A	14-05-1996	AT 210979 T	15-01-2002
			AU 706486 B2	17-06-1999
			AU 1791895 A	23-11-1995
			CA 2148871 A1	13-11-1995
			CY 2332 A	06-02-2004
			DE 69524679 D1	31-01-2002
			DE 69524679 T2	13-06-2002
			DK 691130 T3	11-03-2002
			EP 0691130 A1	10-01-1996
			ES 2166802 T3	01-05-2002
			HK 1010333 A1	04-04-2002
			JP 8040901 A	13-02-1996
			NZ 272092 A	27-07-1997
			PT 691130 T	28-06-2002
			SI 691130 T1	30-04-2002
			US 5665728 A	09-09-1997
			US 5646160 A	08-07-1997
			US 5563146 A	08-10-1996
			AT 194493 T	15-07-2000
			AU 665041 B2	14-12-1995
			AU 3107993 A	15-07-1993
			CA 2086642 A1	10-07-1993
			DE 69328981 D1	17-08-2000
			DE 69328981 T2	16-11-2000

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No
PCT/US2004/015903

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5516781	A	DK 551182 T3	09-10-2000
		EP 0551182 A1	14-07-1993
		ES 2147740 T3	01-10-2000
		GR 3034479 T3	29-12-2000
		HK 1010332 A1	29-12-2000
		JP 2644955 B2	25-08-1997
		JP 6009390 A	18-01-1994
		LV 12603 A ,B	20-01-2001
		NZ 245630 A	27-07-1997
		PT 551182 T	29-12-2000
		SG 47639 A1	17-04-1998

WO 03009773	A	06-02-2003	CA 2454871 A1
			EP 1424960 A2
			WO 03009773 A2
			US 2003024534 A1
			06-02-2003
			06-02-2003

US 6010530	A	04-01-2000	NONE
