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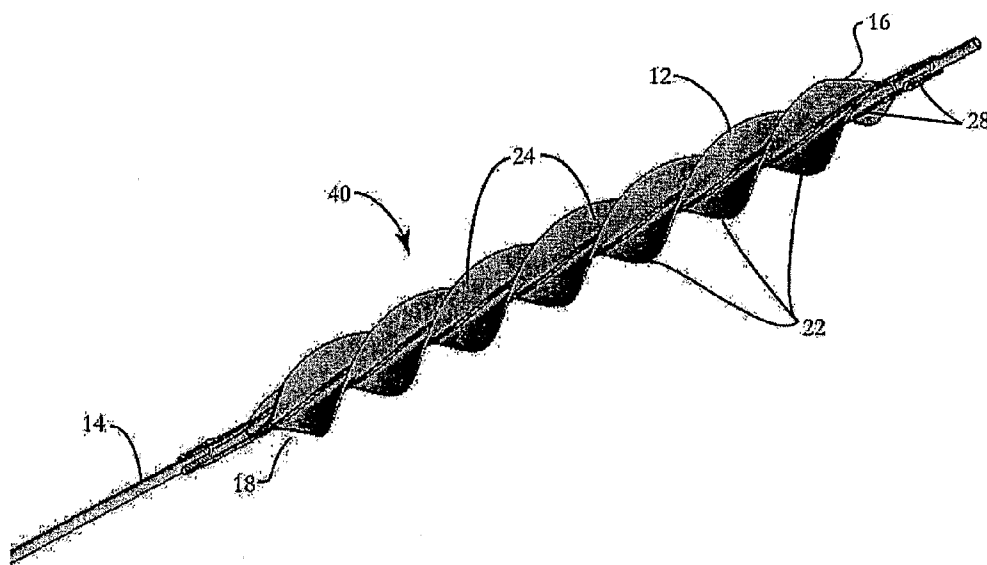
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- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

[Continued on next page]

(54) Title: BALLOON CATHETER WITH SPIRAL FOLDS



(57) Abstract: The balloon catheter (10) comprises a radially expansible, polymeric balloon (12) having one or more permanent helical fold lines (22) so that the balloon can be spirally folded upon delivery of the catheter to or removal of the vessel. A scoring structure (28) may be carried over the balloon in between the folds to score a stenosed region in a blood vessel. Fabrication devices and methods for spirally folding the balloon are also disclosed.

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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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/02669

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61M 31/00(2007.01);A61M 29/00(2007.01)

USPC: 604/509;606/194

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)

U.S. : 604/509;606/194

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 practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,792,415 A (Hijlkema) 11 August 1998 (11.08.1998), see entire document	1-4, 6
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Y		5, 7-20
Y	US 2002/0151924 A1 (Shiber) 17 October 2002 (17.10.2002), figs 5, 8, 10, 11 and paragraph 39.	9-20
Y	US 2002/0077606 A1 (Trotta) 20 June 2002 (20.06.2002), paragraph 33.	5
Y	US 4,276,874 A (Wolvek et al) 07 July 1981 (07.07.1981), fig 5.	8
X	US 6,468,243 B1 (Miyagawa et al) 22 October 2002 (22.10.2002), column 3 lines 24-33 and fig. 1.	54, 55
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Y		7

☐ Further documents are listed in the continuation of Box C.

☐ See patent family 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 application or patent 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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/02669

Box No. 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.:
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 No. 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:
Please See Continuation 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 additional fees, this Authority did not invite payment of any additional fees.
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.: 1-20, 54 and 55

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/02669

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-20, 54, and 55, drawn to a balloon catheter and method of using.

Group II, claim(s) 21-53, drawn to a method of forming folds on a balloon catheter.

Group III, claim(s) 56-73, drawn to a device for forming folds on a balloon catheter.

The inventions listed as Groups I, II, and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of Group I is directed at a balloon, while the invention of Group III is a device for folding a balloon in which the particulars of the device correspond to special technical features of balloon folding devices, not balloons themselves. The invention of Group II is related to a different inventive concept from the other groups in that it is directed to a method of folding a balloon. The inventive concept deals with the methodology, not the balloon itself.