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[Continued on next page]

(54) Title: CATHETER DELIVERABLE ARTIFICIAL MULTI-LEAFLET HEART VALVE PROSTHESIS AND INTRAVASCULAR DELIVERY SYSTEM FOR A CATHETER DELIVERABLE HEART VALVE PROSTHESIS

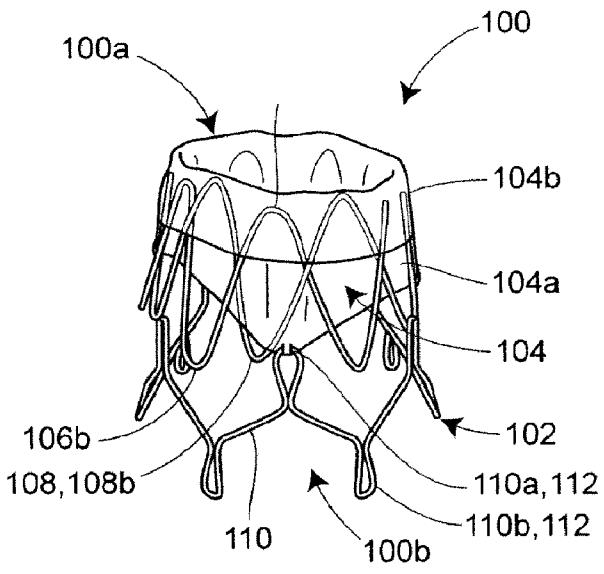


FIG. 3A

(57) Abstract: A heart valve prosthesis includes a collapsible stent and a one-piece multi- leaflet valve. The stent includes at least one length of wire having a series of turns forming a spring-like stent. The one-piece multi-leaflet valve is attached to the stent and includes a cylinder of polyester material secured thereto at three points. The stent is collapsible in a radial direction between a contracted state and an expanded state. The contracted state has a radial dimension smaller than a radial dimension of the expanded state. The stent is spring biased toward the expanded state such that it occupies an active state when implanted into a heart. The active state has a radial dimension that is between the radial dimension of the contracted state and the radial dimension of the expanded state such that a radial load generated by the bias of the collapsible stent is sufficient to retain the heart valve prosthesis in the heart.

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OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
18 February 2010

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/24(2006.01)i, A61M 25/00(2006.01)i, A61M 39/22(2006.01)i, A61F 2/02(2006.01)i

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 A61F 2/24, A61F 1/24, A61N 1/37

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)
eKOMPASS(KIPO internal), USPTO, JPO, Delphion

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4687486 (John Fisher et. al.) 18 August 1987 See abstract; figures 1-6; columns 1-5; and claims 1-14	1-17
A	WO 01/41679 A1 (Aortech Europe Limited) 14 June 2001 See abstract; pages 1-50; claims 1-60; and figures 1-14	1-17
A	JP 3489643 B2 (ATS Medical Inc.) 07 November 2003 See claims 1-14; pages 2-5; and figures 1-3	1-17
A	US 4167045 (Philip N. Sawyer) 11 September 1979 See abstract; figures 1A-6B; columns 1-12; and claims 1-2	1-17

☐ 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 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 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	Date of mailing of the international search report
29 DECEMBER 2009 (29.12.2009)	**30 DECEMBER 2009 (30.12.2009)**

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Korean Intellectual Property Office
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INTERNATIONAL SEARCH REPORT

International application No.
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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:

Group 1 : claims 1-10 feature a heart valve prosthesis comprising a collapsible stent, a one-piece multi-leaflet valve and so on.
Group 2 : claims 11-15 feature a system for intravascular delivery of a heart valve prosthesis comprising a handle, a flexible elongated sheath, a cavity and so forth.
Group 3 : claims 16-17 feature a device for loading a collapsible heart valve prosthesis into a flexible elongated sheath of an intravascular heart valve delivery system comprising a handle, a pin, a loop of material and so on.
The single general concept linking Groups 1-3 together is merely "a heart valve prosthesis".
This common concept is, however, described in US 4687483, 18 Aug. 1987, (John fisher et al., US) and, therefore, does not represent any contribution over the prior art.

1. ☒ As all required addtional 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.:

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

Information on patent family members

International application No.

PCT/US2009/035121

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 04687483 A	18.08.1987	EP 0179562 A1	30.04.1986
		EP 0179562 B1	12.07.1989
		JP 61-179147 A	11.08.1986
		JP 63-059702 B	21.11.1988
		JP 1510682 C	09.08.1989
WO 2001-041679 A1	14.06.2001	AT 418937 T	15.01.2009
		AU 2001-21894 A1	07.12.2000
		AU 5203435 BB	16.10.2008
		AU 0121894 A	18.06.2001
		CA 2393216 A1	14.06.2001
		CA 2450600 A1	19.12.2002
		DE 60041272 D1	12.02.2009
		EP 1235537 A1	04.09.2002
		EP 1235537 B1	31.12.2008
		EP 1395205 B1	16.07.2008
		EP 1395205 A1	10.03.2004
		EP 1235537 B8	07.10.2009
		GB 9928905 D0	02.02.2000
		JP 04-319906 B2	05.06.2009
		JP 04-335487 B2	03.07.2009
		JP 2003-516182 A	13.05.2003
		JP 2005-512611 A	12.05.2005
		PA 02005643 A	10.09.2004
		US 2003-0097175 A1	22.05.2003
		US 2006-0290027 A1	28.12.2006
		WO 2002-100301 A1	19.12.2002
JP 3489643 B2	26.01.2004	JP 9066114 A	11.03.1997
US 04167045 A	11.09.1979	EP 0000949 A1	07.03.1979
		EP 0000949 B1	18.05.1983
		JP 1562236 C	12.06.1990
		JP 01-037154 B	04.08.1989
		JP 54-063588 A	22.05.1979