

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 1846265-0017-172	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2018/040079	International filing date (<i>day/month/year</i>) 28 June 2018 (28-06-2018)	(Earliest) Priority Date (<i>day/month/year</i>) 28 June 2017 (28-06-2017)
Applicant ABIOMED, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 8 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- the international application in the language in which it was filed
- a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. **Certain claims were found unsearchable** (See Box No. II)

3. **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,

- the text is approved as submitted by the applicant
- the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- the text is approved as submitted by the applicant
- the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 2
 - as suggested by the applicant
 - as selected by this Authority, because the applicant failed to suggest a figure
 - as selected by this Authority, because this figure better characterizes the invention
- b. none of the figures is to be published with the abstract

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

[0057] An access sleeve (200) can be attached to a medical device having first and second ends, the first end being positioned inside of a patient and the second end being positioned external to a patient. The access sleeve includes a tubular sleeve body (210) having first (225) and second (235) open ends that define a first lumen (215) extending along a longitudinal axis (205) of the sleeve body. An opening (260) in the sleeve body connects the first lumen to an outer surface of the sleeve body. The access sleeve can be selectively attached to the medical device (e.g. catheter of a heart pump) and inserted into the access site when the medical device is positioned in the patient. The access sleeve can maintain vascular access to a patient's access site such as an arteriotomy and can be removed without disturbing the position of the medical device.

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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.: 25-30
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. Claims Nos.: 25-30
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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:

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 fees, this Authority did not invite payment of 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.:

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.

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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/06 A61M25/09 A61B17/00 A61B90/00
ADD.
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)
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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2017/031243 A1 (ABIOMED INC [US]) 23 February 2017 (2017-02-23)	1-16
A	the whole document	17
X	WO 2007/044907 A2 (FLOWMEDICA INC [US]; ELKINS JEFFREY M [US]; GOODSON HARRY B [US]; BALL) 19 April 2007 (2007-04-19)	1-16
A	the whole document	17
X	US 2008/015625 A1 (VENTURA CHRISTINE P [US] ET AL) 17 January 2008 (2008-01-17)	1-16
X	WO 2011/109307 A1 (TYCO HEALTHCARE [US]; HANLON JAMES GEORGE [US]; MCCRAE ROBERT GORDON []) 9 September 2011 (2011-09-09)	1-16
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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</p> <p>"&" document member of the same patent family</p>
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Date of the actual completion of the international search 31 January 2019	Date of mailing of the international search report 06/02/2019
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Amaro, Henrique
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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.
A	US 6 579 264 B1 (ROSSI DANIEL [FR]) 17 June 2003 (2003-06-17) the whole document	17
A	----- GB 2 033 236 A (TECHNOLOGICAL SUPPLY) 21 May 1980 (1980-05-21) the whole document -----	17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2017031243	A1	23-02-2017	AU 2016308193 A1 08-03-2018
			BR 112018003164 A2 25-09-2018
			CA 2995707 A1 23-02-2017
			EP 3337530 A1 27-06-2018
			JP 2018523541 A 23-08-2018
			KR 20180078226 A 09-07-2018
			US 2017049947 A1 23-02-2017
			WO 2017031243 A1 23-02-2017

WO 2007044907	A2	19-04-2007	EP 1933920 A2 25-06-2008
			JP 2009511199 A 19-03-2009
			US 2007167913 A1 19-07-2007
			WO 2007044907 A2 19-04-2007

US 2008015625	A1	17-01-2008	US 2008015625 A1 17-01-2008
			US 2011257592 A1 20-10-2011

WO 2011109307	A1	09-09-2011	EP 2542294 A1 09-01-2013
			US 2011264133 A1 27-10-2011
			US 2014379012 A1 25-12-2014
			WO 2011109307 A1 09-09-2011

US 6579264	B1	17-06-2003	CA 2315361 A1 20-04-2000
			EP 1037684 A1 27-09-2000
			FR 2784299 A1 14-04-2000
			JP 2002527156 A 27-08-2002
			US 6579264 B1 17-06-2003
			WO 0021603 A1 20-04-2000

GB 2033236	A	21-05-1980	BE 879600 A 24-04-1980
			ES 246040 U 16-01-1980
			FR 2439591 A1 23-05-1980
			GB 2033236 A 21-05-1980

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16

A vascular access sleeve comprising:
a tubular sleeve body extending along a longitudinal axis of the access sleeve, the sleeve body having first and second open ends; a first lumen extending along the longitudinal axis between the first and second open ends of the sleeve body; and a lateral opening in the sleeve body connecting the first lumen to an outer surface of the sleeve body, wherein the lateral opening of the access sleeve is configured to be selectively expanded to attach the access sleeve to a medical device.

2. claims: 17-24

An access system comprising:
a medical device configured for insertion into an arteriotomy of a patient, the medical device having a first end and a second end; and an access sleeve having a a tubular sleeve body extending along a longitudinal axis, the sleeve body having first and second open ends: a first lumen extending along the longitudinal axis between the first and second open ends of the sleeve body; and a lateral opening in the sleeve body connecting the first lumen to an outer surface of the sleeve body, the lateral opening comprising a slit that extends along the length of the sleeve body wherein the access sleeve is configured to be selectively expanded to attach the access sleeve to the medical device such that the medical device is positioned in the first lumen and the first lumen allows for the passage of at least the medical device.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 25-30

Independent claim 25 intends to define a method of attaching an access sheath to a medical device; one of the defined steps includes positioning the access sheath within the vasculature, which contradicts Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy. Therefore claims 25-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT and consequently, no opinion will be formulated with respect to novelty, inventive step and industrial applicability (Article 34(4)(a)(i) PCT).

Continuation of Box II.2

Claims Nos.: 25-30

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.