(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 September 2016 (22.09.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/149653 A3

(51) International Patent Classification:
A61M 25/00 (2006.01) *A61M 25/10* (2006.01)

(21) International Application Number:
PCT/US2016/023223

(22) International Filing Date:
18 March 2016 (18.03.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/135,528	19 March 2015 (19.03.2015)	US
62/135,552	19 March 2015 (19.03.2015)	US
62/135,609	19 March 2015 (19.03.2015)	US
62/135,603	19 March 2015 (19.03.2015)	US
62/135,576	19 March 2015 (19.03.2015)	US
62/136,152	20 March 2015 (20.03.2015)	US
62/136,390	20 March 2015 (20.03.2015)	US
62/136,370	20 March 2015 (20.03.2015)	US
62/136,230	20 March 2015 (20.03.2015)	US
62/136,326	20 March 2015 (20.03.2015)	US
62/136,123	20 March 2015 (20.03.2015)	US
62/136,180	20 March 2015 (20.03.2015)	US
62/136,571	22 March 2015 (22.03.2015)	US
62/204,804	13 August 2015 (13.08.2015)	US

(71) Applicant: **PRYTIME MEDICAL DEVICES, INC.** [US/US]; 229 North Main Street, Boerne, TX 78006 (US).

(72) Inventors: **FRANKLIN, Curtis, J.**; 229 North Main Street, Boerne, TX 78006 (US). **SPENCER, David**; 229 North Main Street, Boerne, TX 78006 (US). **KRUMMENACHER, Todd J.**; 229 North Main Street, Boerne, TX 78006 (US).

(74) Agents: **BUTLER, Dennis J.** et al.; Panitch Schwarze Belisario & Nadel LLP, One Commerce Square, 2005 Market Street, Suite 2200, Philadelphia, PA 19103 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

[Continued on next page]

(54) Title: SYSTEM FOR LOW-PROFILE OCCLUSION BALLOON CATHETER

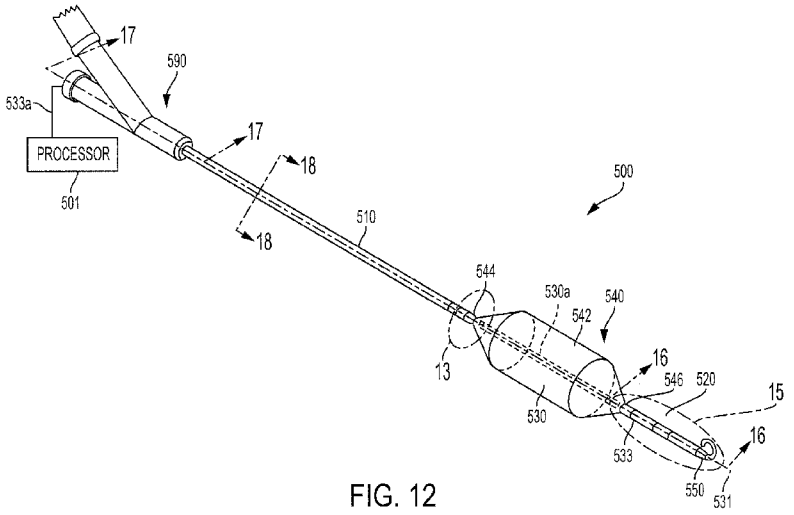

FIG. 12

(57) Abstract: An occlusion catheter system (500) includes a proximal hub (590) having an inflation connection port and an inflation pathway. An inflation catheter member (510) is connected to the proximal hub and has an inflation lumen (610). A stiffener member (530) defines a longitudinal axis. The proximal end of the stiffener member is connected to the proximal hub. The stiffener member extends through a portion of the inflation lumen. An occlusion balloon (540) has a proximal balloon end and a distal balloon end. A distal catheter member (520) is positioned substantially on the longitudinal axis and is connected to the distal end of the stiffener member. An atraumatic tip (550) is positioned on a distal end of the distal catheter member. The atraumatic tip has a substantially circular profile in a relaxed configuration. A pressure sensor (533) is connected to the occlusion catheter system distally relative to the occlusion balloon.

WO 2016/149653 A3

— *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:
24 November 2016

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/023223

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:

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/023223

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 A61M25/10
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 2015/035393 A1 (PRYOR MEDICAL DEVICES INC [US]) 12 March 2015 (2015-03-12)	13-22
Y	figures 1, 3, 4, 5, 6, 9, 9A, 10-17 paragraph [0010] paragraph [0012] paragraph [0015] paragraph [0017] paragraph [0018] paragraph [0025] paragraph [0036] - paragraph [0037] paragraph [0043] -----	1-12
Y	EP 1 911 484 A2 (DATASCOPE INVESTMENT CORP [US]) 16 April 2008 (2008-04-16) paragraph [0040]; figures 1, 2 -----	1-12

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 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	Date of mailing of the international search report
14 October 2016	25/10/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Przykutta, Andreas

2

Form PCT/ISA/210 (second sheet) (April 2005)

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 2003/032974 A1 (LESCHINSKY BORIS [US] ET AL) 13 February 2003 (2003-02-13) paragraph [0025] - paragraph [0026]; figure 1	1-12
A	US 2012/109057 A1 (KROLIK JEFFREY A [US] ET AL) 3 May 2012 (2012-05-03) paragraph [0095]	1-12
A	WO 98/34670 A2 (ADVANCED CARDIOVASCULAR SYSTEM [US]) 13 August 1998 (1998-08-13) figures 1, 4, 7	13-22
X	US 2007/219488 A1 (FRANCESCATTI DARIUS [US]) 20 September 2007 (2007-09-20) figures 2, 3, 5, 6 paragraph [0022] paragraph [0026]	23-31
X	EP 1 094 861 B1 (BOSTON SCIENT LTD [BB]) 6 April 2005 (2005-04-06) figures 1, 8, 11 paragraph [0031] paragraph [0051]	32-39
A	EP 2 716 323 A1 (FLIP TECHNOLOGIES LTD [IE]) 9 April 2014 (2014-04-09) figures 15-19	32-39
X	US 2005/261725 A1 (CRAWFORD LYNN D [US] ET AL) 24 November 2005 (2005-11-24) figures 1, 2 paragraph [0051] paragraph [0052] paragraph [0053] paragraph [0062] paragraph [0101]	40-49

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/023223

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2015035393 A1	12-03-2015	AU 2014317859 A1	07-04-2016
		CA 2923419 A1	12-03-2015
		EP 3043858 A1	20-07-2016
		JP 2016530031 A	29-09-2016
		US 2016213893 A1	28-07-2016
		WO 2015035393 A1	12-03-2015
EP 1911484 A2	16-04-2008	AT 387927 T	15-03-2008
		AU 2027102 A	24-06-2002
		EP 1409057 A2	21-04-2004
		EP 1419796 A2	19-05-2004
		EP 1764124 A2	21-03-2007
		EP 1911484 A2	16-04-2008
		WO 0247751 A2	20-06-2002
US 2003032974 A1	13-02-2003	NONE	
US 2012109057 A1	03-05-2012	AU 2012328908 A1	15-05-2014
		CA 2853350 A1	02-05-2013
		CN 104010581 A	27-08-2014
		EP 2771056 A1	03-09-2014
		JP 2014534861 A	25-12-2014
		SG 11201401779U A	26-09-2014
		US 2012109057 A1	03-05-2012
		US 2014303554 A1	09-10-2014
		WO 2013063101 A1	02-05-2013
WO 9834670 A2	13-08-1998	US 5830181 A	03-11-1998
		WO 9834670 A2	13-08-1998
US 2007219488 A1	20-09-2007	US 2007219488 A1	20-09-2007
		WO 2007075545 A2	05-07-2007
EP 1094861 B1	06-04-2005	AT 292489 T	15-04-2005
		CA 2322642 A1	10-09-1999
		DE 69924611 D1	12-05-2005
		DE 69924611 T2	15-09-2005
		EP 1094861 A2	02-05-2001
		JP 4295919 B2	15-07-2009
		JP 2002505165 A	19-02-2002
		US 6517515 B1	11-02-2003
		WO 9944666 A2	10-09-1999
EP 2716323 A1	09-04-2014	EP 2405965 A2	18-01-2012
		EP 2716323 A1	09-04-2014
		US 2012035642 A1	09-02-2012
		US 2015289783 A1	15-10-2015
		WO 2010103502 A2	16-09-2010
US 2005261725 A1	24-11-2005	AT 319498 T	15-03-2006
		AU 7132001 A	02-01-2002
		AU 2001271320 B2	06-10-2005
		CA 2412670 A1	27-12-2001
		DE 60117796 T2	30-11-2006
		EP 1289597 A2	12-03-2003
		JP 2003535652 A	02-12-2003
		US 2002010488 A1	24-01-2002
		US 2005261725 A1	24-11-2005

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/023223

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 0197743 A2	27-12-2001

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-12

An occlusion catheter system for occlusion of a relatively large vessel and sensing pressure, the occlusion catheter system comprising:
a proximal hub having an inflation connection port and an inflation pathway defined in the connection port;
an inflation catheter member connected to the proximal hub, the inflation catheter member having an inflation lumen and a first port proximate a distal end of the inflation catheter member;
a stiffener member having a proximal end and a distal end and defining a longitudinal axis, the proximal end of the stiffener member connected to the proximal hub, the stiffener member being substantially solid and extending through at least a portion of the inflation lumen;
an occlusion balloon having a proximal balloon end and a distal balloon end, the proximal balloon end connected proximate to the distal end of the inflation catheter;
a distal catheter member positioned substantially on the longitudinal axis and connected to the distal end of the stiffener member, an atraumatic tip on a distal end of the distal catheter member, the atraumatic tip having a substantially circular profile in a relaxed configuration with an unconnected end positioned proximate the longitudinal axis;
a pressure sensor connected to the occlusion catheter system distally relative to the occlusion balloon, the pressure sensor connected to a processor by electrical wiring.

---

2. claims: 13-22

A occlusion catheter system for occluding major vessels and injecting fluid into the major vessel, the occlusion catheter system comprising:
a first catheter member having a first lumen extending longitudinally therethrough and a first opening at a distal end of the first catheter member, the first catheter member defining a longitudinal axis;
a second catheter member having a second lumen extending longitudinally therethrough and a second opening at a distal end of the second catheter member, the second catheter member positioned around a proximal section of the first catheter member, the first catheter member extending beyond the distal end of the second catheter member,
an atraumatic tip member having a proximal section co-axially coupled to the distal end of the second catheter member, the atraumatic tip having a substantially circular profile in a relaxed configuration, the circular profile positioned at a distal end of the atraumatic tip with an unconnected end positioned proximate the longitudinal axis,

the circular profile of the atraumatic tip being configured to unfold to an insertion configuration such that the distal end of the atraumatic tip is substantially coaxial with the longitudinal axis;
an expandable occlusion member having a proximal balloon end and a distal balloon end, the proximal balloon end connected to the second catheter member proximate the second opening and connected to at least one of the distal end of the first catheter member and the proximal section of the atraumatic tip with a portion of the first catheter member extending along the longitudinal axis within the expandable occlusion member; and
a plurality of side ports in one of the distal end of the first catheter member and the proximal section of the atraumatic tip, the plurality of side ports in fluid communication with the first lumen.

---

3. claims: 23-31

An occlusion/perfusion balloon system for at least partially occluding a vessel of a patient, the occlusion/perfusion balloon system comprising:
a proximal catheter including an inflation lumen therein, the proximal catheter defining a longitudinal axis;
a balloon connected to the proximal catheter, the balloon being in fluid communication with the inflation lumen of the proximal catheter, the balloon including radially projecting members thereon with channels defined between the radially projecting members, the channels configured to permit flow of fluid over an outer surface of the balloon along the longitudinal axis when the balloon is at least partially inflated and positioned within the vessel; and
a distal catheter positioned on the longitudinal axis, the balloon connected to the proximal catheter at a proximal balloon end and the distal catheter at a distal balloon end.

---

4. claims: 32-39

An occlusion catheter system for occlusion of a relatively large vessel, the occlusion catheter system comprising:
a proximal hub having an inflation connection port and an inflation pathway defined in the connection port;
an inflation catheter member connected to the proximal hub, the inflation catheter member having an inflation lumen and a first port proximate a distal end of the inflation catheter member, the inflation catheter member defining a longitudinal axis;
an occlusion balloon having a proximal balloon end and a distal balloon end, the proximal balloon end connected proximate to the distal end of the inflation catheter; the first port opening into an internal space of the occlusion balloon;
a distal catheter member positioned substantially on the

longitudinal axis and connected to the distal balloon end;
an atraumatic tip on a distal end of the distal catheter member, the atraumatic tip having a substantially circular profile in a relaxed configuration with an unconnected end positioned proximate the longitudinal axis, the atraumatic tip including a tip shaft with a guide lumen therein, the guide lumen including an exit port proximate the distal end of the atraumatic tip positioned proximate the longitudinal axis; and
a guide wire configured for slidable movement within the guide lumen and extendable out of the exit port beyond the atraumatic tip.

---

5. claims: 40-49

An occlusion catheter system for occlusion of a relatively large vessel in a field environment, the occlusion catheter system comprising:
a proximal hub having an inflation connection port and an inflation pathway defined in the inflation connection port;
an inflation catheter member connected to the proximal hub, the inflation catheter member having an inflation lumen and a first port proximate a distal end of the inflation catheter member, the inflation catheter defining a longitudinal axis;
an occlusion balloon having a proximal balloon end and a distal balloon end, the proximal balloon end connected proximate to the distal end of the inflation catheter;
a distal catheter member positioned substantially on the longitudinal axis and connected to the distal balloon end,
an atraumatic tip on a distal end of the distal catheter member, the atraumatic tip having a substantially circular profile in a relaxed configuration with an unconnected end positioned proximate the longitudinal axis; and
a sleeve substantially surrounding the inflation catheter member, the occlusion balloon and the distal catheter member in a covered configuration, the sleeve having a proximal sleeve end connected to the proximal hub and a distal sleeve end, the sleeve being constructed at least partially of a flexible material, the distal sleeve end positioned at or beyond the atraumatic tip in the covered configuration, the distal sleeve end slidable along the distal catheter member, the occlusion balloon and the inflation catheter to expose at least portions of the occlusion catheter system in a working configuration when the occlusion catheter system is inserted into the large vessel.
