



- (51) **International Patent Classification:**
A61M 25/10 (2013.01)
- (21) **International Application Number:**
PCT/US2013/051863
- (22) **International Filing Date:**
24 July 2013 (24.07.2013)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/675,168 24 July 2012 (24.07.2012) US
61/788,938 15 March 2013 (15.03.2013) US
- (71) **Applicant: CLEARSTREAM TECHNOLOGIES LIMITED** [IE/IE]; Moyne Upper, Enniscorthy, County Wexford (IE).
- (72) **Inventors; and**
- (71) **Applicants (for US only): BEASLEY, Jim, C.** [US/US]; 7339 North 3rd Avenue, Phoenix, AZ 85021 (US). **KLOCKE, Stephanie** [US/US]; 3151 West Laredo Street, Chandler, AZ 85226 (US). **RAJI-KUBBA, Abtihal** [US/US]; 3109 East Sierra Vista Drive, Phoenix, AZ 85016 (US). **RIGHI, Rob** [US/US]; 2383 West Detroit Place, Chandler, AZ 85224 (US).
- (74) **Agent: DORISIO, Andrew, D.; KING & SCHICKLI, PLLC**, 247 N. Broadway, Lexington, KY 40507 (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, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, 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, 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, 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).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

- *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:**
17 April 2014



WO 2014/018659 A3

(54) **Title:** BALLOON CATHETER WITH ENHANCED LOCATABILITY

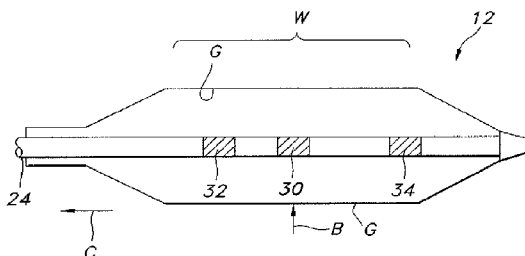


FIG. 17

(57) **Abstract:** A balloon catheter for insertion in a vessel includes a catheter shaft (24) and an inflatable balloon (12) attached to the catheter shaft. Markings (30,32,39) along a longitudinal axis of the catheter are provided in an interior of the balloon, such as for measuring a distance within the vessel. A first distance separating a first marking from a second adjacent marking may be different from a second distance separating the second marking from a third adjacent marking. The markings may also be used for ensuring the proper positioning of the balloon and, in particular, the working surface thereof, relative to a treatment area.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/051863

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | WO 02/34161 A1 (SCIMED LIFE SYSTEMS INC [US]) 2 May 2002 (2002-05-02) page 4, line 15 - line 20 page 4, line 24 - line 30 figure 1 | 1-3,19 |
| A | ----- EP 0 850 659 A1 (CORDIS CORP [US]) 1 July 1998 (1998-07-01) column 7, line 9 - line 14 figure 1 | 3 |
| A | ----- US 2006/210605 A1 (CHANG JOHN Y [US] ET AL) 21 September 2006 (2006-09-21) paragraph [0183] figure 8C | 3 |
| | ----- -/-- | |

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 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 26 February 2014 | Date of mailing of the international search report 06/03/2014 |
|---|--|

| | |
|--|---|
| 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 |
|--|---|

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/051863

| 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 2008/097404 A1 (YRIBARREN TRAVIS R [US] ET AL) 24 April 2008 (2008-04-24) paragraph [0024] - paragraph [0027] figures 5,6 figure 5 ----- | 7,20,43 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/051863

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.: **54-65**
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.:
1-3, 7-12, 19, 20, 43-53

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-3, 19

A balloon catheter comprising: A balloon. An inner tubular member defining a guidewire lumen; the inner tubular member comprising three radiopaque markers spaced along a longitudinal axis of the inner tubular member in the interior of the balloon, wherein a first distance separating a first marking from the adjacent second marking is different from a second distance separating the second marking from a third adjacent marking. An outer wall having at least one of the first or second radiopaque markers.

2. claim: 4

A balloon catheter comprising a shaft . A balloon attached to the shaft and at least three radiopaque markers spaced along a longitudinal axis of the shaft in the interior of the balloon, wherein a first distance separating a first marking from the adjacent proximal second marking is smaller from a second distance separating the second marking from the proximal third adjacent marking.

3. claim: 5

A balloon catheter comprising a shaft . A balloon attached to the shaft and at least three radiopaque markers spaced along a longitudinal axis of the shaft in the interior of the balloon, wherein the at least three radiopaque markings are arranged in a pattern comprising a plurality of adjacent pairs, and wherein the adjacent pairs are alternatingly separated by the first and second distances

4. claim: 6

A balloon catheter comprising a shaft . A balloon attached to the shaft and at least three radiopaque markers spaced along a longitudinal axis of the shaft in the interior of the balloon, wherein the at least three radiopaque markings are arranged in a pattern comprising adjacent radiopaque markings spaced at progressively larger distances from one another from a distal point on the catheter to a proximal point on the catheter.

5. claims: 7-12, 20, 43-53

A balloon catheter comprising a shaft. A balloon attached to the shaft and at least three radiopaque markers spaced along a longitudinal axis of the shaft in the interior of the

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

balloon, wherein a first distance separating a first marking from an adjacent second marking is different from a second distance separating the second marking from a third adjacent marking.

The balloon includes an uninflated midpoint location and an uninflated midpoint location wherein at least one of the markers substantially aligns with the inflated midpoint position of the balloon

6. claims: 13-17

A balloon catheter comprising a shaft. A balloon attached to the shaft and at least three radiopaque markers spaced along a longitudinal axis of the shaft in the interior of the balloon, wherein a first distance separating a first marking from an adjacent second marking is different from a second distance separating the second marking from a third adjacent marking. At least an extra fourth radiopaque marker is defined located external to the interior of the balloon.

7. claim: 18

A balloon catheter comprising a shaft. A balloon attached to the shaft and at least three radiopaque markers spaced along a longitudinal axis of the shaft in the interior of the balloon, wherein a first distance separating a first marking from an adjacent second marking is different from a second distance separating the second marking from a third adjacent marking, wherein the markers comprise bands formed at least partially of a radiopaque material.

8. claims: 21-24

A balloon catheter comprising an elongated, tubular shaft; an inflatable balloon, supported by the shaft, and including a working surface having a midpoint in an inflated condition; at least one first radiopaque marking corresponding to the location of at least one end of the working surface in the inflated condition and at least a second radiopaque marking corresponding to the location of the midpoint of the working surface in the inflated condition

9. claims: 25-34

A balloon catheter comprising an elongated, tubular shaft; an inflatable balloon supported by the shaft and including a working surface; first and second radiopaque markings corresponding to the location of the ends of the working surface and a third radiopaque marking positioned between the first and second radiopaque markings.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

10. claims: 35-42

A balloon catheter comprising an elongated shaft; an inflatable balloon supported by the shaft and having an interior; a plurality of first radiopaque markers proximal of the balloon, and; a plurality of radiopaque markers within the interior of the balloon.

INTERNATIONAL SEARCH REPORT

Information on patent family members

| |
|---|
| International application No PCT/US2013/051863 |
|---|

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|--|------------------|-------------------------|-----------------------------|
| WO 0234161 | A1 | 02-05-2002 | AU 8698001 A 06-05-2002 |
| | | | CA 2424994 A1 02-05-2002 |
| | | | EP 1341478 A1 10-09-2003 |
| | | | JP 4314030 B2 12-08-2009 |
| | | | JP 2004512092 A 22-04-2004 |
| | | | US 6656211 B1 02-12-2003 |
| | | | WO 0234161 A1 02-05-2002 |
| | | | ----- |
| EP 0850659 | A1 | 01-07-1998 | DE 69719708 D1 17-04-2003 |
| | | | DE 69719708 T2 05-02-2004 |
| | | | EP 0850659 A1 01-07-1998 |
| | | | US 5779731 A 14-07-1998 |
| ----- | | | |
| US 2006210605 | A1 | 21-09-2006 | EP 1896113 A2 12-03-2008 |
| | | | EP 2491973 A1 29-08-2012 |
| | | | EP 2491974 A1 29-08-2012 |
| | | | JP 2009500051 A 08-01-2009 |
| | | | JP 2012192196 A 11-10-2012 |
| | | | US 2006210605 A1 21-09-2006 |
| | | | US 2007135789 A1 14-06-2007 |
| | | | US 2008125626 A1 29-05-2008 |
| | | | US 2009093823 A1 09-04-2009 |
| | | | US 2010042046 A1 18-02-2010 |
| | | | US 2010174138 A1 08-07-2010 |
| | | | US 2010174308 A1 08-07-2010 |
| | | | WO 2006135853 A2 21-12-2006 |
| ----- | | | |
| US 2008097404 | A1 | 24-04-2008 | NONE |
| ----- | | | |