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MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
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(54) Title: EXPANDABLE BODY DEVICE AND METHOD OF USE

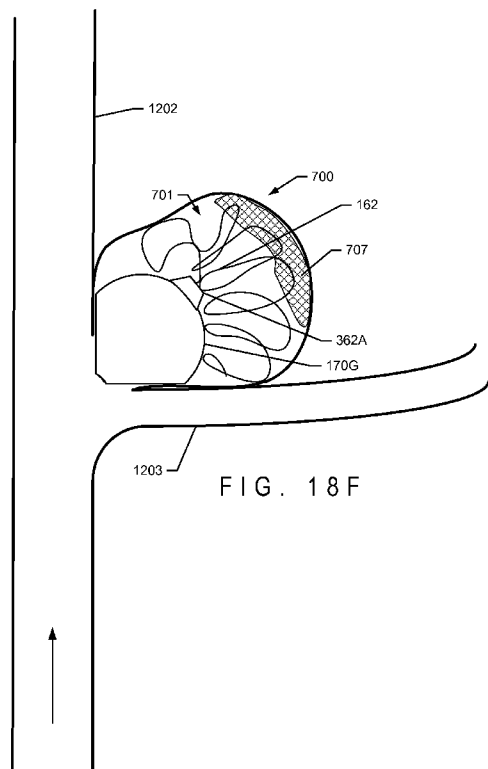


FIG. 18F

(57) Abstract: Disclosed herein are medical devices comprising a single-lobed, thin-walled, expandable body and a flexible, elongated delivery device for treating saccular vascular aneurysms and occluding segments of blood vessels and other biological conduits. The expandable bodies may include gold and other metals that can be compressed, positioned in the lumen of an aneurysm, or other biological conduit and expanded. The external surface of the expandable bodies can be configured to promote local thrombosis and to promote the growth of tissue into and around the surface in order to reduce migration of the expandable body and to occlude and seal the aneurysm or biological conduit. For the treatment of saccular aneurysms, the expandable body may be deployed in combination with one or more coiled wires that contact both the wall of the aneurysm and the expandable body and exert force on the expandable body to aid in sealing the aneurysm neck.





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).

— *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))*

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/30869

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61F 2/02, 2/06; A61M 25/04, 29/02 (2014.01) USPC - 164/47; 205/73; 623/1.12 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(8): A61F 2/02, 2/06; A61M 25/04, 29/02 (2014.01) USPC: 164/47; 205/73; 623/1.12; CPC: A61B 17/12109, 2017/12063, 2017/12054, 2017/12059, 2019/307; A61F 2/06, 2/958; A61M 25/1029 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) MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Public Patent Application Information Retrieval (PAIR); Google/Google Scholar; ProQuest; Pubmed/Medline: saccular, cerebral, brain, aneurysm, aneurism, expandable, expansible, body, frame, form, shape, configuration, neck, collar, bottleneck, tip, metal, metallic, gold diameter, axis, region, proximal, etc.		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/099910 A2 (FRANANO, FN) July 26, 2012; figures 5a, 7b, 8b, 29; paragraphs [0085]-[0087], [0090], [0094]-[0098], [00100], [00149]	1, 3, 6-39, 44, 47, 52-54, 61, 63, 66-99, 104, 107, 113-115, 125-127, 139-145, 161, 163, 166-199, 204, 207, 213-215, 225-227, 239-245
Y		2, 4-5, 40-42, 45-46, 48-49, 62, 64-65, 100-102, 105-106, 108-110, 162, 164-165, 200-202, 205-206, 208-210
Y	US 2012/0283768 A1 (COX, BJ et al.) November 8, 2012; figure 58; paragraph [0262]	2, 62, 162
Y	US 2012/0330348 A1 (STRAUSS, BM et al.) December 27, 2012; figure 3; paragraph [0052]	4, 64, 164
Y	US 8372114 B2 (HINES, RA) February 12, 2013; figure 2; column 9, lines 48-58	5, 65, 165
Y	US 8333798 B2 (GANDHI, D et al.) December 18, 2012; column 7, lines 1-3, 19-26, 40-44	40-42, 45-46, 100-102, 105-106, 200-202, 205-206
Y	US 2012/0296407 A1 (CASELNOVA, RF) November 22, 2012; figure 5; paragraph [0022]	48-49, 108-110, 208-210
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* 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 11 October 2014 (11.10.2014)		Date of mailing of the international search report 07 NOV 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/30869

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.: -***- Continued on Extra Sheet -***-
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 I: Claims 1-50, 52-55, 61-116, 125-129, 132-135, 139-147, 161-216, 225-229 and 239-247 are directed toward a metallic expandable body configured for location in a saccular aneurysm.

Group II: Claims 263-321 and 323-329 are directed toward a method for filling a saccular aneurysm of a patient with an expandable body.

-***- Continued on Extra 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 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.:
1-50, 52-55, 61-116, 125-129, 132-135, 139-147, 161-216, 225-229 and 239-247

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/US14/30869

-Continued from Box No. II.3 - Observations where certain claims were found unsearchable-

Claims 43, 50, 51, 55-60, 103, 111, 112, 116-124, 128-130, 131A, 131B, 132-138, 146-160, 203, 211, 212, 216-224, 228-238, 246-262, 284, 285, 303, 320, 321, 322, 325, 326

-Continued from Box No. III - Observations where unity of invention is lacking-

The inventions listed as Groups I-II 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 special technical features of Group I include a second medical device comprising a wire configured for passage through the catheter delivery device and permanent implantation into a saccular aneurysm, which are not present in Group II; the special technical features of Group II include b) determining a size of an opening from a parent vessel into a lumen of the saccular aneurysm and determining an overall size of the lumen of the saccular aneurysm, and selecting an expandable body that can cover the opening from the parent vessel into the lumen of the saccular aneurysm, occupy a portion of the lumen of the saccular aneurysm and reduce a flow of blood from the parent vessel into the lumen of the saccular aneurysm when expanded, c) delivering the expandable body into the lumen of the saccular aneurysm of the patient in a deliverable configuration via a delivery device having a distal end operably coupled to the proximal neck of the expandable body, d) delivering a fluid medium into the interior volume of the expandable body via the delivery device to cause the expandable body to assume the expanded configuration wherein the expanded expandable body fills a portion of the aneurysm lumen and is in contact with a portion of the wall of the aneurysm but leaves a portion of the aneurysm lumen unfilled between the expanded expandable body and a wall of the aneurysm opposite the opening from the parent vessel into the lumen of the aneurysm; e) delivering one or more coiled wires from the proximal end of the delivery catheter, through the expanded expandable body and to the distal end of the delivery catheter, and placing those coiled wires into the unfilled region of the aneurysm lumen between the distal end of the expanded expandable body and the wall of the aneurysm opposite the opening from the parent vessel into the lumen of the aneurysm, wherein the coiled wires contact the outer wall of the distal portion of the expanded expandable body and the wall of the aneurysm opposite the opening from the parent vessel to the lumen of the aneurysm, f) causing the expanded expandable body to decouple from the catheter delivery device and removing the delivery device from the patient while leaving the expanded expandable body and the coiled wires in place in the aneurysm, which are not present in Group I.

The common technical features of Groups I and II are a metallic expandable body configured for location in a saccular aneurysm; a main body including a proximal neck, a proximal region and a distal region, a distal neck wherein the proximal neck is joined to the proximal region, the proximal region is joined to the distal region, and the distal region is joined to the distal neck, and a wall extending generally continuously through the proximal neck, proximal region, distal region, and distal neck to define an exterior surface of the expandable body and an interior surface of the expandable body, the interior surface defining an interior volume of the expandable body, wherein the expandable body is configured to assume a single lobed shape with expansion, the expandable body configured to expand from a deliverable configuration to an expanded configuration, and wherein, when expanded, the expandable body is further defined by a first axis and a second axis transverse to the first axis, the first axis extending between the proximal and distal necks.

These common technical features are disclosed by US 2011/0152993 A1 to Marchand et al. (hereinafter 'Marchand'). Marchand discloses a metallic expandable body configured for location in a saccular aneurysm (device for treatment of a patient's vasculature; claim 1); a main body including a proximal neck, a proximal region and a distal region; a distal neck wherein the proximal neck is joined to the proximal region, the proximal region is joined to the distal region, and the distal region is joined to the distal neck, and a wall extending generally continuously through the proximal neck, proximal region, distal region, and distal neck to define an exterior surface of the expandable body and an interior surface of the expandable body, the interior surface defining an interior volume of the expandable body (a self-expanding resilient permeable shell having a proximal end, a distal end, a longitudinal axis; claim 1), wherein the expandable body is configured to assume a single lobed shape with expansion (expanded globular shape; claim 1), the expandable body configured to expand from a deliverable configuration to an expanded configuration, and wherein, when expanded, the expandable body is further defined by a first axis and a second axis transverse to the first axis, the first axis extending between the proximal and distal necks (an expanded relaxed state with a globular and longitudinally shortened configuration relative to the radially constrained state with the woven filaments forming the self-expanding resilient permeable shell in a smooth path radially expanded from the longitudinal axis between the proximal end and distal end; claim 1).

Since the common technical features are previously disclosed by the Marchand reference, the common features are not special and so Groups I and II lack unity.