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- (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,

[Continued on next page]

(54) Title: DEVICE FOR ESTABLISHING RETROGRADE CAROTID ARTERIAL BLOOD FLOW

(57) Abstract: Devices and methods establish and facilitate retrograde or reverse flow blood circulation in the region of the carotid artery bifurcation in order to limit or prevent the release of emboli into the cerebral vasculature such as into the internal carotid artery. The methods are particularly useful for interventional procedures performed through a transcervical approach or transfemoral into the common carotid artery.

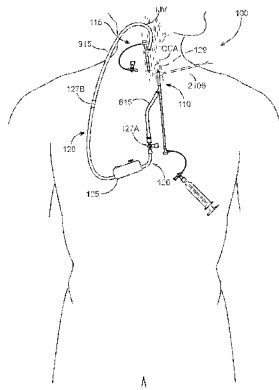


FIG. 1A

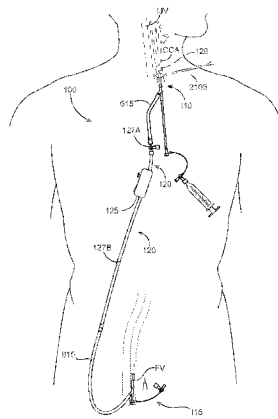


FIG. 1B

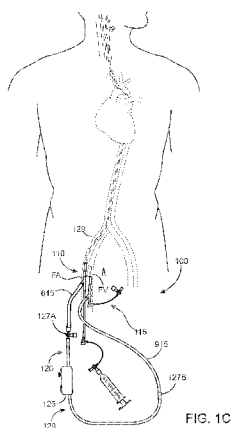


FIG. 1C

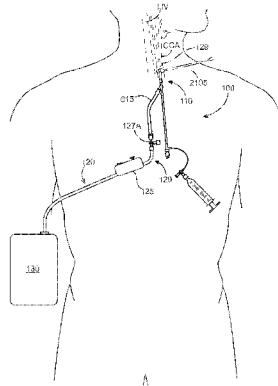


FIG. 1D





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, 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, 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.

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))*
- *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/US14/32060

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61B 5/02; A61F 2/06, 2/90 (2014.01) CPC - A61B 2017/00778, 2017/320716; A61F 2/90 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8): A61B 5/02; A61F 2/06, 2/90; A61M 5/00 (2014.01) CPC: A61B 2017/00778, 2017/320716; A61F 2/90, 2/954, 2002/065; A61M 1/3659, 25/10, 2025/1052; USPC: 600/504; 604/9; 623/1.11 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, DE-G, DE-A, DE-T, DE-U, GB-A, FR-A); Google; Google Scholar; Google Patent; ProQuest; PubMed/Medline; Search terms used: stopper, sheath, retrograde, bend, bent, deform*, "first shape", "second shape", carotid		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 8083788 B2 (ACOSTA, P et al.) December 27, 2011; abstract; figures 2A-2B, 7A-7E, 11B-11C; column 10, lines 53-58; column 11, lines 1-6; column 16, lines 52-57; column 19, lines 38-45, 50-55	1-5, 13-17
Y	US 8157760 B2 (CRIADO, E et al.) April 17, 2012; figures 6A, 7A; column 6, lines 43-48; column 12, lines 20-22, 63-64; column 13, lines 25-26, 30-33, 37-40	1-5, 15-17
Y	WO 1999/040945 A2 (HAMMOND, HK) August 19, 1999; page 32, lines 19-21	4, 13-17
<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 September 2014 (11.09.2014)		Date of mailing of the international search report <b>19 NOV 2014</b>
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/US14/32060

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 I: Claims 1-5 and 13-17 are directed toward a device for use in accessing and treating a carotid artery comprising a stopper member.

Group II: Claims 6-12 are directed toward a device for use in accessing and treating a carotid artery comprising a flow control assembly.

Group III: Claims 18-28 are directed toward a device for use in accessing and treating a carotid artery wherein the distance from the arteriotomy site to a target treatment site is in the range of about 5cm to about 10cm.

Group IV: Claims 29-33 are directed toward a method for accessing and treating a stenosis in a carotid artery.

\*\*\*See Supplemental Sheet Below\*\*\*

- 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.:  
1-5, 13-17

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.

\*\*\*Continuation of Box No. III - Observations where unity of invention is lacking:\*\*\*

The inventions listed as Groups I-IV 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 stopper member that may be positioned over the distal section of the sheath, wherein the stopper member limits insertion of the sheath into the carotid artery to no more than a portion of the length of a distal-most portion of the distal sheath, wherein the stopper member may be deformed from a first shape to a second shape and wherein the stopper member retains the second shape after deformation, which are not present in Groups II-IV; the special technical features of Group II include a flow control assembly coupled to the shunt and adapted to regulate blood flow through the shunt between at least a first blood flow state and at least a second blood flow state, wherein the flow control assembly includes one or more components that interact with the blood flow through the shunt, which are not present in Groups I and III-IV; the special technical features of Group III include wherein the distance from the arteriotomy site to a target treatment site is in the range of about 5cm to about 10cm, which are not present in Groups I-II and IV; the special technical features of Group IV include forming a transcervical incision in a neck of a patient, forming a penetration in a wall of a common carotid artery proximal to the stenosis via the transcervical incision, which are not present in Groups I-III.

The common technical features of Groups I-IV are a system/method for accessing and treating a carotid artery, comprising: an arterial access sheath introduced into a common carotid artery.

These common technical features are disclosed by US 2011/0082408 A1 (CHANG). Chang discloses a system/method for accessing and treating a carotid artery, comprising: an arterial access sheath introduced into a common carotid artery (method of treating a carotid artery, comprising: forming a puncture opening through a wall of the common carotid artery; positioning through the puncture an arterial access sheath and dilator system; claim 1).

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

The additional common technical features of Groups II and III are a shunt fluidly connected to the arterial access device, wherein the shunt provides a pathway for blood to flow from the arterial access device to a return site.

These common technical features are disclosed by the Chang reference. Chang discloses a shunt fluidly connected to the arterial access device, wherein the shunt provides a pathway for blood to flow from the arterial access device to a return site (a shunt fluidly connected to the arterial access sheath provides a pathway for blood to flow from the arterial access device to a return site; claim 18).

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