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- (71) Applicant: **CARDIOVANTAGE MEDICAL, INC.**
[US/US]; 951 Mariners Island Blvd., Suite 300, San Mateo, CA 94404 (US).
- (72) Inventors: **ZHANG, Ji**; 9160 Mona Avenue, Burnaby, BC V3N5A7 (CA). **WALSH, Brandon, G.**; 1392 W. 2176 S, Syracuse, UT 84075 (US).
- (74) Agents: **HARLOCKER, Susan L.** et al.; McDermott Will & Emery LLP, 500 North Capitol Street Nw, Washington, DC 20001 (US).
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[Continued on next page]

(54) Title: TISSUE AND VASCULAR CLOSURE DEVICES AND METHODS OF USE THEREOF

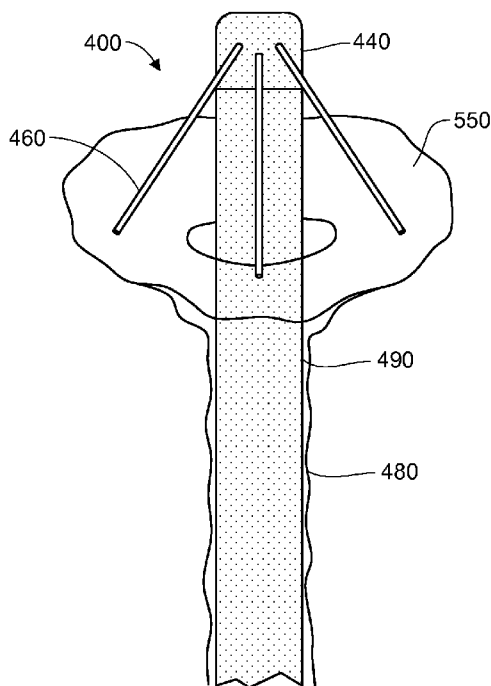


FIG. 1

(57) Abstract: Devices and methods for closing access points in tissue are described. The devices include a tubular element fabricated form, for example, biologic material, a biologic tubular structure, or synthetic material. Using minimally invasive procedures, the devices and methods described herein allow implantation of the tubular element through the access point or wound such that it traverses the tissue. The tube has a sealed end which prevents leakage of fluid from, for example, the heart or a vessel upon securing the tube to the tissue.



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- *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/US14/25003

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/00, 17/03; A61M 5/00 (2014.01)
 USPC - 606/158, 213, 215; CPC: A61B 17/0643, 18/148, 2017/00672

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): A61B 17/00, 17/03; A61M 5/00 (2014.01)
 USPC: 606/158, 213, 215, 216; A61B 17/0643, 17/1285, 18/148, 2017/00672, 2017/00862, 2018/00595

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); Google/Google Scholar; ProQuest;
 Pubmed/Medline: tube, tubular, tubing, knot, end, tying, tied, vascular, vessel, vasculature, vein, artery, close, repair, seal, adhesive,
 sticky, sheath, push, cable, counter, closure, film, membrane, barb, cup, anchor, pericardial, biodegradable, bioabsorbable, arms, etc

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/0106148 A1 (GINN, RS et al.) May 5, 2011; figures 23-24, 38a-b, 39a-b; paragraphs [0189], [0196]-[0197], [0225], [0231]-[0232], [0235]-[0236], [0239]-[0241] [0244], [0285]-[0286]	1, 3, 5/1, 5/3
Y		2, 5/2, 4, 5/4
Y	WO 2010/085449 A1 (KOEHLER, CS) July 29, 2010; paragraphs [0006], [0066], [00111]	2, 5/2
Y	US 7351250 B2 (ZAMIEROWSKI, DS) April 1, 2008; figure 8; column 9, lines 17-25	4, 5/4

 Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

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Authorized officer:

Shane Thomas

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/25003

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

- Group I: Claims 1-5 are directed toward a vascular closure device.
Group II: Claims 6-9 are directed toward a spiral closure device.
Group III: Claim 10 is directed toward a tissue locating device.
Group IV: Claims 11-12 are directed toward a method for using a vascular closure device comprising inserting an insertion device.

-Continued Within the Next Supplemental Box-

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

- 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/US14/25003

-Continued from 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 pusher cable positioned within the flexible tube, wherein the distal end of the pusher cable comprises one or more counters, wherein the pusher cable is moveably associated with the sealing tube, and wherein the sealing tube is moveably associated with the sheath, and wherein the outer surface of a distal portion of the sealing tube comprises an adhesive element, which are not present in Groups II-IV; the special technical features of Group II include a spiral needle which is hollow, and a suture encases at least partially by the spiral needle, which are not present in Groups I and III-IV; the special technical features of Group III include comprising one or more locating members, a straight wire member attached at its distal end to each of the one or more locating members, which are not present in Groups I-II and IV; the special technical features of Group IV include a loop portion, and wherein the overlapping portion is encased by the insertion device and the loop portion is located inside the vessel; manipulating the insertion device to expand the loop to contact and line the interior surface of the vessel wall; manipulating the insertion device to remove excess film which remains outside of the vessel; and pulling the insertion device proximally to remove the insertion device from the patient, which are not present in Groups I-III.

The common technical features of Groups I-IV are a vascular closure device; and outer sheath.

These common technical features are disclosed by US 2012/0089171 A1 to Hastings, et al. (hereinafter 'Hastings'). Hastings discloses a vascular closure device (device 10 for sealing an opening 1 in the wall of a vessel; figure 1; paragraph [0024]) and outer sheath (non-stick outer sheath 20; figures 1; paragraph [0025]).

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

The additional common technical features of Groups I, II and IV are a sealing tube/flexible film folded onto itself.

These common technical features are disclosed by the Hastings reference. Hastings discloses a sealing tube/flexible film folded onto itself (adhesive (sealing) film 40; film 40 may be elongated and generally cylindrical (tubular); figure 1; paragraphs [0025], [0030]).

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