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(71) Applicant: ACCESS SCIENTIFIC, LLC [US/US]; 3910 Sorrento Valley Blvd., Suite 200, San Diego, CA 92121 (US).

(72) Inventors: BIERMAN, Steven, F.; 143 Eighth Street, Del Mar, CA 92014 (US). PLUTH, Richard, A.; 5643 Glenstone Way, San Diego, CA 92121 (US). NGUYEN, Tu; 711 E. 17th Avenue, Escondido, CA 92025 (US).

(74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson & Bear, Llp, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

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[Continued on next page]

(54) Title: VASCULAR ACCESS DEVICE

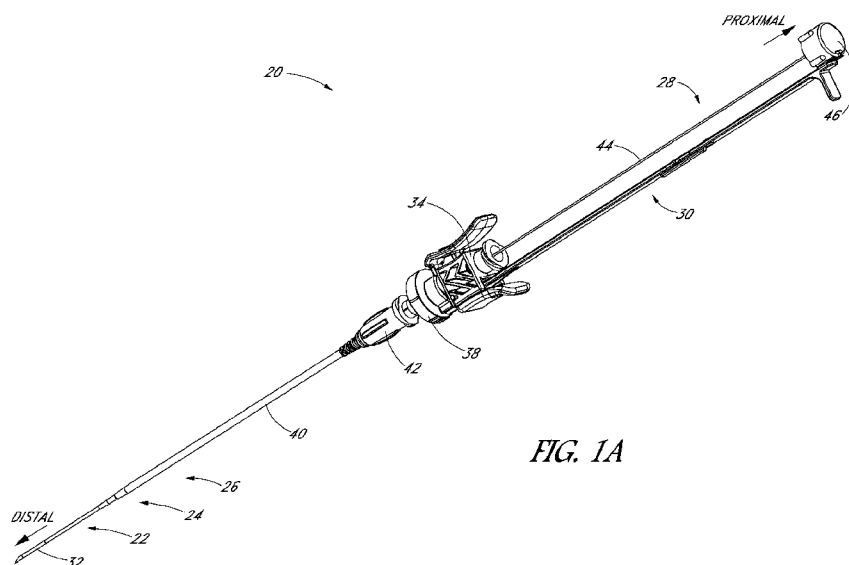


FIG. 1A

(57) Abstract: An access device for placing a medical article within a body space includes a needle, a dilator, and a sheath. The dilator can be coaxially and slideably disposed about the needle, and the sheath can be coaxially and slideably disposed about the dilator. The access device can further include an inner member coaxially disposed between the needle and dilator. The needle can include a fenestration in fluid communication with a space between the needle and inner member. When the needle punctures a blood vessel, the fenestration allows blood to flow into the space between the needle and inner member to provide a visual indicator to a physician or healthcare professional that the needle is in a vessel.

**Declarations under Rule 4.17:**

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
- *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:

4 December 2014

Published:

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/26803

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/32; A61M 1/14, 5/178, 25/00, 25/04, 25/06, 25/08, 29/02, 29/04 (2014.01)

USPC - 604/104, 164.1, 166.01, 506, 507, 538

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 17/32; A61M 1/14, 5/178, 25/00, 25/04, 25/06, 25/08, 29/02, 29/04 (2014.01)

USPC: 604/104, 164.1, 166.01, 506, 507, 538; CPC: A61M 25/09, 2025/0008

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; Google Patent; ProQuest; PubMed/Medline; Search terms used: guidewire, guide-wire, "guide wire", remov*, withdraw*, postoperat*, post-operat*, ruler "tape measure", measur*, mark*, length

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0015039 A1 (CASSIDY, KT et al.) January 19, 2006; paragraphs [0001]-[0005], [0010]	1-5
Y		6
Y	WO 2013/026045 A1 (BIERMAN, SF et al.) February 21, 2013; paragraphs [0011], [0088]-[0089], [0092], [0235]; figures 1A-1B	6
A	US 2012/0316500 A1 (BIERMAN, SF et al.) December 13, 2012; entire document	1-6

☐ Further documents are listed in the continuation of Box C.

* 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

01 OCT 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/US14/26803

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 1-6 are directed toward a method for accessing a body space and a kit comprising an access device and a postoperative guidewire measurement tool.

Group II: Claims 7-18 are directed toward access device for placing a medical article within a body space comprising a needle and dilator.

Group III: Claims 19-28 are directed toward a splittable sheath assembly.

-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.:
1-6

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/US14/26803

-Continued from Box III - Observations where unity of invention is lacking-

The inventions listed as Groups I-III 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 inserting a guidewire into a body; advancing a medical article into the body over the guidewire; withdrawing the guidewire from the body; placing the guidewire on a postoperative guidewire measurement tool, the postoperative guidewire measurement tool comprising: a surface on which the guidewire can be placed for measurement after being withdrawn from the body space and the needle; and at least one marking configured to indicate an acceptable postoperative length for the guidewire, which are not present in Groups II-III; the special technical features of Group II include a needle comprising a fenestration near a distal end of the needle; a dilator disposed about the needle, a distal end of the dilator positioned distal to the fenestration; and an inner member coaxially disposed between the needle and the dilator, a distal end of the inner member positioned distal to the fenestration and proximal to the distal end of the dilator; wherein a space between an outer diameter of the needle and an inner diameter of the inner member defines a blood flash channel in fluid communication with the fenestration to allow blood to flow from an interior of the needle through the fenestration to the blood flash channel when the needle punctures a blood vessel, which are not present in Groups I and III; the special technical features of Group III include a splittable sheath body comprising a generally flexible tubular structure, a proximal end, and a distal end, the sheath body defining a longitudinal axis and being splittable into two portions along a pre-determined line generally parallel to the longitudinal axis; a splittable sheath hub extending from the proximal end of the sheath body defining a longitudinal axis generally aligned with the longitudinal axis of the sheath body, the sheath body and sheath hub forming an inner cavity along their respective longitudinal axes; and a valve element comprising: a resilient plate comprising a sealing portion extending radially inwardly from a side of the inner cavity; a sealing element comprising a domed first sealing surface and being supported by the resilient plate such that the sealing element is biased toward a position against a second sealing surface to substantially seal the inner cavity; and an annular member comprising the second sealing surface, the annular member having a central bore and a tapered top surface that decreases from an outer edge of the annular member to the central bore, the domed first sealing surface corresponding to the central bore of the annular member, which are not present in Groups I-II.

The common technical feature of Groups I and II is an access device; and a needle.

These common technical features are disclosed by US 4,861,341 A (WOODBURN). Woodburn discloses an access device and a needle (a system of a subcutaneous venous access device or injection port and needle, wherein the port includes a self-closing septum for repeatedly and periodically receiving a predetermined section of an injection needle, and which septum covers an injection-receiving chamber in communication with a vein; abstract).

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

Since none of the special technical features of the Groups I and III inventions or Groups II and III inventions are found in more than one of the inventions, unity is lacking.