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**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))*
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(54) Title: DEVICES AND METHODS FOR MANIPULATING BODILY TISSUE

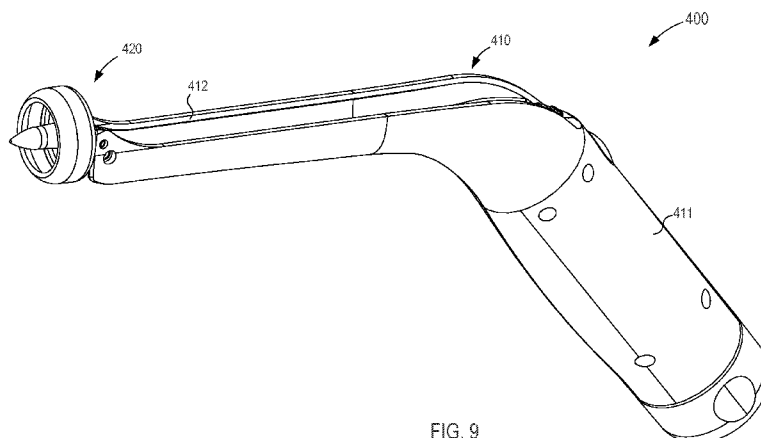


FIG. 9

(57) Abstract: A device includes an insertion member having a distal end portion configured to be removably engaged with an implant, and a sheath having an exit portion and defining a lumen. The exit portion of the sheath includes a set of dilation members configured to be moved from a first configuration to a second configuration. The set of dilation members forms a dilation surface when the set of dilation members is in the first configuration and defines an opening when the set of dilation members is in the second configuration. The sheath includes a hinge configured to facilitate movement of the set of dilation members between the first configuration and the second configuration. The distal end portion of the insertion member configured to move within the lumen to convey the implant from within the lumen via the opening when the set of dilation members is in the second configuration.



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/43417

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC(8) - A61B 17/42 (2014.01)<br>CPC - A61B 17/4241<br>According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                  |                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>IPC(8): A61B 17/42 (2014.01)<br>CPC: A61B 17/4241<br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>USPC: 606/119-123, 33,193,198, 213<br>CPC: A61B 17/4241, A61B 17/42<br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>PatBase(Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO); Google Scholar (Articles and Patents)<br>Search Terms Used: IUD uterus; implant ; dilat* expand*; (tube* OR sheath* OR shroud* OR needle* OR lumen*); soft* OR hard* OR elastic* OR compliant;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                  |                                                                                            |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                  |                                                                                            |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Citation of document, with indication, where appropriate, of the relevant passages                               | Relevant to claim No.                                                                      |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                  | 1, 6-13, 15                                                                                |
| --                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                  | -----                                                                                      |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | CA 2,857,529 A1 (Cappiello et al.) 06 June 2013 (06.06.2013) entire document, especially fig. 52 and para [1200] | 2-5, 14                                                                                    |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 2008/0058833 A1 (Rizvi) 06 March 2008 (06.03.2008), fig. 21 and para [0041]                                   | 2, 5                                                                                       |
| Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | US 2010/0198214 A1 (Layton et al.) 05 August 2010 (05.08.2010) fig. 8 and para [0069]                            | 3, 4, 14                                                                                   |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                  |                                                                                            |
| * Special categories of cited documents:<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"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)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"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<br>"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<br>"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<br>"&" document member of the same patent family |                                                                                                                  |                                                                                            |
| Date of the actual completion of the international search<br>19 November 2014 (19.11.2014)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                  | Date of mailing of the international search report<br><b>05 DEC 2014</b>                   |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                  | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 14/43417

## 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:

(please see 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.:  
1-15

### 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/US 14/43417

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 1-15, directed to an apparatus comprised of a sheath with an insertion member coupled to an implant

Group II: Claims 16-27, directed to an apparatus comprised of a connection portion and an engagement portion with vacuum ports for suction attachment to tissue.

The inventions listed as Groups I and 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:

Group I includes at least a sheath with an insertion member coupled to an implant, which is not present in Group II.

Group II includes a connection portion and an engagement portion with vacuum ports for suction attachment to tissue, which is not present in Group I.

Groups I and II share the technical features of dilation members configured to be moved from a first configuration to a second configuration.

However, these shared technical feature do not represent a contribution over the prior art, as shown as being anticipated by CA 2857529 A1 to Cappiello et al. (hereinafter Cappiello): Cappiello discloses dilation members (movable cover 5674, comprising movable flaps, see fig. 44 and para [1183]) configured to be moved from a first configuration (see fig. 52) to a second configuration (see fig. 55), the dilation members forming a dilation surface (see fig. 42) when the dilation members are in the first configuration, the plurality of dilation members defining an opening when the dilation members are in the second configuration (see fig. 55).

Therefore, Groups I and II lack unity under PCT Rule 13.