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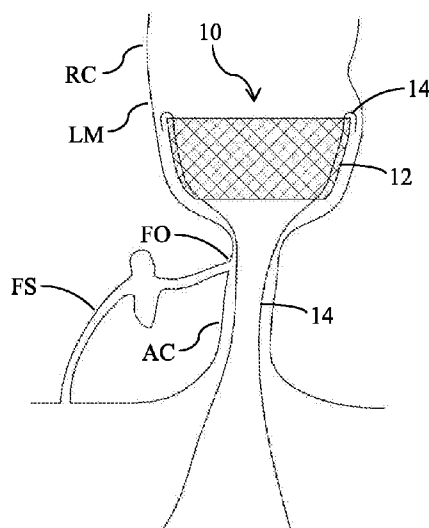


Figure 1

(57) Abstract: The present invention includes devices and methods to treat fistulas. The treatments include diversion or isolation of the flow of enteric matter, fecal matter, urine, or any matter entering the fistula and interfering with the natural healing process. By isolating the fistula from the flow the normal healing response is allowed to occur thus promoting fistula closure.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/65107

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 5/00 (2016.01)

CPC - A61M 27/002, 27/008; A61F 2/04, 2/043, 2002/045, 2002/047, 2002/048

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)

CPC: A61M 27/002, 27/008; A61F 2/04, 2/043, 2002/045, 2002/047, 2002/048 IPC(8): A61M 5/00 (2016.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 606/213; 604/8, 9, 10; 623/1.11, 1.12, 1.13, 23.64 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase; Google Patents; Google

Search Terms Used: fistula, external, exterior, outside, body, patient, bypass*, shunt*, clamp*, lumen, vessel, tissue, bifurcat*, stent, graft, ratchet*, anal, urogenital, gastrointestinal, sleeve

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0208357 A1 (MELANSON et al) 28 August 2008 (28.08.2008) fig 3, 4, para [0018], [0038]-[0041], [0051]	1-2, 4, 7, 9, 11, 13, 18
Y		5-6, 8
X	US 6,468,301 B1 (AMPLATZ et al) 22 October 2002 (22.10.2002) col 1, ln 6-19, col 4, ln 1-9, col 4, ln 49-62, col 8, ln 48-51	1-3
X	US 2007/0185565 A1 (SCHWAMMENTHAL et al) 09 August 2007 (09.08.2007) fig 9, 10, 11, para [0052], [0063]-[0064]	1, 12
X	US 2009/0234430 A1 (FLEMING et al) 17 September 2009 (17.09.2009) fig 2, para[0036]-[0037]	1, 10
Y	US 5,441,515 A (KHOSRAVI et al) 15 August 1995 (15.08.1995) fig 16, col 5, ln 51 to col 6, ln 21	5-6
Y	US 2013/0204216 A1 (MATAR) 08 August 2013 (08.08.2013) para [0015]	0

☐ 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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 15/65107

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 1-13, 18 directed to a device for treating a fistula having an expandable sealing element.

Group II: Claims 14-17, 19 directed to a device for treating a fistula having a vacuum source.

----Continued on Supplemental Page----

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.:
1-13, 18

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 15/65107

Continuation of Box 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:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of an expandable sealing element and a sleeve, not required by the claims of Group II.

The invention of Group II includes the special technical feature of a tissue engagement portion, a vacuum source, a lumen providing fluid communication between the vacuum source and the tissue engagement component, not required by Group I.

COMMON TECHNICAL FEATURES

Groups I and II share no common elements that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.