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(54) Title: SYSTEM AND METHOD FOR SEALING ACCESS

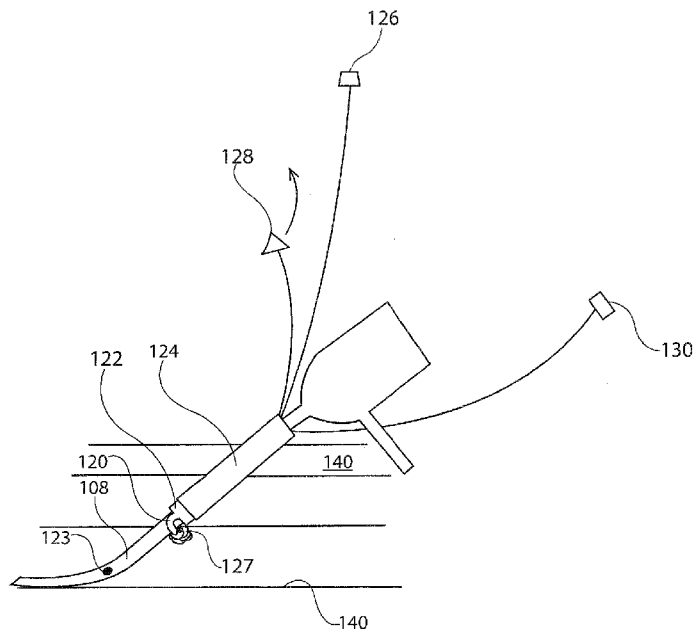


Fig. 3C

(57) Abstract: The present invention relates to an apparatus and a method for sealing a puncture in a tubular tissue structure or the wall of a body cavity. More specifically, the present invention is directed to an apparatus and method for sealing a puncture site in the wall of a tubular tissue structure, or in the wall of a body cavity with a stabilizer used to stabilize the material used to seal the puncture site as the material is positioned. The material is inserted into the puncture site as a ribbon or sheet on an introducer element such as a needle, a cannula, a guide wire, an introducer element adapted for dialysis, an introducer element adapted for catheterization, a trocar, or any other introducer element used to access the lumen of a tubular tissue structure or used to access a body cavity.

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— *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/US12/26777

**A. CLASSIFICATION OF SUBJECT MATTER**  
**IPC(8) - A61B 17/08; A61F 2/06 (2012.01)**  
**USPC - 606/213, 151**  
 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 17/08; A61F 2/06 (2012.01)  
 USPC: 606/213, 151

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); DialogPRO; IEEE; Google/Google Scholar; MedLine: catheter\*, puncture\*, access\*, hole\*, opening\*, tube\*, tubular, sheath\*, sheet\*, ribbon\*, cuff\*

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X - Y	US 2006/0004408 A1 (MORRIS, E. et al.) January 05, 2006, figures 1E, 2A, 6A-7, 10B, 11A-F; paragraphs [0045]-[0047], [0049]-[0051], [0062]-[0068], [0070], [0071], [0111]-[0115]	11-19, 21 ----- 1-10, 20
Y	US 7879061 B2 (KEITH, P.T. et al.) February 1, 2011, figures 1E, 2A; column 5, lines 14-59; column 6, lines 19-57	20
Y	US 6719781 B1 (KIM, D.) April 13, 2004, figures 48, 51; column 38, lines 23-43; column 39, lines 63-67 to column 40, lines 1-62	1-10
Y	US 6,033,427 A1 (LEE, B.) March 07, 2000, figures 1-10; column 6, lines 12-36; column 7, lines 29-60; column 8, lines 1-23; column 12, lines 40-57.	8, 10

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	

Date of the actual completion of the international search 13 August 2012 (13.08.2012)	Date of mailing of the international search report <b>06 SEP 2012</b>
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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
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**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/US12/26777

**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 fees must be paid.

Group I: Claims 1-21 are directed toward a method of sealing a puncture site in the wall of a tubular tissue structure or in the wall of a body cavity, said method comprising the step of: inserting an introducer into the puncture site, the introducer having a sheath, a stabilizer, and a ribbon or sheet of material, wherein the ribbon or sheet of material has at least one tether, an extended portion and a cuff, wherein the cuff of the ribbon or sheet remains outside of the punctured wall and the extended portion of the ribbon or sheet is positioned in the lumen of the tubular tissue structure or the body cavity; contacting the stabilizer with the cuff to stabilize the cuff; and positioning the ribbon or sheet to substantially seal the puncture site while the stabilizer is in contact with the cuff.

Group II: Claim 22 is directed toward a stabilizer for use with an apparatus used to seal a puncture site in a tubular structure comprising a hollow tube and a clip to detachably couple the stabilizer to the apparatus.

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.:  
  
Claims 1-21

**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.