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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))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

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(54) Title: DEVICES, SYSTEMS, AND METHODS FOR ACCESSING THE EPICARDIAL SURFACE OF THE HEART

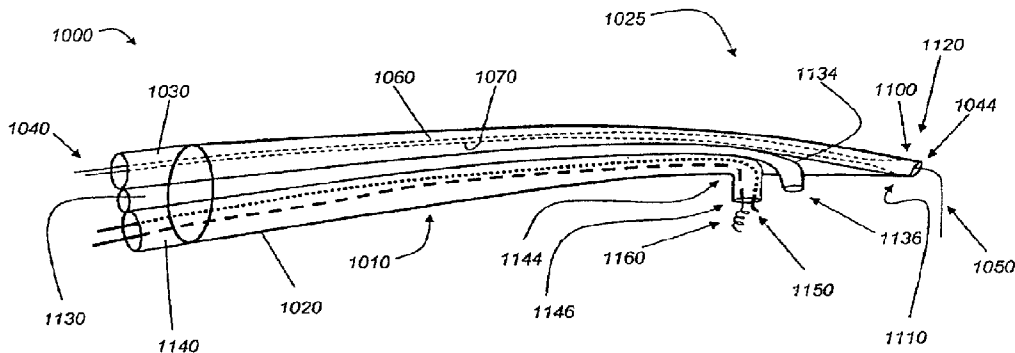


Fig. 7

(57) Abstract: Devices, systems, and methods for accessing the internal and external tissues of the heart are disclosed. At least some of the embodiments disclosed herein provide access to the external surface of the heart through the pericardial space for localized delivery of leads to the heart tissue. In addition, various disclosed embodiments provide devices, systems, and methods for closing a hole in cardiac tissue.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/53061

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 18/04; A61B 18/18 (2008.04) USPC - 606/32; 606/41 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) USPC- 606/32; 606/41 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC- 623/2.36, 623/2.11, 623/23.64, 623/32 and 623/41 (text search) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Electronic Databases Searched: pubWEST, USPTO, Google, Answers.com, Google Patents: vacuum, lead, placing, tissue, cardiac, heart, insertion, port, wall, catheter, seal, retracted, pericardial, perpendicular, angle, aspirate, lumen, pacing, steering, guide, wire, rotatable, spool, channel, torque, enlarge		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0010708 A1 (NESS) 11 Jan 2007 (11.01.2007); para [0003], [0008], [0009], [0011], [0012], [0019], [0020], [0022]-[0024], [0033], [0041]-[0043], [0046], [0049], [0059], [0061], [0062], [0064], [0065], [0068], [0069], [0072] and [0121]; Figs. 16-17	1-12, 30-36, 61-71
Y	US 2005/0261673 A1 (BONNER) 24 Nov 2005 (24.11.2005); para [0018], [0068], [0071], [0083]-[0085], [0092], [0093], [0097]-[0099], [0119], [0121], [0151], [0152], [0156], [0157] and [0166]	1-12, 33-36
Y	US 2004/0087938 A1 (LECKRONE et al) 06 May 2004 (06.05.2004); para [0004], [0007], [0041], [0045]-[0048], [0063] and [0140]	30-36, 61-71
Y	US 2006/0207612 A1 (JACKSON et al.) 21 Sep 2006 (21.09.2006); para [0149], [0191], [0194] and [0203]	10, 34-36 and 63
Y	US 2003/0009145 A1 (STRUJIKER-BOUDIER et al.) 09 Jan 2003 (09.01.2003); para [0150]	32 and 70-71
Y	US 2006/0240113 A1 (HUNTER et al.) 26 Oct 2006 (26.10.2006); para [0014] and [0098]	64-67
Y	Huang. Engineering RGD-Modified Liposomes for Targeted Drug Delivery to Activated Platelets. PhD Thesis, Case Western Reserve University, Aug. 2006 [Retrieved from the Internet on 26 Sep 2008]; < http://www.ohiolink.edu/etd/send-pdf.cgi?acc_num=case1153187042>	68
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* 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 25 September 2008 (25.08.2008)		Date of mailing of the international search report 01 OCT 2008
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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/53061

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:
Group I, claims 1-12, 30-36, 61-71, drawn to a system for use with a vacuum source for placing a lead into a tissue of a heart.

Group II, claims 13-29, 56-60, drawn to a delivery catheter for use in accessing a pericardial space surrounding the external surface of a heart.

Group III, claims 37-55, 72-78, drawn to a system and a method for closing a hole in a targeted tissue of a heart.

***** SEE SUPPLEMENTAL PAGE TO CONTINUE *****

- 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.:
1-12, 30-36, 61-71

- 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.

***** SUPPLEMENTAL PAGE *****

In continuation of 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:

Although Groups I -III do share the technical feature of a delivery catheter for use in accessing a pericardial space surrounding the external surface of a heart, this shared technical feature does not represent a contribution over the prior art of US 2006/0079951 A1 to Dolan et al. (13 Apr 2006) that teaches such a delivery catheter ("a guide catheter that includes a central lumen. A stent delivery device that includes a delivery catheter and a stent disposed on the delivery catheter is slidably received in the central lumen. ... The stent carried on the stent delivery device is expanded after being positioned at a location beyond a distal end of the guide catheter, " Abstract). As the above delivery catheter for use in accessing a pericardial space surrounding the external surface of a heart was known at the time, as evidenced by the teaching of Dolan et al., this cannot be considered a special technical feature that would otherwise unify the groups.

As to Groups I and III, a method for delivery of a medicament into the pericardial space, as required by Group I, is materially different from a method for closing a hole in a targeted tissue of a heart, as required by Group III.

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