US009308015B2

(12) **United States Patent**
**Vassiliades et al.**

(10) **Patent No.:** **US 9,308,015 B2**
(45) **Date of Patent:** ***Apr. 12, 2016**

(54) **CONDUIT DEVICE AND SYSTEM FOR IMPLANTING A CONDUIT DEVICE IN A TISSUE WALL**

(71) Applicants: **Emory University**, Atlanta, GA (US); **Georgia Tech Research Corporation**, Atlanta, GA (US)

(72) Inventors: **Thomas A. Vassiliades**, Atlanta, GA (US); **Ajit Yoganathan**, Tucker, GA (US); **Jorge Hernan Jimenez**, Atlanta, GA (US)

(73) Assignees: **Emory University**, Atlanta, GA (US); **Georgia Tech Research Corporation**, Atlanta, GA (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/475,068**

(22) Filed: **Sep. 2, 2014**

(65) **Prior Publication Data**

US 2014/0371518 A1 Dec. 18, 2014

**Related U.S. Application Data**

(63) Continuation of application No. 13/845,960, filed on Mar. 18, 2013, now Pat. No. 8,858,489, which is a continuation of application No. 12/901,810, filed on Oct. 11, 2010, now Pat. No. 8,430,836, which is a continuation of application No. 11/739,151, filed on Apr. 24, 2007, now Pat. No. 7,846,123.

(51) **Int. Cl.**
***A61B 17/3205*** (2006.01)
***A61M 1/10*** (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ........... ***A61B 17/32053*** (2013.01); ***A61F 2/064*** (2013.01); ***A61M 1/10*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ............. A61B 17/11; A61B 17/32053; A61B 2017/00123; A61B 2017/00243; A61B 2017/00252; A61B 2017/3488; A61B 2018/00351; A61B 2018/00392; A61F 2/064; A61M 1/10; A61M 1/1008; A61M 1/12; A61M 1/122; Y10S 623/904
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,512,519 A 5/1970 Hall
3,540,451 A 11/1970 Zeman
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2526920 2/2009
CN 1842354 10/2006
(Continued)

OTHER PUBLICATIONS

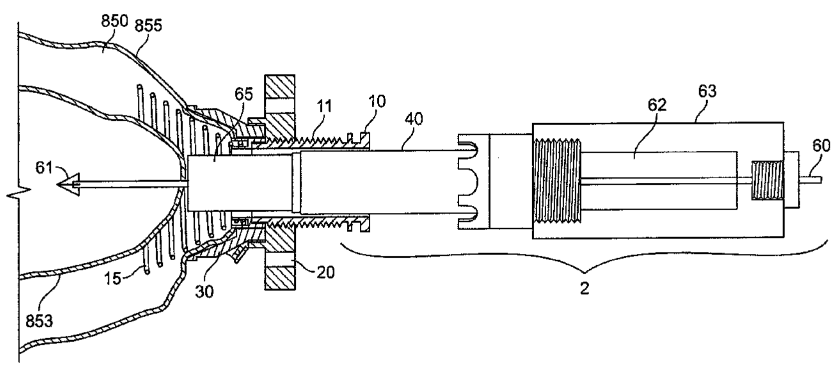
International Search Report and Written Opinion for International Patent Application No. PCT/US2008/061404, dated Aug. 19, 2008.
(Continued)

*Primary Examiner* — Adam Marcetich
(74) *Attorney, Agent, or Firm* — Alston & Bird LLP

(57) **ABSTRACT**

Various embodiments of the present invention provide a conduit device including an attaching device configured for defining a helical pathway through a tissue wall and complementary ring in cooperation for securing the device within an aperture defined in the tissue wall. Some embodiments of the present invention further provide a system for implanting a conduit device in a tissue wall. More specifically, some embodiments provide a system including a coring device for defining an aperture in a tissue by removing and retaining a tissue core and securely implanting a conduit device therein so as to provide fluid communication between a first and second surface of the tissue wall via the conduit device.

**44 Claims, 8 Drawing Sheets**



(51) **Int. Cl.**
***A61M 1/12*** (2006.01)
***A61F 2/06*** (2013.01)
*A61B 17/00* (2006.01)
*A61B 17/34* (2006.01)
*A61B 17/11* (2006.01)
*A61B 18/00* (2006.01)

(52) **U.S. Cl.**
CPC .............. ***A61M 1/1008*** (2014.02); ***A61M 1/12*** (2013.01); ***A61M 1/122*** (2014.02); *A61B 17/11* (2013.01); *A61B 2017/00123* (2013.01); *A61B 2017/00243* (2013.01); *A61B 2017/00252* (2013.01); *A61B 2017/3488* (2013.01); *A61B 2018/00351* (2013.01); *A61B 2018/00392* (2013.01); *Y10S 623/904* (2013.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS


3,856,021 A 12/1974 McIntosh
4,366,819 A 1/1983 Kaster
4,769,031 A 9/1988 McGough et al.
4,904,264 A 2/1990 Scheunemann
5,098,369 A 3/1992 Heilman et al.
5,129,913 A 7/1992 Ruppert
5,139,517 A 8/1992 Corral
5,158,563 A 10/1992 Cosman
5,222,980 A 6/1993 Gealow
5,256,160 A 10/1993 Clement
5,291,179 A 3/1994 Ooe et al.
5,387,193 A 2/1995 Miraki
5,447,533 A 9/1995 Vachon et al.
5,456,714 A 10/1995 Owen
5,577,993 A 11/1996 Zhu et al.
5,582,616 A 12/1996 Bolduc et al.
5,695,504 A 12/1997 Gifford et al.
5,755,697 A 5/1998 Jones et al.
5,782,844 A 7/1998 Yoon et al.
5,797,933 A 8/1998 Snow et al.
5,810,836 A 9/1998 Hussein et al.
5,810,851 A 9/1998 Yoon
5,814,005 A 9/1998 Barra et al.
5,824,070 A 10/1998 Jarvik
5,824,071 A 10/1998 Nelson et al.
5,827,316 A 10/1998 Young et al.
5,843,088 A 12/1998 Barra et al.
5,893,369 A 4/1999 LeMole
5,910,153 A 6/1999 Mayenberger
5,924,424 A 7/1999 Stevens et al.
5,944,730 A 8/1999 Nobles et al.
5,976,174 A 11/1999 Ruiz
5,984,956 A 11/1999 Tweden et al.
5,989,278 A 11/1999 Mueller
6,001,056 A 12/1999 Jassawalla et al.
6,007,576 A 12/1999 McClellan
6,022,324 A 2/2000 Skinner
6,022,367 A 2/2000 Sherts
6,039,748 A 3/2000 Savage et al.
6,066,085 A 5/2000 Heilman et al.
6,079,414 A 6/2000 Roth
6,080,173 A 6/2000 Williamson, IV et al.
6,080,176 A 6/2000 Young
6,146,325 A 11/2000 Lewis et al.
6,241,743 B1 6/2001 Levin et al.
6,254,564 B1 7/2001 Wilk et al.
6,267,732 B1 7/2001 Heneveld et al.
6,273,862 B1 8/2001 Privitera et al.
6,290,728 B1 9/2001 Phelps et al.
6,346,071 B1 2/2002 Mussivand
6,390,976 B1 5/2002 Spence et al.
6,401,720 B1 6/2002 Stevens et al.
6,409,739 B1 6/2002 Nobles et al.
6,443,957 B1 9/2002 Addis
6,458,140 B2 10/2002 Akin et al.
6,537,300 B2 3/2003 Girton
6,551,319 B2 4/2003 Lieberman
6,551,332 B1 4/2003 Nguyen et al.
6,589,277 B1 7/2003 Fabiani et al.
6,607,541 B1 8/2003 Gardiner et al.
6,638,237 B1 10/2003 Guiles et al.
6,651,670 B2 11/2003 Rapacki et al.
6,669,708 B1 12/2003 Nissenbaum et al.
6,673,043 B1 1/2004 Landesberg
6,676,678 B2 1/2004 Gifford, III et al.
6,689,147 B1 2/2004 Koster, Jr.
6,695,859 B1 2/2004 Golden et al.
6,699,256 B1 3/2004 Logan et al.
6,705,988 B2 3/2004 Spence et al.
6,726,648 B2 4/2004 Kaplon et al.
6,732,501 B2 5/2004 Yu et al.
6,740,101 B2 5/2004 Houser et al.
6,776,787 B2 8/2004 Phung et al.
6,802,806 B2 10/2004 McCarthy et al.
6,808,498 B2 10/2004 Laroya et al.
6,824,071 B1 11/2004 McMichael
6,827,683 B2 12/2004 Otawara
6,863,677 B2 3/2005 Breznock
6,942,672 B2 9/2005 Heilman et al.
6,984,241 B2 1/2006 Lubbers et al.
6,994,666 B2 2/2006 Shannon et al.
7,018,384 B2 3/2006 Skakoon
7,033,372 B1 4/2006 Cahalan
7,048,681 B2 5/2006 Tsubouchi et al.
7,056,286 B2 6/2006 Ravenscroft et al.
7,077,801 B2 7/2006 Haverich
7,083,631 B2 8/2006 Houser et al.
7,163,525 B2 1/2007 Franer
7,182,771 B1 2/2007 Houser et al.
7,214,234 B2 5/2007 Rapacki et al.
7,232,421 B1 6/2007 Gambale et al.
7,258,694 B1 8/2007 Choi et al.
7,309,343 B2 12/2007 Vargas et al.
7,331,956 B2 2/2008 Hovda et al.
7,404,792 B2 7/2008 Spence et al.
7,510,561 B2 3/2009 Beane et al.
7,637,919 B2 12/2009 Ishikawa et al.
7,717,844 B2 5/2010 Cohn
7,744,527 B2 6/2010 Cohn
7,766,811 B2 8/2010 Haverich
7,799,041 B2 9/2010 Beane et al.
7,842,068 B2 11/2010 Ginn
7,846,123 B2 12/2010 Vassiliades et al.
7,846,179 B2 12/2010 Belef et al.
7,931,581 B2 4/2011 Cohn
7,942,805 B2 5/2011 Shambaugh, Jr.
7,993,392 B2 8/2011 Righini et al.
8,226,670 B2 7/2012 Beane et al.
8,430,836 B2 4/2013 Vassiliades et al.
8,556,930 B2 10/2013 Ellingwood
8,579,790 B2 11/2013 Jeffery et al.
8,840,538 B2 9/2014 Jeffery et al.
8,858,489 B2 10/2014 Vassiliades et al.
2001/0051809 A1 12/2001 Houser et al.
2002/0019623 A1 2/2002 Altman et al.
2002/0019643 A1 2/2002 Gifford et al.
2002/0032462 A1 3/2002 Houser et al.
2002/0038127 A1 3/2002 Blatter et al.
2002/0045846 A1 4/2002 Kaplon et al.
2002/0058958 A1 5/2002 Walen
2002/0095210 A1 7/2002 Finnegan et al.
2002/0099394 A1 7/2002 Houser et al.
2002/0116018 A1 8/2002 Stevens et al.
2002/0177865 A1 11/2002 McIntosh
2002/0183786 A1 12/2002 Girton
2002/0193806 A1 12/2002 Moenning et al.
2003/0014064 A1 1/2003 Blatter
2003/0023255 A1 1/2003 Miles et al.
2003/0032979 A1 2/2003 Mortier et al.
2003/0040765 A1 2/2003 Breznock
2003/0045834 A1 3/2003 Wing et al.
2003/0078592 A1 4/2003 Heilman et al.
2003/0130668 A1 7/2003 Nieman et al.
2003/0181843 A1 9/2003 Bibber et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 2004/0002624 A1 | 1/2004 | Yu et al. | |
| 2004/0050393 A1 | 3/2004 | Golden et al. | |
| 2004/0068299 A1 | 4/2004 | Laske et al. | |
| 2004/0077989 A1 | 4/2004 | Goode et al. | |
| 2004/0092858 A1 | 5/2004 | Wilson et al. | |
| 2004/0097973 A1 | 5/2004 | Loshakove et al. | |
| 2004/0098011 A1 | 5/2004 | Vargas et al. | |
| 2004/0133155 A1 | 7/2004 | Varner et al. | |
| 2004/0153112 A1 | 8/2004 | Nissenbaum et al. | |
| 2004/0162608 A1 | 8/2004 | Haverich | |
| 2004/0167547 A1 | 8/2004 | Beane et al. | |
| 2004/0171905 A1 | 9/2004 | Yu et al. | |
| 2004/0186490 A1 | 9/2004 | Gifford, III et al. | |
| 2004/0225306 A1 | 11/2004 | Blatter et al. | |
| 2004/0236170 A1 | 11/2004 | Kim | |
| 2005/0033107 A1 | 2/2005 | Tsubouchi | |
| 2005/0043781 A1 | 2/2005 | Foley | |
| 2005/0075656 A1 | 4/2005 | Beaupre | |
| 2005/0101982 A1 | 5/2005 | Ravenscroft et al. | |
| 2005/0101983 A1 | 5/2005 | Loshakove et al. | |
| 2005/0131451 A1 | 6/2005 | Kleshinski et al. | |
| 2005/0137609 A1 | 6/2005 | Guiraudon | |
| 2005/0149093 A1* | 7/2005 | Pokorney | A61B 17/3415 606/185 |
| 2005/0154411 A1 | 7/2005 | Breznock et al. | |
| 2005/0171479 A1 | 8/2005 | Hruska et al. | |
| 2005/0187568 A1 | 8/2005 | Klenk et al. | |
| 2005/0192604 A1 | 9/2005 | Carson et al. | |
| 2005/0209502 A1 | 9/2005 | Schmid et al. | |
| 2005/0251187 A1 | 11/2005 | Beane et al. | |
| 2006/0020326 A9 | 1/2006 | Bolduc et al. | |
| 2006/0036313 A1 | 2/2006 | Vassiliades | |
| 2006/0074484 A1 | 4/2006 | Huber | |
| 2006/0089707 A1 | 4/2006 | Vassiliades et al. | |
| 2006/0099716 A1 | 5/2006 | Tipler et al. | |
| 2006/0142634 A1 | 6/2006 | Anstadt et al. | |
| 2006/0161193 A1 | 7/2006 | Beane et al. | |
| 2006/0167333 A1 | 7/2006 | Moore et al. | |
| 2006/0241659 A1 | 10/2006 | Tulleken et al. | |
| 2006/0259050 A1 | 11/2006 | De Winter | |
| 2007/0055357 A1 | 3/2007 | Pokorney et al. | |
| 2007/0066943 A1 | 3/2007 | Prasad et al. | |
| 2007/0088375 A1 | 4/2007 | Beane et al. | |
| 2007/0100363 A1 | 5/2007 | Dollar et al. | |
| 2007/0106315 A1 | 5/2007 | Gregoric et al. | |
| 2007/0106328 A1 | 5/2007 | Wardle et al. | |
| 2007/0112361 A1 | 5/2007 | Schonholz et al. | |
| 2007/0167968 A1 | 7/2007 | Pandey | |
| 2007/0167969 A1 | 7/2007 | Pandey | |
| 2007/0173879 A1 | 7/2007 | Pandey | |
| 2007/0197856 A1 | 8/2007 | Gellman et al. | |
| 2007/0265643 A1 | 11/2007 | Beane et al. | |
| 2008/0004640 A1 | 1/2008 | Ellingwood | |
| 2008/0009668 A1 | 1/2008 | Cohn | |
| 2008/0009887 A1 | 1/2008 | Cohn | |
| 2008/0009891 A1 | 1/2008 | Cohn | |
| 2008/0039883 A1 | 2/2008 | Nohilly | |
| 2008/0058846 A1 | 3/2008 | Vosough | |
| 2008/0076959 A1 | 3/2008 | Farnan et al. | |
| 2008/0161826 A1 | 7/2008 | Guiraudon | |
| 2008/0177301 A1 | 7/2008 | Svensson | |
| 2008/0255597 A1 | 10/2008 | Pravong et al. | |
| 2009/0012552 A1 | 1/2009 | Pandey et al. | |
| 2009/0082778 A1 | 3/2009 | Beane et al. | |
| 2009/0112062 A1 | 4/2009 | Bakos | |
| 2009/0204206 A1 | 8/2009 | Parquet et al. | |
| 2010/0004739 A1 | 1/2010 | Vesely | |
| 2010/0010500 A1 | 1/2010 | Beane et al. | |
| 2010/0049225 A1 | 2/2010 | To et al. | |
| 2010/0087907 A1 | 4/2010 | Lattouf | |
| 2010/0161040 A1 | 6/2010 | Braido et al. | |
| 2010/0168778 A1 | 7/2010 | Braido | |
| 2011/0106116 A1 | 5/2011 | Ducharme et al. | |
| 2011/0118770 A1 | 5/2011 | Pokorney et al. | |
| 2011/0118833 A1 | 5/2011 | Reichenbach et al. | |
| 2011/0144680 A1 | 6/2011 | Nguyen et al. | |
| 2011/0190811 A1 | 8/2011 | Shanley | |
| 2012/0059212 A1 | 3/2012 | LaRose et al. | |
| 2012/0089181 A1 | 4/2012 | Shanley et al. | |
| 2012/0226096 A1 | 9/2012 | Callaway et al. | |
| 2013/0012761 A1 | 1/2013 | Gregoric et al. | |
| 2013/0110228 A1 | 5/2013 | Braido | |
| 2013/0218169 A1 | 8/2013 | Vassiliades et al. | |
| 2013/0253641 A1 | 9/2013 | Lattouf | |
| 2014/0039375 A1 | 2/2014 | Jimenez et al. | |
| 2014/0194833 A1 | 7/2014 | Andrus | |

FOREIGN PATENT DOCUMENTS

| | | |
|---|---|---|
| EP | 1669042 | 6/2006 |
| EP | 1691884 | 3/2011 |
| EP | 1628702 | 5/2013 |
| EP | 1706168 | 11/2013 |
| JP | 11500642 | 1/1999 |
| JP | 2002518082 | 6/2002 |
| JP | 2006518624 | 8/2006 |
| JP | 2007510522 | 4/2007 |
| WO | 9325148 | 12/1993 |
| WO | 9625886 | 8/1996 |
| WO | 9713463 | 4/1997 |
| WO | 9965409 | 12/1999 |
| WO | 0000193 | 1/2000 |
| WO | 0015147 | 3/2000 |
| WO | 0015149 | 3/2000 |
| WO | 0041759 | 7/2000 |
| WO | 0074747 | 12/2000 |
| WO | 03001980 | 1/2003 |
| WO | 2004026147 | 4/2004 |
| WO | 2004096059 | 11/2004 |
| WO | 2005046783 | 5/2005 |
| WO | 2006019755 | 2/2006 |
| WO | 2006020651 | 2/2006 |
| WO | 2006093970 | 9/2006 |
| WO | 2007038109 | 4/2007 |
| WO | 2007047212 | 4/2007 |
| WO | 2007117612 | 10/2007 |
| WO | 2008131453 | 10/2008 |
| WO | 2008153872 | 12/2008 |
| WO | 2009100198 | 8/2009 |
| WO | 2009117435 | 9/2009 |
| WO | 2012040233 | 3/2012 |
| WO | 2012103546 | 8/2012 |
| WO | 2012106422 | 8/2012 |
| WO | 2013064529 | 5/2013 |

OTHER PUBLICATIONS

International Preliminary Report on Patentability for International Patent Application No. PCT/US2008/061404, dated Oct. 27, 2009.
Office Action for European Patent Application No. 08 799 829.0, dated Apr. 19, 2012.
Office Action for European Patent Application No. 08 799 829.0, dated Nov. 2, 2012.
Office Action for Japanese Patent Application No. 2010-606491, dated Nov. 13, 2012.
Office Action for European Patent Application No. 08 799 829.0, dated May 27, 2013.
Office Action for Japanese Patent Application No. 2010-606491, dated Jul. 5, 2013.
Extended European Search Report for European Patent Application No. 13 186 508.1, dated Feb. 6, 2014.
Office Action or European Patent Application No. 13 186 508.1, dated Mar. 17, 2014.
Office Action for Japanese Patent Application No. 2013-175430, dated Jul. 8, 2014.
Office Action for Canadian Patent Application No. 2,719,951, dated Apr. 30, 2014.

* cited by examiner

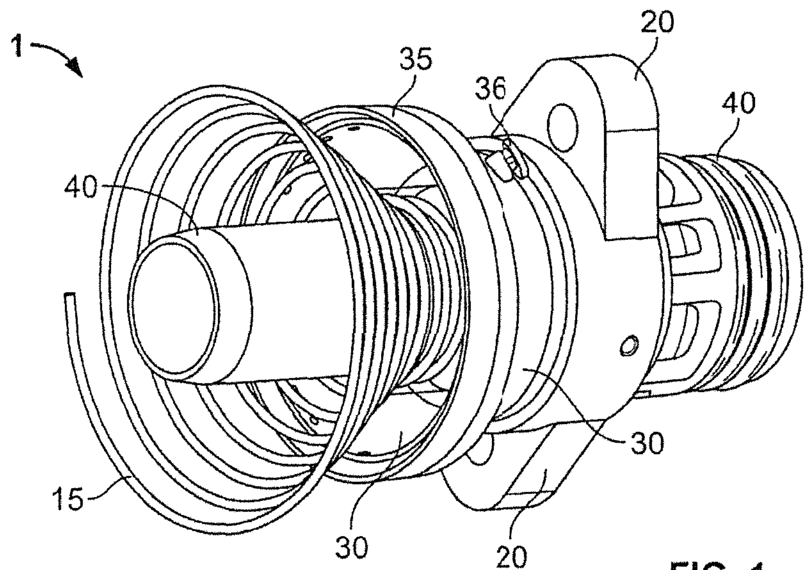



FIG. 1

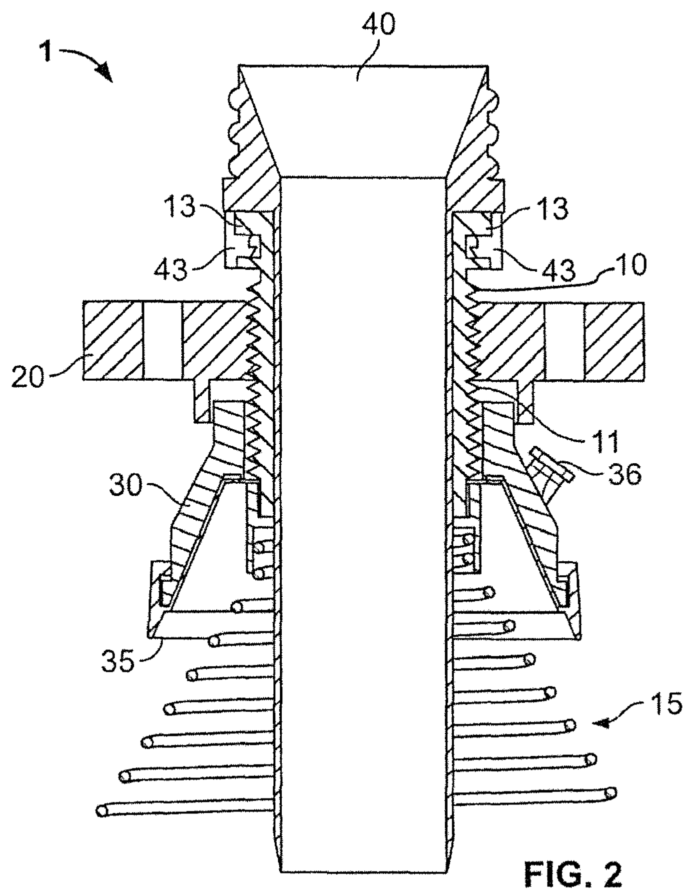



FIG. 2

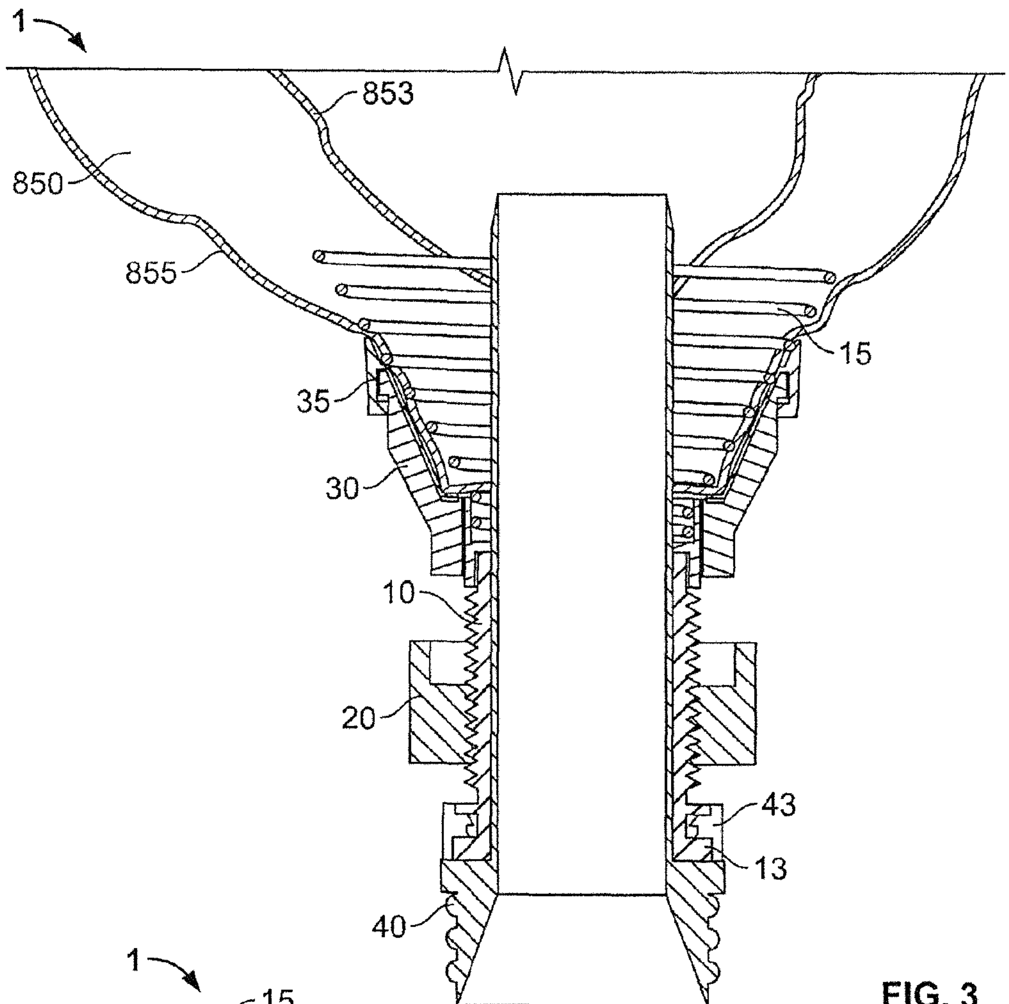



FIG. 3

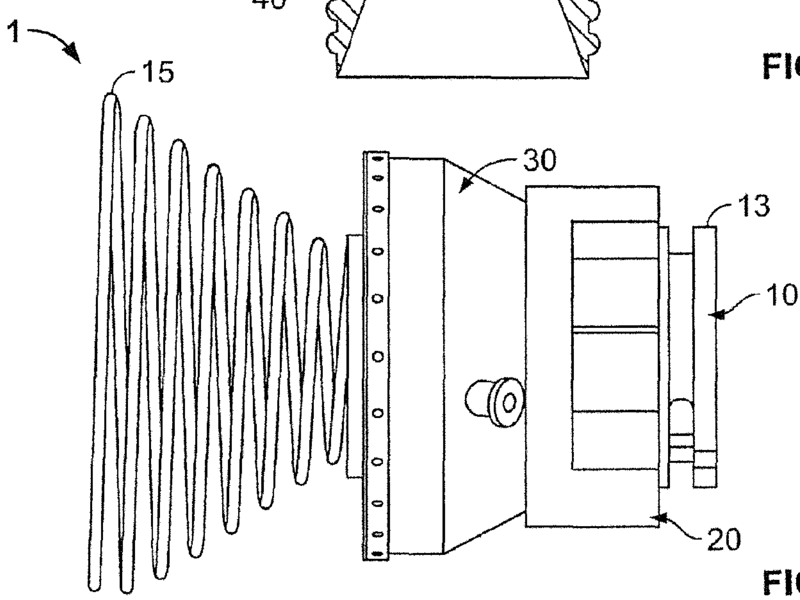



FIG. 4

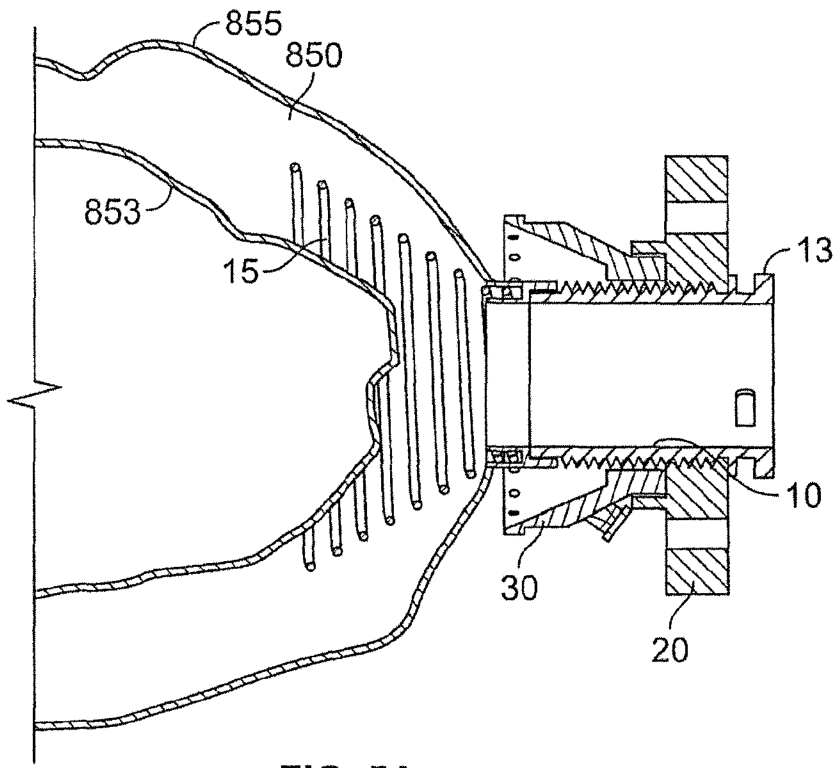



FIG. 5A

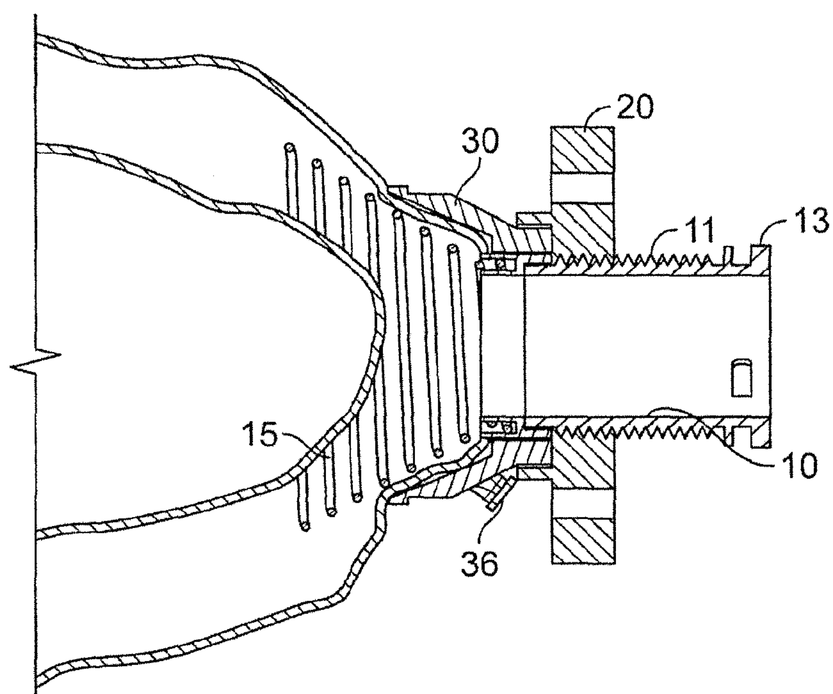



FIG. 5B

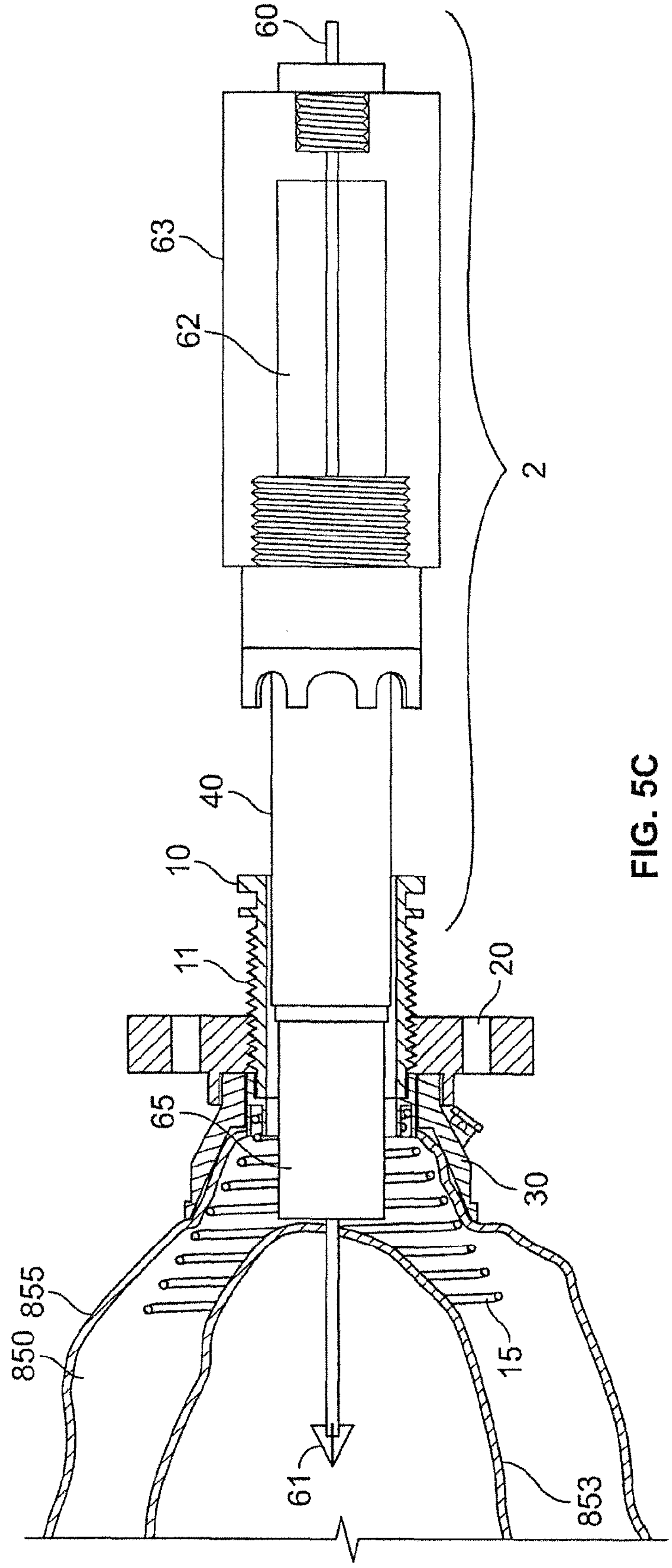



FIG. 5C

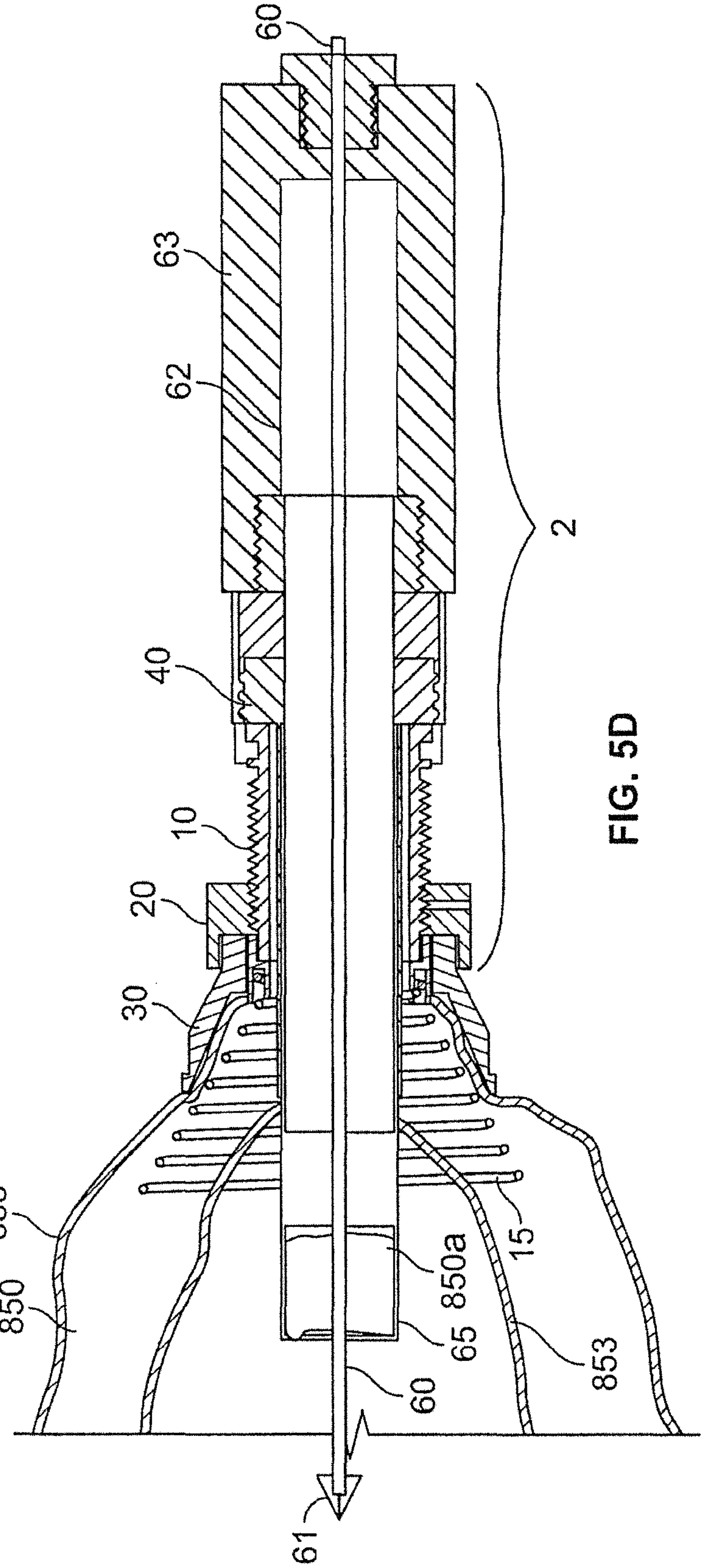



FIG. 5D

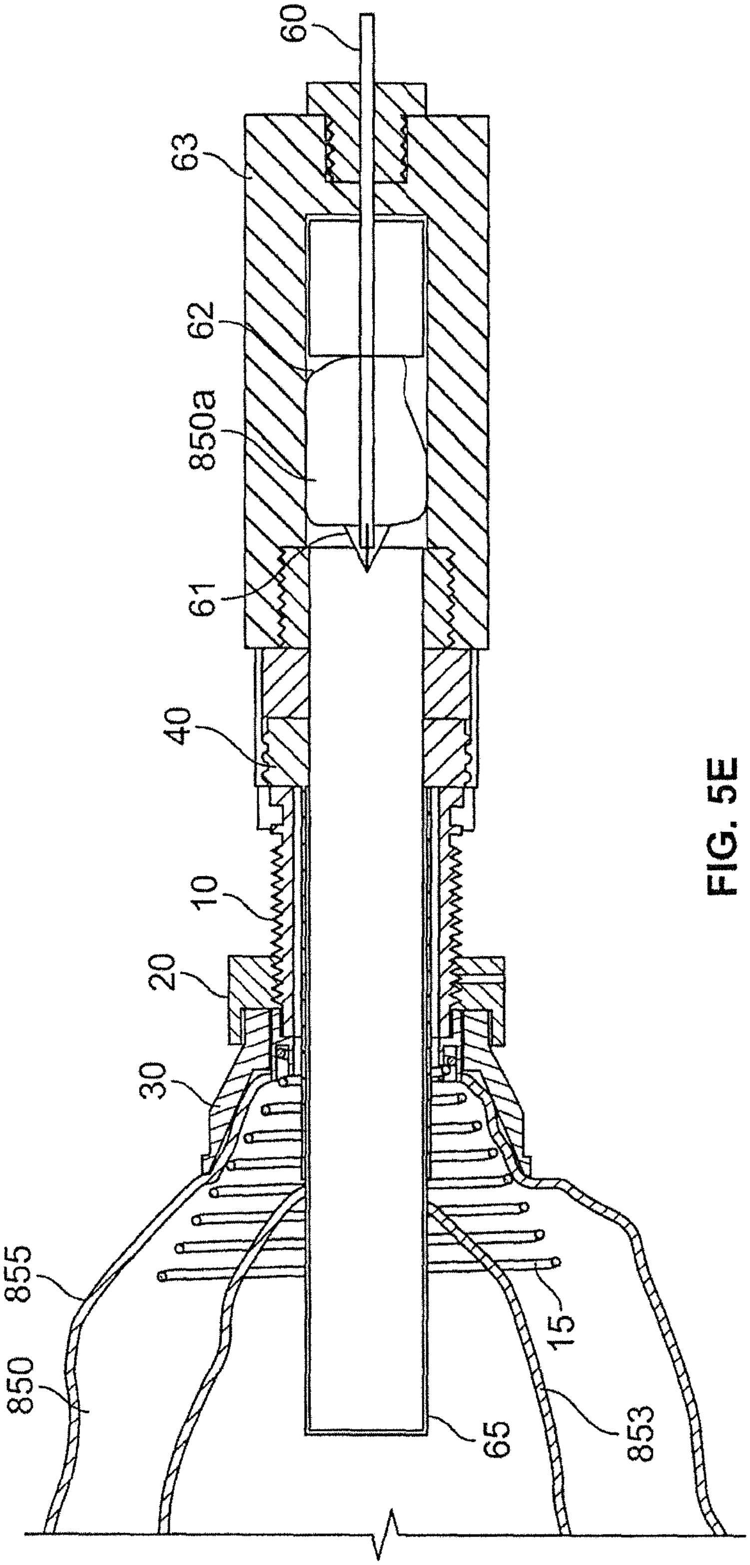



FIG. 5E

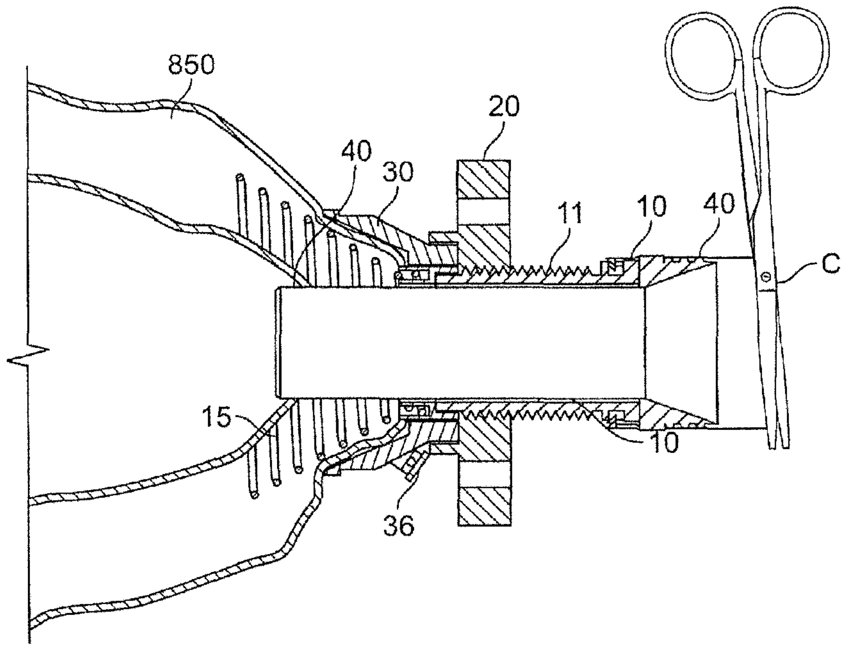



FIG. 5F

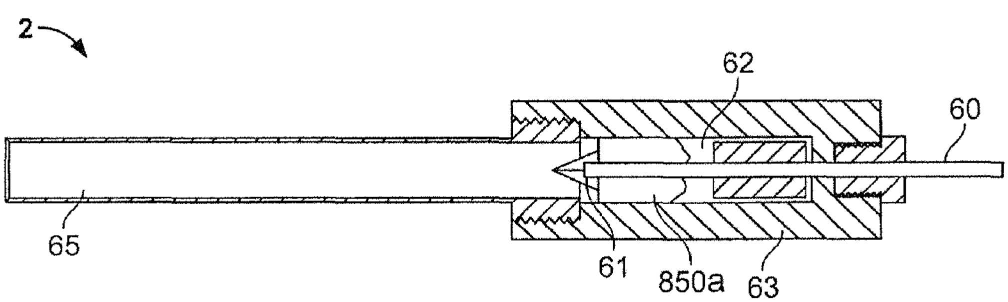



FIG. 5G

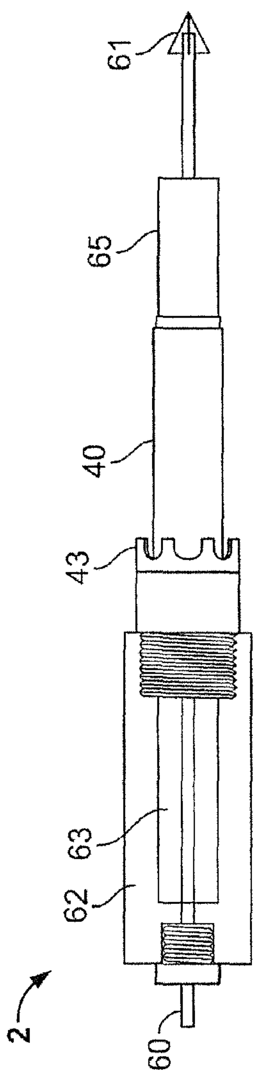



FIG. 6

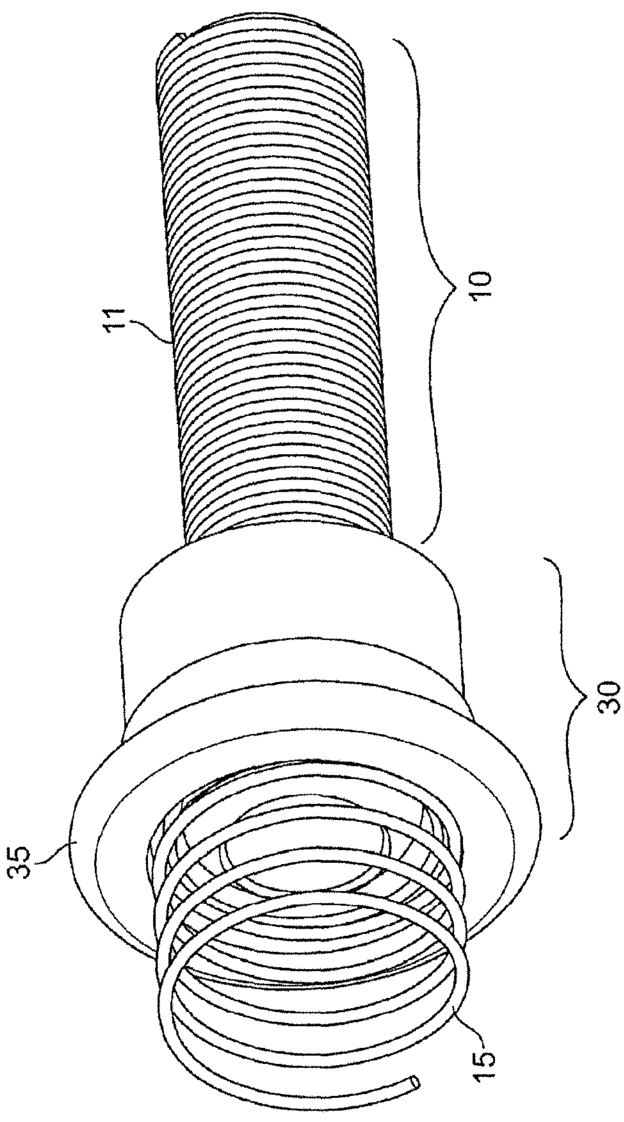



FIG. 7

# CONDUIT DEVICE AND SYSTEM FOR IMPLANTING A CONDUIT DEVICE IN A TISSUE WALL

## CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of copending U.S. patent application Ser. No. 13/845,960, filed on Mar. 18, 2013, which is a continuation of U.S. patent application Ser. No. 12/901,810, filed on Oct. 11, 2010, now U.S. Pat. No. 8,430,836 issued on Apr. 30, 2013, which is a continuation of U.S. patent application Ser. No. 11/739,151, filed on Apr. 24, 2007, now U.S. Pat. No. 7,846,123 issued on Dec. 7, 2010, which are hereby incorporated by reference in their entirety herein.

## FIELD OF INVENTION

This invention relates to devices and methods for creating and maintaining a fluid conduit to establish fluid communication between opposing surfaces of a tissue wall.

## BACKGROUND OF THE INVENTION

Construction of an alternative conduit between the left ventricle and the aorta (an apicoaortic conduit, or AAC) to create a double-outlet left ventricle (LV) has been successfully employed to treat a variety of complex congenital LV outflow obstruction (fibrous tunnel obstruction, aortic annular hypoplasia, tubular hypoplasia of the ascending aorta, and patients with diffuse septal thickening, severe LV hypertrophy and a small LV cavity) as well as adult-onset aortic stenosis in patients with complicating preoperative conditions (previous failed annular augmentation procedures, previous infection, previous CABG with patent anterior internal mammary artery grafts, and a porcelain ascending aorta).

However, the AAC insertion procedure has been poorly accepted, primarily because of early valve failures using first-generation bioprostheses as well as the success of direct LVOTO repair and aortic valve replacement. In the United States, despite an aging population, the unadjusted mortality for isolated aortic valve operations in 2001 remained under 4%. Further, the AAC insertion operation, with or without cardiopulmonary bypass, has not been as technically straightforward as direct aortic valve replacement. For most surgeons, AAC insertion is not a familiar operation and is of historical interest only.

Nonetheless, several studies have demonstrated that AAC insertion successfully lessens the LV-aortic pressure gradient, preserves or improves ventricular function and maintains normally distributed blood flow through the systemic and coronary circulation. While there have been several techniques described, the most commonly employed method is the lateral thoracotomy approach with placement of the AAC to the descending aorta. Other techniques include a median sternotomy approach with insertion of the distal limb of the AAC to the ascending aorta, to the transverse part of the aortic arch, or to the intra-abdominal supraceliac aorta.

In general, the thoracic aorta and the left ventricle apex are exposed through a left lateral thoracotomy, and a needle is passed through the apex and into the left ventricle. While the connector is still spaced apart from the apex, the sutures that will fix the connector to the apex are threaded through a cuff on the connector and through the apex in a matching pattern. The cuff is set back from the end of the connector by 1-2 centimeters to allow the end of the connector to extend



through the heart muscle and into the left ventricle. Once the sutures are in place, a ventricular coring device is used to remove a core of ventricular muscle, and the pre-threaded sutures are then pulled to draw the connector into the opening until the cuff comes to rest: on the apex. The sutures are tied off, and additional sutures may be added. Either before or after this procedure, the opposite end of the connector is attached to a valved conduit which terminates at the aorta.

The current techniques and technology available to perform AAC insertion were originally designed to be performed on-pump; either with an arrested or fibrillating heart. While off-pump cases have been described, they can be technically difficult due to the shortcomings of presently available conduits and systems for installing such conduits. For example, because existing conduits require the use of sutures to reliably secure the connector in place, it is often difficult for surgeons or other clinicians to insert such sutures reliably in active cardiac and/or vascular tissue.

Some devices and methods have been devised to install an AAC conduit, such as those described generally in U.S. patent application Ser. No. 11/251,100, filed on Oct. 14, 2005, and U.S. patent application Ser. No. 10/915,691, filed on Aug. 11, 2004, both of which are hereby incorporated herein in their entirety by reference. However, these AAC conduit devices and installation systems rely on the use of a flexible flange that is inserted through a pre-defined aperture in the ventricular apex. Thus, such methods require the use of a hemostatic device (such as an occlusion balloon and/or "umbrella" device) to prevent blood loss from the aperture during installation of the AAC conduit.

## SUMMARY OF THE INVENTION

Various embodiments of the present invention provide an improved system and method for the insertion of a conduit (such as an AAC conduit) that will significantly simplify the in vivo insertion of a graft into the beating cardiac apex or other tissue walls (such as other areas of the heart including the anterior, lateral, posterior walls of the left or right ventricle, the left or right atrium, the aortic wall, ascending, transverse, or descending, or other blood vessel walls), such that vascular conduit insertions (including AAC procedures) may be rendered far more attractive to clinicians. Because vascular conduits and systems of the present invention may be used to create alternate outflow tracts in "off-pump" procedures, the embodiments of the present invention may effectively reduce and/or negate the detrimental effects of both cardio-pulmonary by-pass (CPB) and global cardiac ischemia. Additionally, because some conduit embodiments of the present invention (for AAC procedures, for example) may be inserted into a ventricular or atrial free wall or cardiac apex, the conduction system of the heart may be avoided, along with the native coronary arteries and grafts from previous surgical revascularization. In some embodiments of the present invention, wherein the system is used to implant an AAC, a small size valve (19 to 21 mm for typical adult body surface areas) is usually adequate; as the effective postoperative orifice is the sum of the native and prosthetic aortic valves. Further, the present invention provides vascular conduits that may be compatible with newer generation biologic valves, such that valved conduit failure is far less likely. Various embodiments of the present invention may also provide general conduit devices (and systems for implanting) suitable for establishing fluid communication between opposing surfaces of tissue walls in a variety of applications, including the establishment of a fluid conduit through the tissue wall of a mammalian urinary bladder.

In one exemplary embodiment, a system is provided for implanting a conduit device (such as an AAC component) in a tissue wall having a first surface and an opposing second surface. According to some embodiments, the system comprises an outer tube defining a guide aperture extending axially through the outer tube and an attaching device extending from a distal end of said outer tube. The attaching device is configured for advancing along a helical path at least partially through the tissue wall such that at least a portion of the attaching device becomes disposed substantially between the first surface and the opposing second surface of the tissue wall when the outer tube is rotated relative to the first surface of the tissue wall. The attaching device, in some system embodiments, comprises at least one of a helical static coil and a helical elastic spring having a sharpened distal end adapted for piercing the tissue wall as the outer tube is rotated relative to the first surface of the tissue wall. According to some such embodiments, the attaching device may define a radially-expanding helix as the attaching device extends away from the distal end of the outer tube.

In some embodiments, the system also comprises a ring operably engaged about an outer surface of the outer tube and configured for cooperating with the attaching device such that at least a portion of the tissue wall is secured between the attaching device and the ring so as to operably engage said outer tube with the tissue wall. According to some such embodiments, the system may further comprise a plurality of ridges disposed on the outer surface of the outer tube. In such embodiments, the ring comprises at least one deformable pawl member operably engaged therewith for releasably engaging the plurality of ridges on the outer surface of the outer tube. In some other embodiments, the system may comprise threading on at least a portion of the outside surface of the outer tube and corresponding threading on at least a portion of an inside surface of the ring. The threading may thus be configured to cooperate for axially securing the ring relative to the outer tube. Furthermore, some system embodiments may further comprise a nut operably engaged about an outer surface of the outer tube and proximal to the ring. The nut may comprise threading on at least a portion on an inside surface thereof, wherein the threading may be configured for cooperating with the threading on at least a portion of the outside surface of the outer tube. Furthermore, the nut may be configured for cooperating with the ring to advance the ring towards the distal end of the outer tube.

In some embodiments, various system components, such as the outer tube and the ring, may be configured to conform to and/or establish a substantially fluid-tight seal with at least a portion a surface of the tissue wall. For example, in some embodiments, the system may comprise a sealing member operably engaged with a distal end of the ring. According to such embodiments, the sealing member may be configured for establishing a substantially fluid tight seal between the ring and the first surface of the tissue wall. In some embodiments, the system may be configured to cooperate and/or operably engage a tissue wall comprising a substantially curved tissue wall. According to some such embodiments, the ring may comprise a frusto-conical assembly configured for receiving at least a portion of the substantially curved tissue wall so as to form a substantially fluid-tight seal between the frusto-conical assembly and the tissue wall.

In some embodiments, the system further comprises an inner tube configured for insertion into the guide aperture defined by the outer tube. According to such embodiments, the inner tube defines a conduit aperture extending axially therethrough. Furthermore, in some such embodiments, the outer tube may comprise a first securing device operably engaged with a proximal end of the outer tube and the inner tube may comprise a complementary second securing device operably engaged with a proximal end of said inner tube. Thus, according to such embodiments, the second securing device may be configured for selectively operably engaging the first securing device so as to operably engage the inner tube with the outer tube to install and maintain the conduit.

In some embodiments, the system may also comprise a coring device configured for advancing through the conduit aperture defined by the inner tube and through the tissue wall to define an aperture therein by removing a tissue core. The coring device may be further configured for carrying the inner tube through the aperture such that the inner tube extends at least partially through the aperture so as to establish fluid communication between the first and second surfaces of the tissue wall. The coring device may define a coring bore extending axially therethrough and configured for receiving the tissue core removed by the coring device. In some embodiments, the coring device may further comprise a piercing rod slidably advancable and retractable within the coring bore. The piercing rod may further comprise a retrieval device operably engaged with a distal end thereof and configured for axially retaining the tissue core removed by the coring device. Thus, in some embodiments, the piercing rod may be configured for advancing so as to pierce the tissue wall prior to removal of the tissue core and/or retracting after removal of the tissue core such that the tissue core is retrievable via a proximal end of the coring device. In some such embodiments, the coring device may further comprise a handle operably engaged with the proximal end of the coring device. The handle may define a tissue core chamber in communication with the coring bore, the tissue core chamber configured for receiving the tissue core retrieved by the retraction of the piercing rod. Furthermore, in some such embodiments, at least a portion of the handle may comprise a transparent material such that the tissue core received therein is visible from a position outside the handle.

The various embodiments of the present invention may thus be configured for implanting a conduit device that is adapted for providing a conduit for a medical procedure. Such procedures may include, but are not limited to: bypass; cardiac valve repair or replacement; attachment of a ventricular assist device; establishment of an apicoaortic conduit (AAC) and combinations of such procedures.

Use of this new conduit device, system, and method will significantly improve the ease and safety of conduit insertion (such as the implantation of AAC devices, for example). For example, various embodiments of the present invention may allow the outer tube to be securely operably engaged with the tissue wall (due at least in part to the cooperation of the attaching device and the ring) prior to the removal of a tissue core to define an aperture in the tissue wall. Thus, portions of the system disclosed herein may define a guide aperture extending axially through the outer tube for receiving a coring device that may be configured to be capable of efficiently removing and retrieving a tissue core while substantially simultaneously operably engaging a inner tube in the guide aperture so as to establish fluid communication between first and second opposing surfaces of the tissue wall. As persons of ordinary skill in the art will readily appreciate, the various embodiments of the present invention may also be used in a minimally invasive, endoscopically assisted approach.

## BRIEF DESCRIPTION OF THE DRAWINGS

Having thus described various embodiments of the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

FIG. **1** shows a non-limiting perspective view of an exemplary system for implanting a conduit device, according to one embodiment of the present invention;

FIG. **2** shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device, according to one embodiment of the present invention;

FIG. **3** shows a non-limiting side cross-sectional view of an exemplary conduit device implanted in a tissue wall, according to one embodiment of the present invention;

FIG. **4** shows a non-limiting side view of an exemplary system for implanting a conduit device, according to one embodiment of the present invention;

FIGS. **5**A-**5**G show an exemplary set of views of the installation of a conduit device using an exemplary system, according to one embodiment of the present invention;

FIG. **5**A shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising an attaching device at least partially implanted in a tissue wall, according to one embodiment of the present invention;

FIG. **5**B shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising an attaching device and a ring cooperating to secure at least a portion of the tissue wall between the attaching device and the ring so as to operably engage said outer tube with the tissue wall, according to one embodiment of the present invention;

FIG. **5**C shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising a coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, wherein the coring device is advanced at least partially through the tissue wall so as to remove a tissue core thereof, according to one embodiment of the present invention;

FIG. **5**D shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising a coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, wherein the coring bore defined by the coring device contains a tissue core removed from the tissue wall, according to one embodiment of the present invention;

FIG. **5**E shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device comprising a coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, wherein a piercing rod is retracted through the coring bore after removal of the tissue core such that the tissue core is retrievable via a proximal end of the coring device, according to one embodiment of the present invention;

FIG. **5**F shows a non-limiting side cross-sectional view of an exemplary system for implanting a conduit device, wherein the outer tube and inner tube are installed in the tissue wall so as to establish fluid communication between the first and second surfaces of the tissue wall, according to one embodiment of the present invention;

FIG. **5**G shows a non-limiting side cross-sectional view of an exemplary coring device, wherein a handle operably engaged with a proximal end of the coring device contains a tissue core removed from the tissue wall by the coring device, according to one embodiment of the present invention;

FIG. **6** shows a non-limiting side view of an exemplary coring device carrying an inner tube configured for insertion into a guide aperture defined by the outer tube, according to one embodiment of the present invention; and

FIG. **7** shows a non-limiting perspective view of an exemplary conduit device comprising an attaching device comprising a helical spring, according to one embodiment of the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

The present inventions now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the inventions are shown. Indeed, these inventions may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout. The singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

Although some embodiments of the invention described herein are directed to a conduit device **1** (see FIGS. **1** and **7**, for example) and a system for implanting such a device to form an apicoaortic connector (AAC) between the cardiac apex and the aorta, it will be appreciated by one skilled in the art that the invention is not so limited. For example, aspects of the conduit device **1** and systems of the present invention can also be used to establish and/or maintain conduits in a variety of tissue structures using minimally-invasive and/or invasive delivery techniques. Furthermore, while the embodiments of the invention described herein are directed to the thoracoscopic implantation of the conduit device to form at least one port for establishing an AAC, it should be understood that the system and/or vascular conduit device embodiments of the present invention may be used to establish valved and/or open conduits (including bypass conduits) to augment native blood vessels in order to treat a variety of vascular conditions including, but not limited to: aortic valvular disease, congestive heart failure, left ventricle outflow tract obstructions (LVOTO), peripheral arterial obstructions, small vessel obstructions, and/or other conditions. Furthermore, the vascular conduit device and system of the present invention may also be used to establish a port for inter-ventricular repairs such as, for example, valve repair and/or replacement or ablation procedures. Thus, the conduit device **1** described in further detail below may also comprise a threaded fluid-tight cap, and/or a cap having at least one pawl member (for engaging corresponding ridges defined on an outer surface of the conduit device **1**) for selectively sealing a proximal end of the conduit device **1** such that the inner tube **40** thereof may serve as a re-usable port for repairing and/or treating diseased portions of the cardiac anatomy. Furthermore, the conduit device **1** and system embodiments of the present invention may also be used to implant a conduit and/or port for left ventricular assist devices.

It should be further understood that various embodiments of the conduit device **1** described herein may also be utilized to establish fluid communication between opposing surfaces of a variety of tissue walls and/or anatomical structures. For example, in some embodiments, the conduit device **1** and system for implanting described herein may be used to establish a conduit (and consequently fluid communication) between opposing surfaces of a wall of an anatomical structure that may include, but is not limited to: a urinary bladder; a gall bladder; a diaphragm; a thoracic cavity; an abdominal cavity; an intestinal structure; a cecal cavity; and other tissue wall structures.

It should be understood that the various conduit device **1** components described herein (see, for example, the components shown in FIG. **1**) may comprise a variety of biocompatible materials including, but not limited to: stainless steel; titanium substantially rigid biocompatible polymers; elastomeric biocompatible polymers; and combinations of such materials. For example, in some embodiments, the outer tube **10**, ring **30**, nut **20**, and inner tube **40** may comprise substantially rigid biocompatible polymers. In some embodiments, the attaching device **15** may comprise a biocompatible metal and/or metal alloy that may be embedded substantially within and/or operably engaged with an injection-molded polymer used to form the outer tube **10**. Furthermore, as described further herein, some embodiments of the present invention may further comprise a sealing member **35** operably engaged with a distal end of the ring **30**. In such embodiments, the sealing member **35** may comprise a substantially compliant biocompatible polymer (such as an elastomeric polymer) that may be suitable for establishing a substantially fluid tight seal between the ring **30** a surface of the tissue wall **850**. Similarly, the various components of the coring device **2** described herein may also comprise a combination of biocompatible materials suitable for removing and retaining the tissue core **850***a* in order to define an aperture in the tissue wall **850** such that the inner tube **40** may be installed to establish fluid communication between the opposing first and second surfaces **855**, **853** of the tissue wall **850** (as shown in FIG. **3**, for example).

FIG. **3** shows some exemplary components of a system for implanting a conduit device **1** in a tissue wall **850** having a first surface **855** and an opposing second surface **853**. As shown generally in FIGS. **1** and **2**, such a system may comprise an outer tube **10** defining a guide aperture extending axially therethrough and an attaching device **15** extending from a distal end of the outer tube **10**. As shown in FIG. **3**, for example, the attaching device **15** may be configured for advancing along a helical path at least partially through the tissue wall **850** such that at least a portion of the attaching device **15** becomes disposed substantially between the first surface **855** and the opposing second surface **853** of the tissue wall **850** when the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. As shown generally in FIG. **2**, the attaching device **15** may be integrally formed within the outer tube **10**. For example, the attaching device **15** may, in some embodiments, be placed at least partially in a mold such that the polymeric or other components of the outer tube **10** may be molded substantially around at least a portion of the attaching device **15** (which may comprise a static coil and/or elastic spring, as described further herein). In other embodiments, the attaching device **15** may be operably engaged with at least a portion of the outer tube **10** via adhesive, RF welding, and/or other attachment methods that may be suitable for securely operably engaging the attaching device **15** to the outer tube **10**.

The attaching device **15** may comprise, in some embodiments, a helical static coil having a sharpened distal end adapted for piercing the tissue wall **850** as the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. In other embodiments, the attaching device **15** may comprise a helical elastic spring having a sharpened end adapted for piercing the tissue wall **850** as the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. In some embodiments, as shown in FIG. **4**, wherein the attaching device **15** comprises a helical spring and/or coil, the spring and/or coil may device a radially-expanding helix as the attaching device **15** extends away from the distal end of the outer tube **10**. In some embodiments, wherein the attaching device comprises a conical and/or "radially-expanding" helix, the attaching device **15** may act to compress at least a portion of the tissue wall **850** radially inward and towards an outer surface of the inner tube **40** so as to establish a substantially fluid-tight seal between the outer surface of the inner tube **40** and the portion of the tissue wall **850** that has been urged radially inward. Furthermore, in some such embodiments, the radially-expanding helix of the attaching device **15** may correspond, for example, to a ring **30** comprising a frusto-conical assembly configured for receiving at least a portion of a substantially curved tissue wall **850** (see, for example, FIG. **5**B) so as to form a substantially fluid-tight seal between the frusto-conical assembly of the ring **30** and the tissue wall **850**.

In other embodiments, as shown generally in FIG. **7**, the attaching device **15** may comprise a helical spring and/or coil having a substantially constant helical diameter as the attaching device **15** extends away from the distal end of the outer tube **10**. The substantially consistent helical diameter of the attaching device **15** shown generally in FIG. **7** may be useful for operably engaging the outer tube **10** with a substantially flat tissue wall **850**. Furthermore, as shown generally in FIG. **7**, in some embodiments, the corresponding ring **30** (and the corresponding sealing member **35** that may be operably engaged therewith) may also be configured to provide a substantially flat and/or disc-shaped sealing surface that may be suitable for seating on and/or establishing a substantially fluid-tight seal with a substantially flat first tissue surface **855** that may surround an aperture defined in a correspondingly flat tissue wall **850**.

As described herein, the system may further comprise a ring **30** operably engaged about an outer surface of the outer tube **10**. As shown generally in FIGS. **3** and **5**B, the ring **30** may be configured for cooperating with the attaching device **15** such that at least a portion of the tissue wall **850** is secured between the attaching device **15** and the ring **30** so as to operably engage the outer tube **10** with the tissue wall **850**. Some embodiments may further comprise a plurality of ridges **11** and/or threads disposed on the outer surface of the outer tube **10**. According to such embodiments, the ring **30** may comprise at least one deformable pawl member configured for releasably engaging the plurality of ridges **11** disposed on the outer surface of the outer tube **10**. Other embodiments (as shown generally in FIG. **2**, for example), may also further comprise threading **11** on at least a portion of the outside surface of the outer tube **10** and corresponding threading on at least a portion of an inside surface of the ring **30**. The threading **11** (and corresponding threading on the inner surface of the ring **30**) may be being configured to cooperate for axially securing the ring **30** relative to the outer tube **10**. As shown generally in FIGS. **5**A-**5**B, some embodiments may further comprise a nut **20** operably engaged about an outer surface of the outer tube **10** and proximal to the ring **30**. According to such embodiments, the nut **20** may comprise threading on at least a portion on an inside surface of the nut **20**. The threading disposed on the inside surface of the nut **20** may be configured for cooperating with the threading **11** on at least a portion of the outside surface of the outer tube **11** for axially securing the nut **20** relative to the outer tube **10** and the adjacent ring **20**. As shown in FIGS. **5**A-**5**B, the nut **20** may be configured for cooperating with the ring **30** to advance the ring **30** towards the distal end of the outer tube **10**. As shown generally in FIGS. **5**A-**5**B, the attaching device **15** may provide counter-traction so as to allow for the rotation (and resulting advancement) of the nut **20** (and the ring **30** disposed distally thereto) such that rotation of the nut **20** (and the corresponding movement of the ring **30** toward the first tissue surface **855**) may draw at least a portion of the tissue wall **850** into engagement with an inner surface of the ring **30** such that the conduit device **1** (and particularly the outer tube **10** thereof) is stabilized, engaged in a substantially fluid tight seal, and/or operably engaged with respect to the tissue wall **850** prior to the use of a coring device **2** for removing a tissue core **850***a* via the guide aperture defined axially through the outer tube **10**.

In order to ensure that the ring **30** forms a substantially fluid-tight seal with the first surface **855** of the tissue wall **850** about the aperture defined therein, some embodiments (as shown in FIG. **1**, for example) may further comprise a sealing member **35** operably engaged with a distal end of the ring **30**. The sealing member **35** may comprise, for example, a gasket or other elastomeric component configured for establishing a substantially fluid tight seal between the ring **30** and the first surface **855** of the tissue wall **855**. As described herein, some embodiments of the present invention may be configured for establishing fluid communication between the opposing sides of the walls of a mammalian heart (such as the ventricular apex, for example). In such embodiments, the conduit device **1** may be required to be operably engaged with a substantially curved tissue wall **850** (see FIG. **5**A, for example). In such embodiments, the ring **30** may comprise a frusto-conical assembly configured for receiving at least a portion of the substantially curved tissue wall **850** so as to form a substantially fluid-tight seal between the frusto-conical assembly of the ring **30** and the tissue wall **850**. As shown, for example, in FIG. **5**B, in some embodiments, the ring **30** may be urged towards a distal end of the outer tube **10** by the rotation of a nut **20** about threading **11** disposed on an outer surface of the outer tube **10**. Thus, according to some such embodiments, the cooperation of the attaching device **15** (which may comprise a piercing helical spring and/or coil, for example) with the ring **30** may act to draw at least a portion of the curved tissue wall **850** into the frusto-conical assembly of the ring **30** such that a substantially fluid-tight seal may be formed and maintained between the frusto-conical assembly of the ring **30** and the tissue wall **850**. In some conduit device **1** embodiments, as shown generally in FIG. **2**, the ring **30** may comprise a seal testing aperture **36** that may allow a clinician to selectively test whether or not a substantially fluid-tight seal has been established between the ring **30** and the first surface **855** of the tissue wall **850** when the ring **30** is moved towards the distal end of the outer tube **10** and into engagement with the tissue wall **850**. For example, a clinician may operably engage a fluid source (such as a saline solution bag) with the seal testing aperture **36** (which may comprises a luer lock connector or other connector for operably engaging the fluid source) and introducing a fluid via seal testing aperture **36** and observing the interface between the ring **30** and the first surface **855** of the tissue wall **850** to see if any substantial amount of fluid emerges. If no fluid is readily visible, a clinician may be reasonably assured that the seal formed between the ring **30** and the tissue wall **850** is substantially fluid-tight. By assessing the seal formed between the ring **30** and the tissue wall **850**, a clinician may determine if it is medically safe to introduce the coring device **2** via the guide conduit defined in the outer tube **10** (i.e. determine if blood loss is likely to occur between the ring **30** and the first surface **855** of the tissue wall **850** when the coring device **2** (and the coring cylinder **65** thereof) is advanced through the tissue wall **850** as shown in FIG. **5**C).

In some embodiments, the seal testing aperture **36** may also serve an alternative function for rotationally securing the ring **30** relative to and the first surface **855** of the tissue wall **850**. For example, a clinician may insert a needle and/or other elongate spike through the seal testing aperture **36** defined in the ring **30** and substantially into the tissue wall **850**. The interaction of the needle and/or spike with the ring **30** (via the seal testing aperture **36**) and the tissue wall **850** may thus reduce a chance that the ring **30** (and the helical attaching device **15** extending from the outer tube **10**) are rotatable relative to the tissue wall **850** such that the ring **30** and the helical attaching device **15** may be less prone to "backing out" of the tissue wall **850** once the seal is established between the ring **30** and the first surface **855** of the tissue wall **850**.

In some additional embodiments, as shown generally in FIG. **7**, the ring **30** (and/or the sealing member **35** that may be operably engaged therewith) may define a substantially flat and/or disc-shaped annular sealing surface that may be configured for establishing a substantially fluid-tight seal between the ring **30** and a substantially flat first tissue surface **855** about an aperture defined in the tissue wall **850**.

Referring to FIG. **5**C, for example, some embodiments may further comprise an inner tube **40** defining a conduit aperture extending axially therethrough. The inner tube **40** may be configured for insertion into the guide aperture defined by the outer tube **10**. In some embodiments, as shown in FIG. **6**, the inner tube **40** may be carried by a coring device **2** that may be advanced through the guide aperture defined by the outer tube **10** and configured for substantially simultaneously removing a tissue core **850***a* to define an aperture in the tissue wall **850** and operably engaging the inner tube **40** with the outer tube **10** so as to establish and/or maintain a reliable and engageable pathway for fluid communication between the first and second surfaces **855**, **853** of the tissue wall **850**. In order to facilitate the secure engagement of the outer tube **10** with the inner tube **40**, some conduit device **1** embodiments may comprise a first securing device **13** operably engaged with a proximal end of the outer tube **10** and a complementary second securing device **43** operably engaged with a proximal end of the inner tube **40**. According to such embodiments, as shown generally in FIG. **2**, the second securing device **43** may be configured for selectively operably engaging the first securing device **13** so as to operably engage the inner tube **40** with the outer tube **10**. As shown generally in FIG. **6**, the second securing device **43** may comprise one or more deformable pawls configured for selectively operably engaging the first securing device **13** as shown in FIG. **2** (wherein the first securing device **13** comprises one or more ridges disposed on a proximal portion of the outer surface of the outer tube **10**).

As shown generally in FIG. **6**, some system embodiments for installing a conduit device **1** may further comprise a coring device **2** configured for advancing through the conduit aperture defined by the inner tube **40** and through the tissue wall **850** to define an aperture therein by removing a tissue core **850***a* (see FIG. **5**D, for example, showing the coring device **2** removing a tissue core **850***a* and collecting the tissue core **850***a* in a coring bore defined by a coring cylinder **65**. As shown generally in FIGS. **5**C and **6**, the coring device **2** may be further configured for carrying the inner tube **40** through the aperture such that the inner tube **40** extends at least partially through the aperture (see FIG. **5**F, for example) so as to establish fluid communication between the first **855** and second **853** surfaces of the tissue wall **850**. In some embodiments, as shown in the cross-sectional side view of FIG. **5**D, the coring device **2** (and/or the coring cylinder **65** thereof) defines a coring bore extending axially therethrough configured for receiving the tissue core **850***a* removed by the coring cylinder **65**.

As shown in FIGS. **5**C-**5**E, the coring device **2** may also comprise a piercing rod **60** slidably advancable and retractable within the coring bore defined by the coring device **2**. The piercing rod **60** may further comprise a retrieval device **61** operably engaged with a distal end thereof and configured for axially retaining the tissue core **850***a* removed by the coring cylinder **65**. In various embodiments, the retrieval device **61** may include, but is not limited to: a barb; a hook; corkscrew; expandable balloon; a self-expanding structure; and/or other device configured for initially piercing the tissue wall **850** so as to be capable of retrieving the tissue core **850***a* removed by the coring device **2** as described further herein. As shown generally in FIG. **5**C, the piercing rod **60** may be configured for advancing so as to pierce the tissue wall **850** prior to removal of the tissue core **850***a* (i.e. prior to the advancement of the coring cylinder **65** through the tissue wall **850**). Furthermore, as shown generally in FIG. **5**E, the piercing rod **60** may be further configured for retracting after removal of the tissue core **850***a* such that the tissue core **850***a* is retrievable via a proximal end of the coring device **2**. In some system embodiments for installing a conduit device **1**, the coring device **2** may further comprise a handle **63** operably engaged with a proximal end of the coring device **2** (and/or a proximal end of the coring cylinder **65**). According to such embodiments, as shown generally in FIG. **6**, the handle **63** may define a tissue core chamber **62** in communication with the coring bore defined by the coring cylinder **65**. As shown in FIG. **5**E, the tissue core chamber **62** may thus be configured for receiving the tissue core **850***a* retrieved by retraction of the piercing rod **60** (and the retrieval device **61** operably engaged with a distal end thereof). In order to allow a clinician to positively identify and/or confirm the removal and retraction of the tissue core **850***a*, in some system embodiments at least a portion of the handle **63** may be provided with a substantially transparent material (such as a transparent polycarbonate polymer, for example) such that the tissue core **850***a* received by the tissue core chamber **62** may be visible (to a clinician or an endoscopic imaging device, for example) from a position substantially outside the handle **63**.

FIGS. **5**A-**5**G illustrate the various steps involved in the utilization of one embodiment of the system of the present invention for installing a conduit device **1** in a tissue wall **850** (such as the ventricular apex). It should be understood that various embodiments of the present invention may be utilized for installing the conduit device **1** for use in medical procedures that may include, but are not limited to: bypass; cardiac valve repair or replacement; attachment of a ventricular assist device; and combinations of such procedures. As shown in FIG. **5**A, an exemplary process for installing a conduit device **1** may begin with the implantation of the attaching device **15** in the tissue wall **850**. As described herein, the attaching device **15** may comprise a helical spring and/or coil configured for advancing along a helical path at least partially through the tissue wall **850** such that at least a portion of the attaching device **850** becomes disposed substantially between the first surface **855** and the opposing second surface **853** of the tissue wall **850** when the outer tube **10** is rotated relative to the first surface **855** of the tissue wall **850**. In some embodiments, the attaching device **15** may be sized such that the axial length of the attaching device **15** does not extend substantially distal to the second surface **853** of the tissue wall **850**.

In some embodiments, wherein the attaching device comprises a conical and/or "radially-expanding" helix, the attaching device **15** may act to compress at least a portion of the tissue wall **850** radially inward and towards an outer surface of the inner tube **40** so as to establish a substantially fluid-tight seal between the outer surface of the inner tube **40** and the portion of the tissue wall **850** that has been urged radially inward by the conical and/or radially-expanding helix of the attaching device **15**. Furthermore, in embodiments wherein the attaching device **15** comprises a conical and/or "radially-expanding" helix, the attaching device **15** may act to compress at least a portion of the tissue wall **850** radially inward such that the portion of the tissue wall **850** may be more readily received by ring **30** (which may comprise a frusto-conical structure configured for receiving the compressed portion of the tissue wall **850**). As shown in FIG. **5**B, the conduit device **1** installation process may continue with the advancement and/or tightening of the ring **30** towards a distal end of the outer tube **10**. As described herein, some conduit device **1** embodiments of the present invention may comprise a nut **20** operably engaged about an outer surface of the outer tube **10** proximal to the ring **30**. In some such embodiments, the nut **20** may comprise threading on at least a portion on an inside surface thereof, wherein the threading is configured for cooperating with the threading **11** on at least a portion of the outside surface of the outer tube **10**. The nut **20** may thus be configured to cooperate with the ring **30** to advance the ring **30** towards the distal end of the outer tube **10**, and therefore into contact with the first surface **855** of the tissue wall **850**. As shown generally in FIG. **5**B, once the nut **20** and ring **30** are advanced distally (which may be accomplished by hand-tightening the nut **20**), the ring **30** may cooperate with the attaching device **15** such that at least a portion of the tissue wall **850** is secured between the attaching device **15** and the ring **30** so as to securely operably engage the outer tube **10** with the tissue wall **850**.

As shown in FIG. **5**C, once the outer tube **10** is stabilized relative to the tissue wall **850**, a coring device **2** (which, in some embodiments, as shown in FIG. **6**, may be configured for carrying an inner tube **40**), may be inserted into the guide aperture defined axially within the outer tube **10**. As described herein with respect to FIG. **6**, the coring device **2** may comprise a coring cylinder **65** configured for advancing through the conduit aperture defined by the inner tube **40** and through the tissue wall **850** to define an aperture therein by removing a tissue core **850***a* (see FIG. **5**D, for example). Referring again to FIG. **5**C, some embodiments may further comprise a piercing rod **60** slidably advancable and retractable within the coring bore defined by the coring cylinder **65**. The piercing rod **60** may comprise, in some embodiments, an elongate proximal end that may be manipulated (i.e. extended and/or retracted) by a clinician in order to initially pierce the tissue wall **850** and/or retract the tissue core **850***a* removed therefrom (as described further herein). As shown in FIGS. **5**D and **5**E, the piercing rod **60** may further comprise a retrieval device **61** operably engaged with a distal end thereof and configured for axially retaining the tissue core **850***a* removed by the coring cylinder **65**. The piercing rod **60** may be configured for advancing so as to pierce the tissue wall **850** prior to removal of the tissue core **850***a* (i.e. prior to advancement of the coring cylinder **65**). Furthermore, as shown in FIG. **5**E, the piercing rod **60** may be further configured for retracting after removal of the tissue core **850***a* such that the tissue core **850***a* is retrievable via a proximal end of the coring device **2**.

As shown in FIGS. **5**D and **6**, the coring device **2** may be further configured for carrying the inner tube **40** through the aperture such that the inner tube **40** extends at least partially through the aperture so as to establish fluid communication between the first and second surfaces **855**, **853** of the tissue wall **850** (see also, FIG. **3**, for example). As described herein, with respect to various conduit device **1** embodiments of the present invention the outer tube **10** may comprise a first securing device **13** operably engaged with a proximal end thereof and the inner tube **40** (carried, for example, by the coring device **2** into position relative to the outer tube **10**) may comprise a complementary second securing device **43** operably engaged with a proximal end thereof. As shown generally in FIG. **3**, the second securing device **43** (which may comprise a deformable pawl, for example) may be configured for selectively operably engaging the first securing device **13** (which may comprise a complementary at least one ridge disposed on an outer surface of the outer tube **10**) so as to positively and securely operably engage the inner tube **40** with the outer tube **10**.

Referring again to FIG. **5**E, the coring device **2** may, in some embodiments, comprise a handle **63** operably engaged with a proximal end of the coring device **2**. As described herein, the handle **63** may define a tissue core chamber **62** in communication with the coring bore defined, for example, by the coring cylinder **65**. The tissue core chamber **62** may thus be configured for receiving the tissue core **850***a* retrieved by retraction of the piercing rod **60** (and the retrieval device **61** operably engaged with a distal end thereof). In some embodiments, the coring device **2** may also define a fill aperture configured for operably engaging a source of saline solution or other fluid that may be used to substantially flood the coring bore defined by the coring cylinder **65** and the tissue core chamber **62** so as to reduce the chance of introducing gas bubbles (i.e. air bubbles) into an interior chamber defined by the tissue wall **850** when the coring device **2** is introduced via the outer tube **10**.

As described generally herein with regard to the various system embodiments of the present invention, the conduit device **1** installation process may advantageously allow a clinician to visually confirm that the tissue core **850***a* removed by the coring cylinder **65** has been completely and cleanly removed from the aperture defined in the tissue wall **850**. For example, in some embodiments, at least a portion of the handle **63** may comprise a transparent material such that the tissue core **850***a* received within the tissue core chamber **62** may be directly visible by a clinician and/or an endoscopic imaging device from a position substantially outside the handle **63**. As shown in FIGS. **5**F and **5**G, after the coring device **2** (and the tissue core **850***a* retained in the handle **63** thereof) is retracted and removed from the inner tube **40**, a clamp C may be applied to a proximal end of a graft portion that may be operably engaged with the inner tube **40** of the conduit device **1**. In other embodiments, the inner tube **40** may comprise one or more ridges defined on an outer surface of the proximal end thereof that may be configured for receiving a deformable cap or other cover for temporarily and/or semi-permanently closing the aperture defined by the installed conduit device **1**. As described herein, the conduit device **1** may be utilized as a portion of a two-part bypass system that may comprise another corresponding conduit device **1** installed in a tissue wall **850** defining a wall of the mammalian aorta, for example. The two corresponding conduit devices **1** may then be operably engaged with one another via a valve device so as to form an apicoaortic connection (AAC) in order to bypass, for example, a faulty valve or other mechanical defect present in a subject's cardiac anatomy.

Many modifications and other embodiments of the inventions set forth herein will come to mind to one skilled in the art to which these inventions pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the inventions are not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

That which is claimed:

**1**. A method for establishing fluid communication between a first surface and a second surface of a tissue wall, the method comprising:

engaging the tissue wall with a conduit device such that a substantially fluid-tight seal is established between the conduit device and the tissue wall, the conduit device comprising an outer tube formed of a substantially rigid material; and

after engaging the tissue wall with the conduit device, advancing a coring device through the outer tube of the conduit device and through the tissue wall to core an aperture in the tissue wall extending from the first surface to the second surface of the tissue wall while maintaining the substantially fluid-tight seal between the conduit device and the tissue wall.

**2**. The method of claim **1**, wherein the substantially fluid-tight seal is established between the outer tube of the conduit device and the tissue wall.

**3**. The method of claim **1**, wherein the substantially fluid-tight seal is established between a distal end of the outer tube of the conduit device and the tissue wall.

**4**. The method of claim **1**, wherein the conduit device further comprises a ring positioned about the outer tube, and wherein the substantially fluid-tight seal is established between the ring of the conduit device and the tissue wall.

**5**. The method of claim **4**, wherein the ring is positioned about a distal end of the outer tube.

**6**. The method of claim **4**, wherein the ring has a disc shape configured to abut the tissue wall.

**7**. The method of claim **4**, wherein the ring has a frustoconical shape configured to receive a portion of the tissue wall therein.

**8**. The method of claim **1**, wherein the conduit device further comprises a sealing member positioned about the outer tube, and wherein the substantially fluid-tight seal is established between the sealing member of the conduit device and the tissue wall.

**9**. The method of claim **8**, wherein the sealing member is formed of an elastomeric material.

**10**. The method of claim **1**, further comprising, before advancing the coring device, attaching the conduit device to the tissue wall.

**11**. The method of claim **10**, wherein the conduit device further comprises an attaching device, and wherein attaching the conduit device to the tissue wall comprises advancing the attaching device at least partially through the tissue wall such that at least a portion of the attaching device is disposed substantially between the first surface and the second surface of the tissue wall.

**12**. The method of claim **11**, wherein the attaching device comprises a helical coil or a helical spring member.

**13**. The method of claim **1**, wherein the coring device comprises a coring tube.

**14**. The method of claim **1**, further comprising removing the coring device from the tissue wall while maintaining the substantially fluid-tight seal between the conduit device and the tissue wall.

**15**. The method of claim **1**, further comprising removing the coring device from the outer tube of the conduit device while maintaining the substantially fluid-tight seal between the conduit device and the tissue wall.

**16**. The method of claim **1**, further comprising inserting an inner tube of the conduit device through the outer tube of the conduit device and through the aperture in the tissue wall to maintain fluid communication between the first surface and the second surface of the tissue wall.

17. The method of claim 1, further comprising attaching a ventricular assist device to the tissue wall via the conduit device.

18. The method of claim 1, wherein the tissue wall is a heart tissue wall.

19. The method of claim 1, wherein the tissue wall is a ventricular wall of a beating heart.

20. The method of claim 1, wherein engaging the tissue wall with the conduit device comprises engaging at least the first surface of the tissue wall with the conduit device.

21. The method of claim 20, wherein the first surface of the tissue wall is an outer surface of the tissue wall, and wherein the second surface of the tissue wall is an inner surface of the tissue wall.

22. The method of claim 1, further comprising, before advancing the coring device, fixing a position of the outer tube relative to the tissue wall.

23. The method of claim 1, further comprising, before the advancing the coring device, assessing the seal established between conduit device and the tissue wall.

24. A system for establishing fluid communication between a first surface and a second surface of a tissue wall, the system comprising:

a conduit device configured for engaging the tissue wall such that a substantially fluid-tight seal is established between the conduit device and the tissue wall, the conduit device comprising an outer tube formed of a substantially rigid material; and

a coring device configured for advancing through the outer tube and through the tissue wall to core an aperture in the tissue wall extending from the first surface to the second surface of the tissue wall after engaging the tissue wall with the conduit device and while maintaining the substantially fluid-tight seal between the conduit device and the tissue wall.

25. The system of claim 24, wherein the outer tube of the conduit device is configured for engaging the tissue wall such that the substantially fluid-tight seal is established between the outer tube of the conduit device and the tissue wall.

26. The system of claim 24, wherein a distal end of the outer tube of the conduit device is configured for engaging the tissue wall such that the substantially fluid-tight seal is established between the distal end of the outer tube of the conduit device and the tissue wall.

27. The system of claim 24, wherein the conduit device further comprises a ring positioned about the outer tube and configured for engaging the tissue wall such that the substantially fluid-tight seal is established between the ring of the conduit device and the tissue wall.

28. The system of claim 27, wherein the ring is positioned about a distal end of the outer tube.

29. The system of claim 27, wherein the ring has a disc shape configured for abutting the tissue wall.

30. The system of claim 27, wherein the ring has a frustoconical shape configured for receiving a portion of the tissue wall therein.

31. The system of claim 24, wherein the conduit device further comprises a sealing member positioned about the outer tube and configured for engaging the tissue wall such that the substantially fluid-tight seal is established between the sealing member of the conduit device and the tissue wall.

32. The system of claim 31, wherein the sealing member is formed of an elastomeric material.

33. The system of claim 24, wherein the conduit device is configured for attaching to the tissue wall.

34. The system of claim 33, wherein the conduit device further comprises an attaching device configured for advancing at least partially through the tissue wall such that at least a portion of the attaching device is disposed substantially between the first surface and the second surface of the tissue wall.

35. The system of claim 34, wherein the attaching device comprises a helical coil or a helical spring member.

36. The system of claim 24, wherein the coring device comprises a coring tube.

37. The system of claim 24, wherein the conduit device is configured to maintain the substantially fluid-tight seal between the conduit device and the tissue wall while the coring device is removed from the tissue wall.

38. The system of claim 24, wherein the conduit device is configured to maintain the substantially fluid-tight seal between the conduit device and the tissue wall while the coring device is removed from the outer tube of the conduit device.

39. The system of claim 24, wherein the conduit device further comprises an inner tube configured for inserting through the outer tube of the conduit device and through the aperture in the tissue wall to maintain fluid communication between the first surface and the second surface of the tissue wall.

40. The system of claim 24, wherein the conduit device is configured for attaching a ventricular assist device to the tissue wall.

41. The system of claim 24, wherein the tissue wall is a heart tissue wall.

42. The system of claim 24, wherein the tissue wall is a ventricular wall of a beating heart.

43. A method for establishing fluid communication between a first surface and a second surface of a tissue wall, the method comprising:

engaging the tissue wall with a conduit device such that a substantially fluid-tight seal is established between the conduit device and the tissue wall, the conduit device comprising an outer tube;

after engaging the tissue wall with the conduit device, advancing a coring device through the outer tube of the conduit device and through the tissue wall to core an aperture in the tissue wall extending from the first surface to the second surface of the tissue wall while maintaining the substantially fluid-tight seal between the conduit device and the tissue wall, the coring device comprising a coring tube; and

inserting an inner tube through the outer tube of the conduit device and through the aperture in the tissue wall.

44. A system for establishing fluid communication between a first surface and a second surface of a tissue wall, the system comprising:

a conduit device configured for engaging the tissue wall such that a substantially fluid-tight seal is established between the conduit device and the tissue wall, the conduit device comprising an outer tube;

a coring device configured for advancing through the outer tube and through the tissue wall to core an aperture in the tissue wall extending from the first surface to the second surface of the tissue wall after engaging the tissue wall with the conduit device and while maintaining the substantially fluid-tight seal between the conduit device and the tissue wall, the coring device comprising a coring tube; and

an inner tube configured for inserting through the outer tube of the conduit device and through the aperture in the tissue wall.

* * * * *